5 in 1 Self-Test

SARS-CoV-2 / Flu A / Flu B / ADV/ RSV Antigen Combo Rapid Test Kit (LFIA)

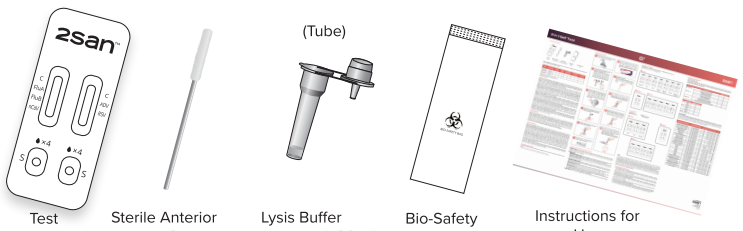
Package Insert - For Self-testing

ENGLISH

Intended Use

The 5 in 1 Self-Test SARS-CoV-2 / Flu A/ Flu B/ ADV/ RSV Antigen Combo Rapid Test Kit (LFIA) is an immunochromatography based one step *in vitro* test. It is designed for the qualitative detection of the SARS-CoV-2 virus, Influenza A virus, Influenza B virus, Adenovirus and Respiratory syncytial virus in human anterior nasal swab samples. The test results are used as an aid for diagnosis of respiratory pathogen infections, and are suitable for people with clinical symptoms such as fever, sore throat, cough, runny nose. The test kit is designed for use as self-testing. This test kit can be used independently by individuals who are 18 or older. For those under the age of 18, it should be performed or supervised by an adult. This test kit is not used in combination with other equipment and is not automated. It is designed to detect SARS-CoV-2 within the first 7 days of symptom onset, and Influenza A/B, ADV, RSV within the first 4 days of symptom onset.

Contents



Test Cassette | Sterile Anterior Nasal Swab | Lysis Buffer and Dropper (430µL) | Bio-Safety Bag | Instructions for Use

REF Number	Specification	Test Cassette	Sterile Swab	Lysis Buffer and Dropper	Bio-Safety Bag	Instructions For Use
123143-01-102-AU01	1pc/box	1	1	1	1	1
123143-02-102-AU01	2pcs/box	2	2	2	2	1
123143-05-102-AU01	5pcs/box	5	5	5	5	1

Materials required but not provided: Timer

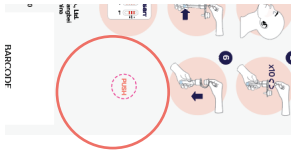
Testing Procedure

1 Bring the kit to room temperature before testing. Wash and dry your hands.

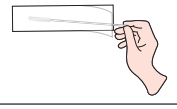
2 Verify the expiration date on the box or foil pouch. Ensure that the test kit components have not been used before, as these disposable items are intended for single use only. Do not open the pouch until you are ready to perform the test.

3 Tear open the seal of the sampling tube and place it into the test tube rack, which is perforated into the box.

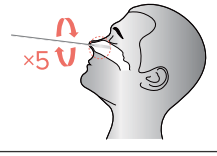
Note: Use the perforation on the back of the retail box to hold your test tube.



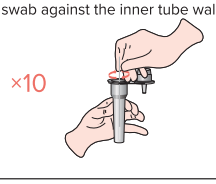
4 Collecting the sample:
Open the package containing the sterile swab. Avoid touching the cotton tip and remove the swab using the plastic handle.



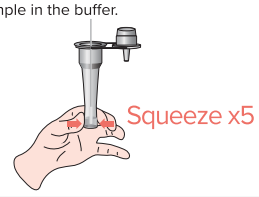
5 Insert the swab into a nostril (2.5 cm). Be sure to collect any nasal drainage that may be present. Carefully rotate the swab in a circular path against the inside of the nostril at least **5 times.** Using the same swab repeat the procedure in the other nostril.



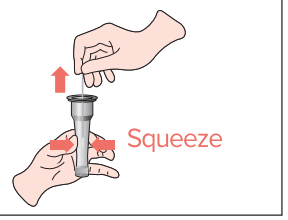
6 After collecting the sample, insert the swab's cotton tip into sampling tubes containing individual Lysis Buffer, rotate the swab against the inner tube wall **10 times.**



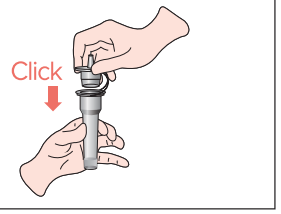
7 Squeeze the swab from the outer tube wall **5 times** to completely dissolve the sample in the buffer.



