COVID-19 & Influenza A/B Antigen Nasal Test Kit for Self-testing

Package Insert - For Self-testing

REF CVF003AU | English

Instructions for Use

COVID-19 & Influenza A/B Antigen Nasal Test Kit for Self-testing

Quick Reference Instructions

Carefully read the instructions before performing the test. Failure to follow the instructions may result in inaccurate test results.

Scan the QR code or visit our website for video instructions https://2san.com/ifu-australia or call our helpline on: 1800 630 750 (9AM to 7PM AEST, 7 days/week)

Scan for more information

INTENDED USE

The COVID-19 & Influenza A/B Antigen Nasal Test Kit for Self-testing is an in vitro immunoassay. The assay is intended for home testing (or self-testing). Children aged between 2 and 18 years old, must be supervised or tested by an adult when carrying out the test. The assay is an in vitro immunochromatographic assay for the qualitative detection of SARS-CoV-2 and Influenza A/B viral nucleoprotein antigens in nasal swab specimens collected from patients against the respiratory infection for COVID-19 (within the first 7 days of the onset of symptoms) and influenza A/B (within the first 4 days of the onset of symptoms). The assay obtains a preliminary result only, aid in the diagnosis of COVID-19 and/or Influenza A/B, for The final confirmation should be based on clinical diagnostic results according to local, state, or territory guidelines. This test has not been cleared for use in asymptomatic individuals.

PRINCIPLE

The COVID-19 & Influenza A/B Antigen Nasal Test Kit for Self-testing detects SARS-CoV-2 viral nucleocapsid proteins and Influenza A&B virus through visual interpretation of colour development on the internal strip. Anti SARS-CoV-2 mAb and Influenza A&B antibodies are immobilised at the test region of the nitrocellulose membrane. Anti-SARS-CoV-2 mAb and Influenza A&B antibodies conjugated to coloured particles are immobilised on the conjugated pad.

During testing, target antigens, if present in the nasal secretions, will be released into the extraction buffer.

As the specimen migrates along the strip by capillary action and then interacts with reagents on the sample pad, the target antigens will bind to anti-SARS-CoV-2 mAb or Influenza A&B antibodies on the conjugate pad. Consequently, the antigen-antibody complex will be captured by the anti-SARS-CoV-2 mAb or Influenza A&B antibodies immobilised at the test region. Excess coloured particles will be captured at the control region of the NC membrane.

The presence of a coloured band in the test region indicates a positive result for the SARS-CoV-2 viral and Influenza A&B antigens, while its absence indicates a negative result. A coloured band at the control region serves as a procedural control, generally indicating that a proper volume of specimen has been added and membrane wicking is working.

WARNINGS & PRECAUTIONS

- For *in vitro* diagnostic use.
- If you feel unwell or need COVID-19 advice for someone in your care, talk with your health provider, or call the healthdirect helpline on 1800 022 222. If you develop symptoms such as severe shortness of breath or chest pain, call triple zero (000) immediately.
- Caution should be taken when inserting the sample collector into the nasal cavity.
- Do not ingest.
- Do not use kit or components beyond the expiration date.
- Do not puncture the membrane in the extraction tube before testing.
- Do not use this test on anyone under 2 years of age.
- Use a separate test for each person, the test can only be used once.
- Testing results should not be the sole basis for treatment or other management decisions.
- Keep the collector clean. Do not touch the collector and make sure it does not touch any surfaces before use.
- Read the Package Insert prior to use. Directions should be read and followed carefully.
- All specimens must be mixed thoroughly before testing to ensure a representative sample prior to testing.
- If infections with SARS-CoV-2, Influenza A virus and/or Influenza B virus are suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions and sent to state or local health departments for testing.
- The test components are packed in foil pouches to protect them from moisture during storage. Check each foil pouch before opening it. Do not use any component that has holes in the film or the pouch has not been completely sealed. Improper storage of test items or components can lead to incorrect results.
- If samples and test components are not brought to room temperature before the test, the test sensitivity may be reduced. Incorrect or unsuitable sampling and storage can lead to false negative test results.
- Avoid eye, skin and mucous membrane contact with the buffer. In the event of contact with buffer, rinse with plenty of water.
- Keep out of the reach of children. Small test components can pose a choking hazard.
- Use only the supplied test components. Do not replace the buffer with any other liquid.
- Keep the collector clean. Do not touch the collector and make sure it does not touch any surfaces before use.
- If you have a nose piercing, dab the other nostril. If pierced on both sides, remove the piercing on one side before wiping it off.
- Dispose all parts of the used test kit into the waste bag, then discard the waste bag in the general waste.

LIMITATIONS OF THE TEST

1. The test is suitable for personal use and may only be used for the qualitative detection of the SARS-CoV-2 viral nucleocapsid proteins and Influenza A&B virus. The intensity of color in a positive band should not be evaluated as "quantitative or semi-quantitative".
2. As with all diagnostic tests, a clinical diagnosis must not be based on the results of a single test, but rather be made by the doctor after all clinical and laboratory results have been evaluated.
3. Failure to follow the TEST PROCEDURE and INTERPRETATION OF RESULTS may negatively affect and / or falsify the test result.
4. Negative results do not completely rule out an infection with SARS-CoV-2 viral and Influenza A&B virus.
5. A negative result does not rule out infection with another type of respiratory virus.
6. Recommend repeat testing (e.g. within 1-3 days) if ongoing suspicion of infection, high risk setting or occupational or other requirement.
7. This test does not discriminate between SARS-coronavirus and SARS-CoV-2 (COVID-19). Positive results may be due to present infection with SARS-CoV.
8. The tests are less reliable in the later phase of infection (more than 7 days after the onset of COVID-19 symptoms or more than 4 days after the onset of Influenza A/B symptoms) and in asymptomatic individuals.
9. Negative results may not mean a person is not infectious and if symptoms are present the person must seek immediate further testing.

QUALITY CONTROL

Internal Procedural Controls

The COVID-19 & Influenza A/B Antigen Nasal Test Kit for Self-testing has built-in (procedural) controls. Each test device has an internal standard zone to ensure proper sample flow. The user should confirm that the coloured band located at the "C" region is present before reading the result.

PERFORMANCE

Analytical Sensitivity

The limit of detection (LOD) of COVID-19 & Influenza A/B Antigen Nasal Test Kit for Self-testing, defined as the concentration of influenza virus and SARS-CoV-2 virus that produces positive COVID-19 & Influenza A/B Antigen Nasal Test Kit for Self-testing results approximately 95% of the time, was identified by evaluating different concentrations of inactivated Flu A, inactivated Flu B and inactivated SARS-CoV-2 in the COVID-19 & Influenza A/B Antigen Nasal Test Kit for Self-testing.

The LOD on SARS-CoV-2 for COVID-19 Test and influenza viral strains for Influenza A/B Test were summarised in the table

SARS-CoV-2	Wild-type	$1\times10^{2.4}$ $TCID_{50}$/mL
Influenza A (H1N1)	A/Michigan/45/2015	1.0×10^{4} $TCID_{50}$/mL
Influenza A (H3N2)	A/Hong Kong/4801/2014	4.3×10^{4} $TCID_{50}$/mL
	A/Switzerland/9715293/2013	1.63×10^{4} $TCID_{50}$/mL
Influenza B (Yamagata lineage)	B/Phuket/3073/2013	2.5×10^{5} $TCID_{50}$/mL
Influenza B (Victoria lineage)	B/Colorado/06/2017	2.2×10^{5} $TCID_{50}$/mL
	B/Brisbane/60/2008	5.5×10^{4} $TCID_{50}$/mL

Analytical Inclusivity:

The analytical inclusivity study demonstrated the performance of COVID-19 & Influenza A/B Antigen Nasal Test Kit for Self-testing was not affected by different inactivated SARS-CoV-2 variants and different live influenza viral strains summarised as below:

SARS-CoV-2:
Alpha (B.1.1.7), Beta (B.1.351), Delta (B.1.617.2), Omicron (B.1.1.529.1), Omicron (B.1.1.529.2)

Influenza A (H1N1):
A/Michigan/45/2015, A/California/07/2009, A/Brisbane/02/2018, A/Victoria/2570/2019, A/Wisconsin/588/2019, A/Sydney/5/2021

Influenza A (H3N2):
A/Singapore/INFIMH-16-0019/2016, A/Hong Kong/4801/2014, A/Hong Kong/2671/2019, A/Hong Kong/45/2019, A/Switzerland/9715293/2013, A/Darwin/6/2021, A/Darwin/9/2021

Influenza B (Yamagata lineage):
B/Massachusetts/2/2012, B/Phuket/3073/2013

Influenza B (Victoria lineage):
B/Colorado/06/2017, B/Brisbane/60/2008, B/Washington/02/2019, B/Austria/1359417/2021

Clinical Evaluation:
The results of all clinical data are summarised in following tables:

COVID-19 Antigen Rapid Test vs. RT-PCR

		RT-PCR +	RT-PCR -	Total
COVID-19 & Influenza A/B Antigen Nasal Test Kit	+	192	1	193
	-	8	500	508
		200	501	701