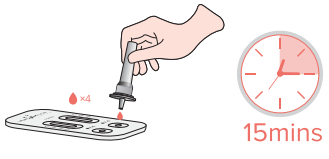
8 Move the swab up until it is resting on the sample solution, squeeze the swab from the outer tube wall in order to leave the sample in the tube as much as possible.



9 Remove and discard the swab, cover the tube with the dropper.



10 Dispense **4 drops** (approximately 100 µL) into each of the 2 sample wells in the test cassette. Read the results after 15 minutes. **Do not read after 20 minutes.**
Note: If the dispensed drop contains air bubbles, add another drop into the well.



11 Dispose all used materials into the Bio-safety bag and seal well.

Display of Results/Expected Values

Negative result: If only the control line (C line) appears and the detection line is not visible, the sample contains **no SARS-CoV-2, Influenza A, Influenza B, ADV, RSV** or the concentration is lower than the limit of detection and the result is negative.

Positive result:

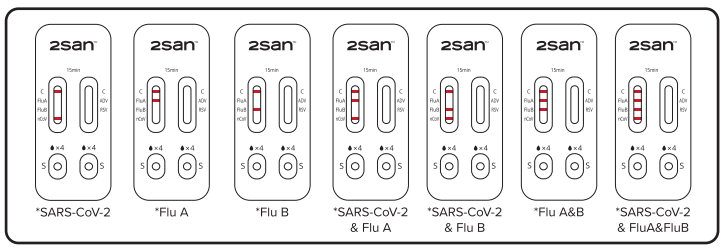
- **SARS-CoV-2 positive result:** If both the control line (C line) and the test line (nCoV line) appear at the same time, it means that SARS-CoV-2 antigen has been detected in the sample and the result of SARS-CoV-2 is positive.
  1. **If you test positive for COVID-19, you should:**
     - Stay at home until your symptoms are gone;
     - Manage and treat your symptoms;
     - Monitor your symptoms – if your symptoms worsen, see your doctor for oral treatments if you are in a high-risk group;
     - Follow the advice of your state or territory health agency.
  2. **If you have serious symptoms – such as severe shortness of breath or chest pain –call 000 immediately.**
  3. **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.**
- **Influenza A positive result:** If both the control line (C line) and the Influenza A test line (Flu A line) appear at the same time, it means that Influenza A antigen has been detected in the sample and the result of Influenza A is positive.
- **Influenza B positive result:** If both the control line (C line) and the Influenza B test line (Flu B line) appear at the same time, it means that Influenza B antigen has been detected in the sample and the result of Influenza B is positive.
- **ADV positive result:** If both the control line (C line) and the test line (ADV line) appear at the same time, it means that ADV antigen has been detected in the sample and the result of ADV is positive.
- **RSV positive result:** If both the control line (C line) and the test line (RSV line) appear at the same time, it means that RSV antigen has been detected in the sample and the result of RSV is positive.
  If the control line (C line) and multiple red lines appear simultaneously in the detection area, this indicates that more than one antigen has been identified. This means the sample contains one or more pathogenic microorganisms, resulting in multiple positive results.

Invalid result: If the control line (C line) does not appear, the result is invalid and a new test must be performed.

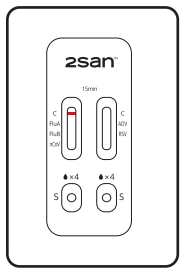
For SARS-CoV-2 & Flu A/B

C: Control Line **Flu A:** Influenza A Test Line **Flu B:** Influenza B Test Line
nCoV: SARS-CoV-2 Test Line **S:** Sample Well