Diagnostic Sensitivity: 96.0% (92.3%~98.0%) *
Diagnostic Specificity: 99.8 % (98.9%~100.0%)*
Overall Agreement: 98.7 % (97.6%~99.3%)*
***95% Confidence Interval**

Influenza A Antigen Rapid Test vs. RT-PCR

		RT-PCR +	RT-PCR -	Total
COVID-19 & Influenza A/B Antigen Nasal Test Kit	+	99	3	102
	-	4	595	599
		102	598	701

Diagnostic Sensitivity: 96.1% (90.4%~98.5%)*
Diagnostic Specificity: 99.5 % (98.5%~99.8%)*
Overall Agreement: 99.0 % (98.0%~99.5%)*
***95% Confidence Interval**

Influenza B Antigen Rapid Test vs. RT-PCR

		RT-PCR +	RT-PCR -	Total
COVID-19 & Influenza A/B Antigen Nasal Test Kit	+	79	2	81
	-	5	615	620
		84	617	701

Diagnostic Sensitivity: 96.1% (90.4%~98.5%)*
Diagnostic Specificity: 99.5 % (98.5%~99.8%)*
Overall Agreement: 99.0 % (98.0%~99.5%)*
***95% Confidence Interval**

Usability Study:

A layperson study was evaluated with 162 laypersons from different age and different education to establish the performance and usability of COVID-19& Influenza A/B Antigen Nasal Test Kit for Self-testing in a self-testing environment. For COVID-19 test, the tests by layperson correctly identified 92.9% (39/42) of positive samples and 100.0% (120/120) of negative samples compared with RT-PCR. For Influenza A test, the tests by layperson correctly identified 90.6% (29/32) of positive samples and 100.0% (130/130) of negative samples compared with RT-PCR. For Influenza B test, the tests by layperson correctly identified 90.0% (9/10) of positive samples and 100.0% (152/152) of negative samples compared with RT-PCR.

Cross Reactivity:

The COVID-19 & Influenza A/B Antigen Nasal Test Kit for Self-testing presented no cross-reactivity with the microorganisms listed below at specified concentrations. Potential cross-reacting microorganisms that may be present in the nasal samples have been validated. Only SARS-CoV produced false positive results with the SARS-CoV-2 test. Given the high homology between SARS-CoV and SARS-CoV-2, this risk remains a possibility.

Adenovirus 1	HCoV-OC43	Candida albicans
Adenovirus 2	HCoV-NL63	Chlamydia pneumoniae
Adenovirus 3	MERS-coronavirus	Group C Streptococcus
Adenovirus 4	Human metapneumovirus	Haemophilus influenzae
Adenovirus 5	Norovirus	Legionella pneumophila
Adenovirus 7	Parainfluenza virus 1	Mycoplasma pneumoniae
Adenovirus 55	Parainfluenza virus 2	Mycobacterium tuberculosis
Epstein-Barr virus	Parainfluenza virus 3	Staphylococcus aureus
Enterovirus EV70	Parainfluenza virus 4	Staphylococcus epidermidis
Enterovirus EV71	Respiratory syncytial virus A	Streptococcus agalactiae
Enterovirus A16	Respiratory syncytial virus B	Streptococcus pneumoniae
Enterovirus A24	Rhinovirus A30	Streptococcus pyogenes
Enterovirus B1	Rhinovirus B52	HCoV-HKU1
Echovirus 6	Bordetella parapertussis	
HCoV-229E	Bordetella pertussis	

Interfering Substances:

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the respiratory tract, were evaluated at the concentrations listed below. None of them were found to affect test performance of COVID-19 & Influenza A/B Antigen Nasal Test Kit for Self-testing.

3 OTC nasal sprays	Dextromethorphan	Oxymetazoline
3 OTC mouth washes	Diphenhydramine	Phenylephrine
3 OTC throat drops	Doxylamine succinate	Phenylpropanolamine
4-acetamidophenol	Flunisolide	Zanamivir
Acetylsalicylic acid	Guaiacol glyceryl ether	Adamantanamine
Albuterol	Mucin	Oseltamivir phosphate
Chlorpheniramine	Whole blood	Tobramycin
Dexamethasone	Mupirocin	Triamcinolone

LITERATURE REFERENCES

1. Forni, D., Cagliani, R., Clerici, M. & Sironi, M. Molecular evolution of human coronavirus genomes. Trends Microbiol. 25, 35-48 (2017).
2. Ithete, N. L. et al. Close relative of human Middle East respiratory syn-drome coronavirus in bat, South Africa. Emerg. Infect. Dis. 19, 1697-1699 (2013).