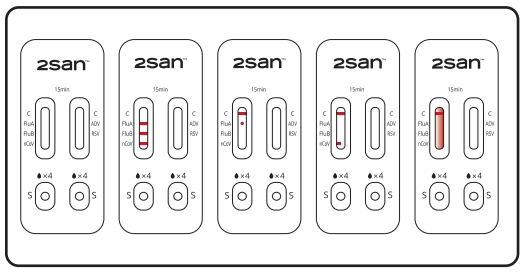
Positive



Negative



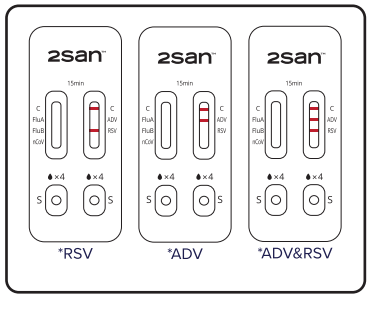
Invalid



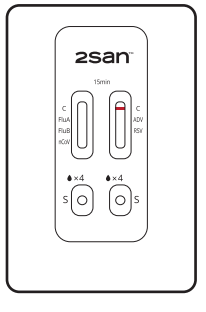
For ADV/RSV

C: Control Line **ADV:** ADV Test Line **RSV:** RSV Test Line **S:** Sample Well

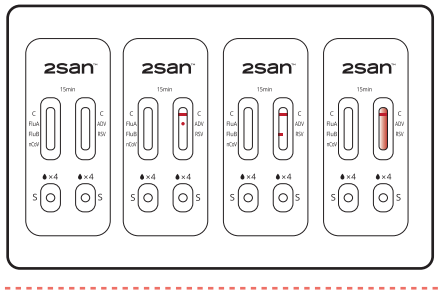
Positive



Negative



Invalid



Note:
The intensity of colour that the test line area (nCoV line/Flu A line/Flu B line) shows will vary according to the concentration of SARS-CoV-2 antigen, Influenza A antigen and Influenza B antigen. The result should be determined on whether the test line is formed or not, and is irrelevant to the colour intensity. Therefore, any intensity of colour in the test area (nCoV line/Flu A line/Flu B line) should be considered positive.
The intensity of colour that the test line area (ADV line/RSV line) shows will vary according to the concentration of ADV antigen, RSV antigen antigen. The result should be determined on whether the test line is formed or not, and is irrelevant to the colour intensity. Therefore, any intensity of colour in the test area (ADV line/RSV line) should be considered positive.

Introduction

Coronavirus (CoV) belongs to the order Nidovirales under the Coronaviridae family with 4 genera: α, β, γ and δ. The α and β genera are only pathogenic to mammals, while γ and δ genera mainly cause bird infections. CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also evidence supporting fecal-oral transmission.
7 kinds of human coronaviruses (HCoV) that cause human respiratory diseases have been identified so far, including: HCoV-229E, HCoV-NL63, HCoV-OC43, HCoV-HKU1, SARS-CoV, MERS-CoV and SARS-CoV-2. SARS-CoV-2 is one of the most contagious viral pathogens that causes human respiratory tract infections (RTI). Currently, the patients infected by SARS-CoV-2 are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The clinical manifestations include fever, fatigue, cough and other symptoms, accompanied by dyspnea, which can rapidly develop into life-threatening severe pneumonia, respiratory failure, acute respiratory vesicle syndrome, septic shock, multiple organ failure, and severe metabolic acid-base imbalance.
Influenza, usually called flu, is an acute respiratory infection caused by Influenza virus. It is highly contagious. It is mainly spread through coughing and sneezing. It usually breaks out in spring and winter. Influenza A viruses and influenza B viruses are thought to be the virus types causing epidemics. Influenza A viruses are highly variable, followed by Influenza B viruses. Therefore, Influenza A viruses are more prevalent and severe, followed by Influenza B viruses. Influenza A includes H1N1, H3N2, H5N1, H7N9, and Influenza B includes Influenza B (Victoria) and Influenza B (Yamagata).
Human adenovirus (ADV) belongs to the adenoviridae family, mammalian adenovirus genus, which is a double-stranded DNA virus without an envelope, mainly infects human respiratory tract, digestive tract and urogenital tract. The main ADV related to respiratory diseases is ADV-B Group (ADV-3, 7, 11, 14, 16, 21, 50, 55), ADV-C Group (ADV-1,2,5,6) and ADV-E group (ADV-4). Acute respiratory adenovirus (ADV) infection which is one of the most common acute respiratory infections in infants and young children. It mainly causes fever, cough, dyspnea and other symptoms.
Respiratory syncytial virus (RSV) belongs to Pneumovirus of Paramyxoviridae with only one serotype, which is a single stranded negative-strand RNA virus with an envelope. RSV infection mainly causes bronchiolitis and pneumonia in infants under 6 months of age and upper respiratory tract infections such as rhinitis and colds in older children and adults.