MEDICAL DEVICE INCIDENT REPORT

You can contact the Therapeutic Goods Administration (TGA) to report poor performance or usability issues via the online Users Medical Device Incident Report, emailing iris@tga.gov.au or calling 1800 809 361 (08: 30am to 5:00pm Monday to Friday) or https://www.tga.gov.au/. Wearing a mask can help protect you and those around you if you are in an area with community transmission and physical distancing is not possible.

SAFETY INFORMATION

Follow the directions of your local state or territory government health department to protect yourself. Test kit solutions should only be used as directed; do not ingest; do not dip the swab into provided solution or other liquid before inserting the swab into the nose; avoid contact with skin and eyes: keep out of the reach of children and pets before and after use. If the extraction buffer comes in contact with the skin or eyes, flush with plenty of water. If irritation persists, seek medical advice from a doctor or your local medical Centre.

GLOSSARY OF SYMBOLS

REF	Catalog number	2℃ 30℃	Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer	Σ	Contains sufficient for <n> tests
2	Do not reuse		Do not use if package is damaged

CUSTOMER SUPPORT CONTACT

For inquiries call our helpline on 1800 630 750 (9AM to 7PM AEST, 7 days/week)

Australian sponsor
2SAN Pty Ltd
Level 35, Tower One
100 Barangaroo Avenue,
Sydney, NSW 2000
www.2san.com
sales.au@2san.com

Assure Tech. (Hangzhou) Co., Ltd.
Building 4, No. 1418-50, Moganshan Road, Gongshu District, Hangzhou,310011 Zhejiang, P.R. China
contact@diareagent.com

Distributed by
2SAN
www.2san.com
helpdesk@2san.com
Helpline 1800 630 750
(9AM to 7PM AEST 7days/week)

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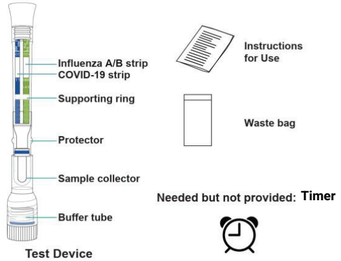
Revision Date: 2024-08-14

COVID-19 & Influenza A/B Antigen Nasal Test Kit for Self-testing

Package Insert - For Self-testing

REF CVF003AU | English

PACKAGE CONTENTS



Test Device

Instructions for Use

Waste bag

Needed but not provided: Timer

STORAGE & STABILITY

1. Store the COVID-19 & Influenza A/B Antigen Nasal Test Kit for Self-testing at 2-30ºC when not in use.
2. DO NOT FREEZE
3. Kit contents are stable until the expiration dates marked on outer packaging and container.
4. Shelf Life: 24 months. Do not use kit or components beyond the expiration date.

Note

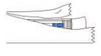
!!! Children aged between 2 and 18 years old, must be supervised or tested by an adult when carrying out the test.

!!! Do not use this test on anyone under 2 years of age.

!!! Caution should be taken when inserting the sample collector into the nasal cavity.

BEFORE THE TEST

1. Bring devices, regeants and specimens to room temperature (15-30ºC) before use.



2. Remove the test device from its packing. For the best results, the assay should be performed within 1 hour.

3. Wash your hands with soap and water or use hand sanitizer for 20 seconds.

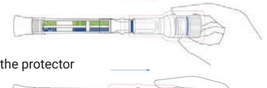
INTENDED USE

The COVID-19 & Influenza A/B Antigen Nasal Test Kit for Self-testing is an in vitro immunoassay. The assay is intended for home testing (or self-testing). Children aged between 2 and 18 years old, must be supervised or tested by an adult when carrying out the test. The assay is an in vitro immunochromatographic assay for the qualitative detection of SARS-CoV-2 and Influenza A/B viral nucleoprotein antigens in nasal swab specimens collected from patients against the respiratory infection for COVID-19 (within the first 7 days of the onset of symptoms) and influenza A/B (within the first 4 days of the onset of symptoms).

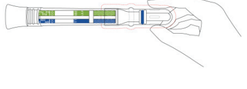
The assay obtains a preliminary result only, aid in the diagnosis of COVID-19 and/or Influenza A/B, for The final confirmation should be based on clinical diagnostic results according to local, state, or territory guidelines. This test has not been cleared for use in asymptomatic individuals.

TAKE YOUR NASAL SWAB

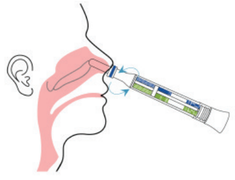
1. Take the test device out of the tube with extraction buffer.