Test Principle

The 5 in 1 Self-Test SARS-CoV-2 / Flu A/ Flu B/ ADV/ RSV Antigen Combo Rapid Test Kit (LFIA) uses a double antibody sandwich method to detect SARS-CoV-2, Influenza A, Influenza B virus, Adenovirus (ADV), Respiratory syncytial virus (RSV) by colloidal gold immunochromatography. When the appropriate amount of test samples treated with lysis buffer is added to the sample well of the test cassette, the sample will move forward along the test strip by capillary action. If the sample contains SARS-CoV-2, Influenza A, Influenza B, Adenovirus (ADV), Respiratory syncytial virus (RSV) antigen, and the concentration is higher than the limit of detection, the antigen will form immune complexes with corresponding nucleocapsid protein antibody labeled with colloidal gold respectively, which are captured by lines nCoV line, Flu A line, Flu B line, ADV line, RSV line. If test sample contains SARS-CoV-2 virus, forming a red nCoV line, indicating a positive result for SARS-CoV-2. If test sample contains Influenza A virus, forming a red Flu A line, indicating a positive result for Influenza A. If test sample contains Influenza B virus, forming a red FluB line, indicating a positive result for Influenza B. If test sample contains Adenovirus, forming a red ADV line, indicating a positive result for Adenovirus. If test sample contains Respiratory syncytial virus, forming a red RSV line, indicating a positive result for Respiratory syncytial virus. The control line (C line) should be formed to indicate that the sample has been transported properly through the membrane regardless of whether sample contains antigens or not. If the C line does not appear, it indicates that the test result is invalid and the test will need to be repeated with a new sample and test cassette.

Storage Instructions

The test kit should be stored away from direct sunlight at 2°C to 30°C. Do not freeze. This test kit should be used within 1 hour after opening the foil pouch.

Warnings and Precautions

- This test kit is used for self-testing (Laymen's test) and for in-vitro diagnostic use only.
- This test kit can be used independently by individuals who are 18 or older. For those under the age of 18, it should be operated or supervised by an adult.
- Bring the kit contents to room temperature before testing.
- Proper protection should be taken during testing to avoid splashing when adding sample.
- The Lysis Buffer included: Tris, NaCl, EDTA, SDS, Triton X-405, Triton X- 100, Proclin 300, Purified water. Safety information – warnings with the lysis buffer (Lysis Buffer should only be used as directed; do not ingest; do not dip the swab into provided lysis Buffer 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 lysis 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)
- If the SARS-CoV-2 test result is positive, there is currently a suspicion of a COVID-19 infection. Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
- If influenza A/B, RSV, ADV test result is positive, it is advised to consult a medical practitioner for follow up clinical care
- Do not re-use the test kit.
- Do not use the test kit if the pouch is damaged, the seal is broken or the test cassette is wet or polluted.
- Do not use the test kit contents beyond the expiration date printed on the outside of the box.
- When collecting an anterior nasal swab sample, use only the Anterior Nasal Swab provided in the Kit.
- If an invalid result is produced, the user should retest with a new test kit.
- Do not mix with kit components from other batches.
- Place the used test casette, sterile swab, lysis buffer and dropper in the bio safety bag to avoid potential risk of sample infection.
- Negative results do not rule out SARS-CoV-2, Influenza A, Influenza B, ADV, RSV infection, particularly in those who have been in contact with the virus.
- A positive result cannot necessarily determine whether a person is infectious.
- False negative results may occur, especially when testing for SARS-CoV-2 is conducted beyond 7 days, or for Influenza/RSV/ADV beyond 4 days, after symptom onset.
- The test is less reliable when used in asymptomatic individuals or used in the condition of later phase of infection.
- Recommend repeat testing (e.g. within 1-3 days) if ongoing suspicion of infection, high risk setting or occupational or other requirement.
- Negative results may not mean a person is not infectious and if symptoms are present the person must seek immediate further testing.