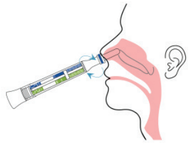
2. Remove the protector



3. Gently insert the sample collector until resistance is met (about 1-2 cm into the nostril). Rotate the collector five times against the nasal wall and remove from the nostril.



4. Pull the swab out of the nose while twisting it slightly.



5. Repeat the sample collection procedure for the other nostril to ensure that sufficient specimen be collected from both nasal cavities.

Note:

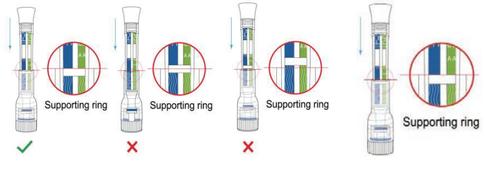
- Caution should be taken when inserting the sample collector into the nasal cavity.
- With children, the maximum depth of insertion into the nostril may be less than 2cm, and you may need to have a second person to hold the child' s head while swabbing.
- This may feel uncomfortable. Do not insert the collector any deeper if you feel strong resistance.

WARNING: Inaccurate test results may occur if the nasal swab specimen is not properly collected.

PROCESS THE SWAB SAMPLE

1. Place the test device vertically into the extraction tube until the top edge of the extraction tube reach the top of the supporting ring

WARNING: When placing the test device vertically into the extraction tube, the edge of the extraction tube must reach the top of the supporting ring. If not, this may lead to lateral flow failure, resulting in an incorrect result or invalid result.



2. Read the results at 15 minutes. Do not read the results after 30 minutes.

3. The used test kit should be put into the waste bag and then discarded as the general waste.

READ AND INTERPRET YOUR RESULTS

For COVID-19 test:

Positive: Two coloured bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).
A positive test result means it is very likely patients currently have COVID-19 disease.

- 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.
- f 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, difficultly 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.

NOTE: There is a very small chance that this test can give a result that is incorrect (a false positive). A positive result does not rule out co-infections with other pathogens.

Negative: Only one coloured band appears, in the control region (C). No apparent coloured band appears in the test region (T).
A negative result for COVID-19 does not mean a person does not have COVID-19. If a person has symptoms, they should follow the guidance from the local state or territory health departments, and if unwell seek medical assistance.

NOTE: Negative results are presumptive and may need to be confirmed with a molecular assay. If symptoms continue or suspected infection, you should be tested again with at least 24 hours and no more than 48 hours between tests as SARS-Cov-2 antigen cannot be precisely detected in all phases of an infection.

Invalid: No coloured band appears in the control region (C), whether a test band(s) is present or not.
Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

For Influenza A/B test:

Influenza A Positive: One coloured band appears in the control region (C), and another coloured band in the A region (A).

Influenza B Positive: One coloured band appears in the control region (C), and another coloured band in the A region (B).

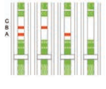
Influenza A+B Positive: One coloured band appears in the control region (C), and two other coloured bands appear in both A region (A) and B region (B).
Co-infection with influenza A and B is rare. The positive results for both A and B should be considered an invalid result, and another test should be performed. If the test is again positive for both influenza A and B, the specimen should be re-tested by another method prior to reporting of results.

A positive test result means that the virus that causes influenza A or influenza B was detected in your sample, and it is very likely that you have influenza A or influenza B. You should adhere to the local epidemic prevention guidelines.

NOTE: There is a very small chance that this test can give a result that is incorrect (a false positive). A positive result does not rule out co-infections with other pathogens or identify any specific influenza A virus subtype.

Negative: Only one coloured band appears in the control region (C), and band appears neither in the A region (A) nor B region (B).
A negative test result means it is unlikely patients have influenza A/B disease. Please continue to observe local hygiene and safety measures.

NOTE: A negative result does not mean a person does not have influenza, and if symptoms persist, the person should seek medical attention and further testing if required.



Invalid: No coloured band appears in the control region (C), whether a test band(s) is present or not.
Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

Assure Tech. (Hangzhou) Co., Ltd.
Building 4, No. 1418-50, Moganshan Road, Gongshu District, Hangzhou,310011 Zhejiang, P.R. China
contact@diareagent.com

Australian sponsor
2SAN Pty Ltd
Level 35, Tower One
100 Barangaroo Avenue,
Sydney, NSW 2000
www.2san.com
sales.au@2san.com

Distributed by
2SAN
www.2san.com
helpdesk@2san.com
Helpline 1800 630 750
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