Scan here for more information

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

5 in 1 Self-Test
SARS-CoV-2 / Flu A / Flu B / ADV/ RSV Antigen Combo Rapid Test Kit (LFIA)

Package Insert - For Self-testing
ENGLISH

2san™

Test Method Limitations

1. The accuracy of the test is dependent on the quality of the sample. Improper sampling or storage, using expired samples or repeated frozen-thawed samples can affect the test results. Test results can also be affected by temperature and humidity.
2. False negative results may be caused by low concentration of SARS-CoV-2, influenza A, influenza B, ADV, RSV antigens in the sample or may be due to some usage errors, therefore cannot completely rule out the possibility of infection.
3. Some medication (e.g. high concentration of over-the-counter (OTC) or prescription medication such as nasal spray) in the collected samples may interfere with the test result. Please perform the test again if in doubt of the result.
4. This product is only for qualitative testing and the specific concentration of each indicator must be measured using other quantitative methodologies.
5. The test results of this kit are for clinical reference only and are not the sole basis for clinical diagnosis. The clinical diagnosis and treatment of patients should be comprehensively considered in combination with their symptoms/signs, medical history, other laboratory tests and treatment response.
6. If the SARS-CoV-2 test result is positive, there is currently a suspicion of a COVID-19 infection. Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
7. If influenza A/B test result is positive, there is currently a suspicion of influenza A/B infection, individuals with a positive result or who are unwell are advised to consult a medical practitioner for follow up clinical care.
8. If ADV/RSV test result is positive, there is a suspicion of ADV or RSV infection, individuals with a positive result or who are unwell are advised to consult a medical practitioner for follow up clinical care.

Product Performance

Limit of Detection-LoD

Limit of Detection (LoD) studies determined the lowest detectable concentration of SARS-CoV-2, Influenza A, Influenza B, ADV, RSV at which 100% of all (true positive) replicates test positive. ($TCID_{50}$/ml: The Common units of virulence of live viruses)

	Virus Strain	LoD ($TCID_{50}$/mL)
COVID-19	BetaCoV/JS02/human/2020	10^1
Influenza A	A/Brisbane/02/2018 (H1N1)	10^4
	A/PUERTO/8/1934 (H1N1)	10^2
	A/Kansas/14/2017 (H3N2)	10^2
	A/Aichi/2/1968 (H3N2)	10^2
	A/Anhui/1/2013 (H7N9)	10^4
Influenza B	B/Colourado/06/2017 (Victoria)	10^0
	B/Phuket/3073/2013 (Yamagata)	10^2
	B/Chaoyang Beijing/12977/2017 (Yamagata)	10^4
ADV	ADV-1	10^5
	ADV-2	10^3
	ADV-3	10^4
	ADV-4	10^4
	ADV-7	10^3
	ADV-55	10^3
RSV	RSV-A	10^4
	RSV-B	10^4

Analytical Inclusivity

The following SARS-CoV-2/FluA/FluB variants can be detected with the 5 in 1 Self-Test SARS-CoV-2 / Flu A/ Flu B/ ADV/ RSV Antigen Combo Rapid Test Kit (LFIA).

SARS-CoV-2		
Alpha	Delta	XBB.1.5
Beta	Omicron	XBB.1.16
Gamma		
FluA		
A/Victoria/4897/2022 (H1N1)	A/Massachusetts/18/2022 (H3N2)	A/Victoria/2570/2019 (H1N1)
A/Croatia/10136RV/2023 (H3N2)	A/Sydney/5/2021 (H1N1)	A/Wisconsin/588/2019 (H1N1)
A/Wisconsin/67/2022 (H1N1)	A/Darwin/9/2021 (H3N2)	A/Hong Kong/2671/2019 (H3N2)
A/District of Columbia/27/2023 (H3N2),	A/Darwin/6/2021 (H3N2)	A/Hong Kong/45/2019 (H3N2)
A/Thailand/8/2022 (H3N2),		
FluB		
B/Austria/1359417/2021	B/Washington/02/2019	B/Victoria/27/2020
B/Phuket/3073/2013	B/Colorado/06/2017	B/Brisbane/60/2008
ADV		
ADV-1	ADV-3	ADV-7
ADV-2	ADV-4	ADV-55
RSV		
RSV Type A/A2	RSV Type B/GZ/1704-8	RSV Type B/B WV-14617-85
RSV Type A/Long	RSV Type B/18537	

Cross Reactivity

Cross reactivity of 5 in 1 Self-Test SARS-CoV-2/Flu A/ Flu B/ ADV/ RSV Antigen Combo Rapid Test Kit (LFIA) was evaluated by testing commensal and pathogenic microorganisms listed in the following table that may be present in the clinical samples. Each of the bacterium, viruses, and yeast were tested in triplicate with no false positive results of Covid-19 virus, Influenza A, Influenza B, ADV, RSV. The following substances have shown no cross-reactivity with this product, as each marker is specific to its target and does not cross-react with the others (e.g., the COVID-19 marker is specific to SARS-CoV-2 and shows no cross-reactivity with H1N1 (2009), Influenza A H1N1Seasonal, Influenza A H3N2, etc.).

Potential Cross-Reactant	
Human coronavirus OC43	RSV-B
Human coronavirus NL63	Parainfluenza virus Type2
Human coronavirus HKU1	Parainfluenza virus Type3
Human coronavirus 229E	Parainfluenza virus Type 4
MERS-coronavirus	Rhinovirus
SARS-coronavirus	*Mycoplasma pneumoniae*
COVID-19	*Staphylococcus aureus*
H1N1(2009)	*Staphylococcus epidermidis*
Influenza A H1N1 Seasonal	*Bordetella pertussis*
Influenza A H3N2	*Legionella pneumophila*
Influenza A H5N1	*Streptococcus pneumoniae*
Influenza A H7N9	*Haemophilus Influenzae*
Influenza B Victoria	*Mycobacterium tuberculosis*
Influenza B Yamagata	*Candida albicans*
Parainuenza virus Type 1	*Streptococcus pyogenes*
Respiratory syncytial virus	*Streptococcus dysgalactiae subspecies*
Enterovirus CA16e	*equisimilis*
ADV-1	*Pneumocystis jirovecii (PJP)*
ADV-2	*Chlamydia pneumoniae*
ADV-3	*Mycobacterium tuberculosis*
ADV-4	*Streptococcus salivarius*
ADV-7	*Pseudomonas aeruginosa*
ADV-55	*Human metapneumovirus (hMPV)*
RSV-A	

Interfering Substances Effect

A study was performed to evaluate and demonstrate that the endogenous substances naturally present or drugs that may be artificially introduced into clinical samples do not inference with the detection of SARS-CoV-2, Influenza A, Influenza B, ADV, RSV in the 5 in 1 Self-Test SARS-CoV-2 / Flu A/ Flu B/ ADV/ RSV Antigen Combo Rapid Test Kit (LFIA).

Type	Potential Interfering Substances
Endogenous Substance	Mucin
	Whole Blood
	Icteric (Bilirubin)
	Rheumatoid factor
	Triglycerides
	Hemoglobin
	Anti-nuclear antibody
	Total IgG
	Total IgM
	Total IgA

Type	Potential Interfering Substances
Exogenous Substance	Mupirocin
	Tamiflu (Oseltamivir Phosphate)
	Fluticasone Propionate
	Fluconazole
	Zincum gluconium (i.e., Zicam)
	Alkalol
	Phenol
	Phenylephrine hydrochloride
	Oxymetazolin hydrochloride
	Cromolyn
	Oxymetazoline
	Galphimia glauca, Sabadilla
	Albuterol
	Acarbose
	Oseltamivir
	Chlorpheniramine
	Diphenhydramine
	Glimepiride (Sulfonylureas)
	Chlorothiazide
	Acetylsalicylic acid
	Amoxicillin

Type	Potential Interfering Substances
Exogenous Substance	Ibuprofen
	Beclomethasone
	Indapamide
	Flunisolide
	Guaiacol glyceryl ether
	Biotin
	Zanamivir
	Tobramycin
	Sulfur
	Ribavirin
	Ephedrine
	Benzocaine
	Menthol
	Budesonide
	Triamcinolone
	Dexamethasone
	Sodium chloride with preservatives
	Lopinavir
	Ritonavir
	Chloroquine phosphate
	Ivermectin

Clinical performance

The performance of 5 in 1 Self-Test SARS-CoV-2 / Flu A/ Flu B/ ADV/ RSV Antigen Combo Rapid Test Kit (LFIA) was evaluated with 1173 anterior nasal swabs and 1173 throat swabs. Two swabs were collected from the same people, an anterior nasal swab tested directly using 5 in 1 Self-Test SARS-CoV-2 / Flu A/ Flu B/ ADV/ RSV Antigen Combo Rapid Test Kit (LFIA) and a throat swab tested by the RT-PCR Test Kit.

1. SARS-CoV-2 Test

5 in 1 Self-Test SARS-CoV-2 / Flu A/ Flu B/ ADV/ RSV Antigen Combo Rapid Test Kit	RT-PCR		
	SARS-CoV-2 Positive	Negative	Total
SARS-CoV-2 Positive	102	0	102
Negative	5	1066	1071
Total	107	1066	1173
Diagnostic sensitivity: 95.33% (89.43%~98.47%) **Diagnostic specificity:** 100.00% (99.65%~100.00%) **Accuracy:** 99.57% (99.01%~99.86%)		**Positive predictive value:** 100.00% (96.45%~100.00%) **Negative predictive value:** 99.53% (98.91%~99.85%) **Kappa:** 0.9737 95% **CI:** 0.9508~0.9967	

2. Influenza A Test

The performance of the 5 in 1 Self-Test SARS-CoV-2 / Flu A/ Flu B/ ADV/ RSV Antigen Combo Rapid Test Kit (LFIA) was evaluated with 1173 anterior nasal swabs and 1173 throat swabs. Two swabs were collected from the same people, an anterior nasal swab tested directly using the 5 in 1 Self-Test SARS-CoV-2 / Flu A/ Flu B/ ADV/ RSV Antigen Combo Rapid Test Kit (LFIA) and a throat swab tested by the RT-PCR Test Kit .

5 in 1 Self-Test SARS-CoV-2 / Flu A/ Flu B/ ADV/ RSV Antigen Combo Rapid Test Kit	RT-PCR		
	Influenza A Positive	Negative	Total
Influenza A Positive	86	0	86
Negative	4	1083	1087
Total	90	1083	1173
Diagnostic sensitivity: 95.56% (89.01%~98.78%) **Diagnostic specificity:** 100.00% (99.66%~100.00%) **Accuracy:** 99.66% (99.13%~99.91%)		**Positive predictive value:** 100.00% (95.80%~100.00%) **Negative predictive value:** 99.63% (99.06%~99.90%) **Kappa:** 0.9754 95% **CI:** 0.9514~0.9995	

3. Influenza B Test

The performance of the 5 in 1 Self-Test SARS-CoV-2 / Flu A/ Flu B/ ADV/ RSV Antigen Combo Rapid Test Kit (LFIA) was evaluated with 1173 anterior nasal swabs and 1173 throat swabs. Two swabs were collected from the same people, an anterior nasal swab tested directly using the 5 in 1 Self-Test SARS-CoV-2 / Flu A/ Flu B/ ADV/ RSV Antigen Combo Rapid Test Kit (LFIA) and a throat swab tested by the RT-PCR Test Kit .

5 in 1 Self-Test SARS-CoV-2 / Flu A/ Flu B/ ADV/ RSV Antigen Combo Rapid Test Kit	RT-PCR		
	Influenza B Positive	Negative	Total
Influenza B Positive	94	0	94
Negative	5	1074	1079
Total	99	1074	1173
Diagnostic sensitivity: 94.95% (88.61%~98.34%) **Diagnostic specificity:** 100.00% (99.66%~100.00%) **Accuracy:** 99.57% (99.01%~99.86%)		**Positive predictive value:** 100.00% (96.15%~100.00%) **Negative predictive value:** 99.54% (98.92%~99.85%) **Kappa:** 0.9718 95% **CI:** 0.9471~0.9965	

4. ADV Test

The performance of the 5 in 1 Self-Test SARS-CoV-2 / Flu A/ Flu B/ ADV/ RSV Antigen Combo Rapid Test Kit (LFIA) was evaluated with 1173 anterior nasal swabs and 1173 throat swabs. Two swabs were collected from the same people, an anterior nasal swab tested directly using the 5 in 1 Self-Test SARS-CoV-2 / Flu A/ Flu B/ ADV/ RSV Antigen Combo Rapid Test Kit (LFIA) and a throat swab tested by the RT-PCR Test Kit.

5 in 1 Self-Test SARS-CoV-2 / Flu A/ Flu B/ ADV/ RSV Antigen Combo Rapid Test Kit	RT-PCR		
	AdV Positive	Negative	Total
ADV Positive	135	0	135
Negative	7	1031	1038
Total	142	1031	1173
Diagnostic sensitivity: 95.07% (90.11%~98.00%) **Diagnostic specificity:** 100% (99.64%~100%) **Accuracy:** 99.39% (98.77%~99.76%)		**Positive predictive value:** 100% (97.30%~100%) **Negative predictive value:** 99.39% (98.62%~99.73%) **Kappa:** 0.9713 95% **CI:** 0.9502~0.9925	

5. RSV Test

The performance of the 5 in 1 Self-Test SARS-CoV-2 / Flu A/ Flu B/ ADV/ RSV Antigen Combo Rapid Test Kit (LFIA) was evaluated with 1173 anterior nasal swabs and 1173 throat swabs. Two swabs were collected from the same people, an anterior nasal swab tested directly using 5 in 1 Self-Test SARS-CoV-2 / Flu A/ Flu B/ ADV/ RSV Antigen Combo Rapid Test Kit (LFIA) and a throat swab tested by the RT-PCR Test Kit.

5 in 1 Self-Test SARS-CoV-2 / Flu A/ Flu B/ ADV/ RSV Antigen Combo Rapid Test Kit	RT-PCR		
	RSV Positive	Negative	Total
RSV Positive	210	0	210
Negative	8	955	963
Total	218	955	1173
Diagnostic sensitivity: 96.33% (92.90%~98.40%) **Diagnostic specificity:** 100% (99.61%~100%) **Accuracy:** 99.32% (98.66%~99.71%)		**Positive predictive value:** 100% (98.26%~100%) **Negative predictive value:** 99.17% (98.37%~99.64%) **Kappa:** 0.9771 95% **CI:** 0.9614~0.9929	

Usability Study

Usability Study has been conducted in Poland. 5 in 1 Self-Test SARS-CoV-2 / Flu A/ Flu B/ ADV/ RSV Antigen Combo Rapid Test Kit (LFIA) was compared to the marketed CE marked RT-PCR method. 210 lay persons performed the self-testing and interpreted the result, which 150 (30 per analyte) were enrolled in diagnostic sensitivity study and 60 were enrolled in diagnostic specificity study.

The test result showed:

Diagnostic specificity of the product was 100%(60/60).

Diagnostic sensitivity of the product per analyte:

SARS-CoV-2: 100%(30/30) **Flu A:** 96.67%(29/30) **Flu B:** 96.67%(29/30)
RSV: 96.67% (29/30) **ADV:** 96.67%(29/30)

Report Performance or Usability Issues

Contact TGA to report poor performance or usability issues in the self-test enyironment. Report an issue via the Users Medical Device Incident Report, email: iris@tga.gov.au or call 1800 809 361.

References

1. LY Wang, PR Chen, G W Zheng, et al. Research progress on novel coronavirus test methods. Modern Medicine and Clinic, 2020, 35(3): 411-416.
2. K Tugba, W Ralph, L Hakho. Molecular and Immunological Diagnostic Tests of COVID-19: Current Status and Challenges. IScience, 2020, 23 (8): Doi: 10.1016/j.isci.2020.101406
3. WHO recommendations on the use of rapid testing for inflfluenza diagnosis, World Health Organisation, July 2005.
4. Tian X , Fan Y , Wang C , et al. Seroprevalence of Neutralizing Antibodies against Six Human Adenovirus Types Indicates the Low Level of Herd Immunity in Young Children from Guangzhou, China[J]. Chinese Journal of Virology: English Edition, 2021, 36(3):9.
5. Jing J , Chen Y , Wang Z . Specific IgG antibodies against F and G glycoproteins of respiratory syncytial virus (RSV) in asthmatic children after infection with the virus[J]. Chinexe Journal of Pediatrics, 1998.

Index of Symbols

IVD	*In Vitro* Diagnostic Medical Device	Σ	Contains sufficient for <n> tests		Manufacturer
LOT	Batch code		Keep dry		Temperature limit
STERILE EO	Sterilized using ethylene oxide		Keep away from sunlight		This way up
	Do Not Re-use		Consult Instructions for Use		Fragile, handle with care
	Do not use if package is damaged		Use-by date		Stacking Limit By number
Caution	Caution		Date of manufacture	REF	Catalogue Number

Jiangsu Medomics Medical Technology Co., Ltd.
Building 01, Phase 6, No.71,
Xinghui Road, Jiangbei New Area,
Nanjing, 210000, Jiangsu, P.R. China

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
(9AM to 7PM AEST 7days/week)

SKU Number: CFA000AU
100000-AU-10
Revision Date: 2026-01-06