SARS-CoV-2/FluA/FluB+ ADV/RSV Antigen Combo Rapid Test Kit (LFIA)

Scan to obtain the e-IFU

Scan to watch the operation video of this test kit

Self-testing

FOR *IN VITRO* DIAGNOSTIC USE ONLY.
FOR SELF-TESTING.
PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST.

Test Kit contents

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

Test kit contains test cassettes, sterile anterior nasal swabs, sampling tubes containing individual lysis buffer, droppers, and instructions for use.

REF	Specification	Test Cassette	Sterile swabs	Lysis Buffer and Dropper	Bio-Safety Bag	Instructions For Use	Test-tube Rack
123143-01-102S	1pc/box	1	1	1	1	1	/
123143-02-102S	2pcs/box	2	2	2	2	1	/
123143-04-102S	4pcs/box	4	4	4	4	1	/
123143-05-102S	5pcs/box	5	5	5	5	1	/
123143-07-102S	7pcs/box	7	7	7	7	1	1
123143-10-102S	10pcs/box	10	10	10	10	2	1

Materials required but not provided: timer

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.

Intended Use

SARS-CoV-2/FluA/FluB+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. It is designed to detect SARS-CoV-2 within the first 7 days of symptom onset, and Influenza A/B, ADV or RSV within the first 4 days of symptom onset.
This test kit is not used in combination with other equipment and is not automated.

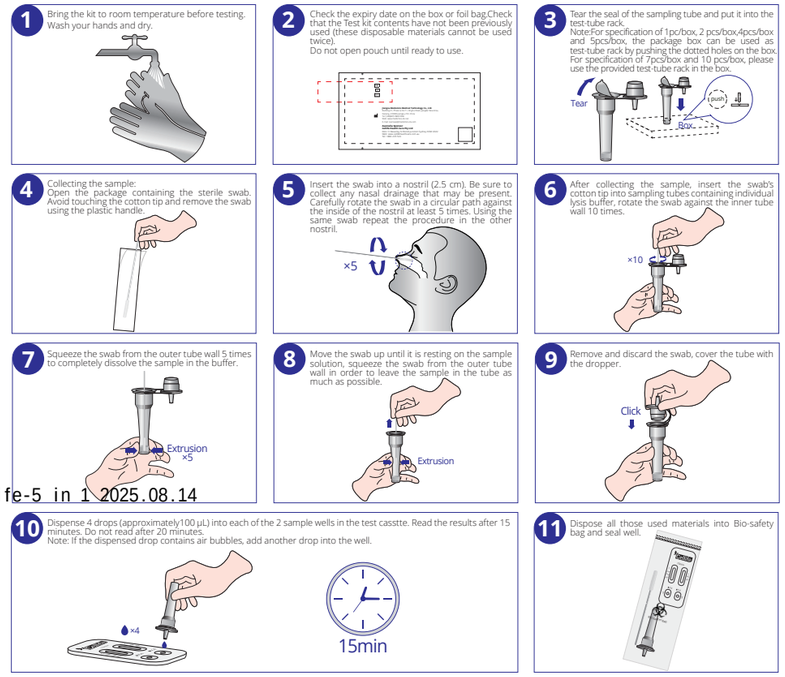
Test Principle

SARS-CoV-2/FluA/FluB+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 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 sample need to retest.

Storage Instructions

The test kit should be stored away from direct sunlight at 2℃ to 30℃ with a shelf-life of 36 months. Do not freeze.
This test kit should be used within 1 hour after opening the foil pouch.

Testing Procedure



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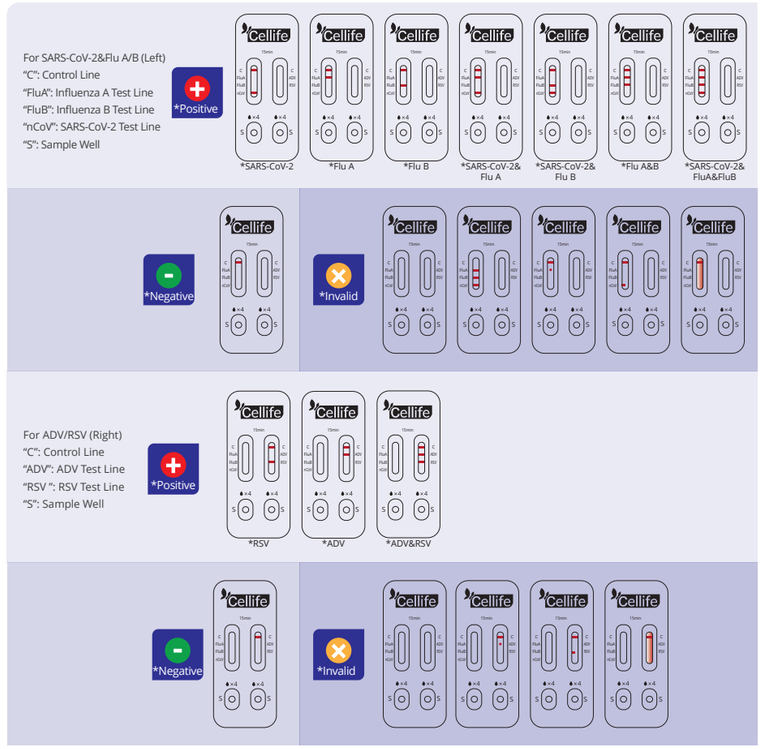
Display of Results/Expected Values

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 and the result is positive.
• 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 quality control C line appears, and more red lines appear in the detection line area, indicating that the sample contains one or more pathogenic microorganisms
What you need to do:
• There is currently a suspicion of a COVID-19&Flu A&Flu B&ADV&RSV infection.
• 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 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.
• Individuals who have tested positive for influenza or who are unwell are advised to consult a medical practitioner for follow-up clinical care.
Negative result:
If only the quality control 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.
What you need to do:
• Continue to comply with all applicable rules regarding contact with others and protective measures.
• There may be an infection even if the test is negative.
• If it is suspected, repeat the test after 1 - 3 days, as the coronavirus cannot be precisely detected in all phases of an infection.
• Invalid result:
Invalid result: If the C line does not appear, the result is invalid and a new test must be performed again.
What you need to do:
• Possibly caused by incorrect test execution.
• Repeat the test with a new kit.
• If the test results remain invalid, contact the sponsor hotline for further guidance.



***Note:**
The intensity of color 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 color intensity. Therefore, any intensity of color in the test area (nCoV line/Flu A line/Flu B line) should be considered positive.
The intensity of color 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 color intensity. Therefore, any intensity of color in the test area (ADV line/RSV line) should be considered positive.

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.Low concentration of SARS-CoV-2, Influenza A， Influenza B ,ADV and RSV antigens in the sample may cause negative results, so the possibility of infection cannot be completely ruled out
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 Some use errors can also lead to false negative, 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 the result is in doubt.
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.Recommend repeat testing (e.g. within 1-3 days) if there is an ongoing suspicion of infection, being in a high risk setting or where there is an occupational risk or other requirement.
7.The test is less reliable when used in the condition of later phase of infection. If testing is not performed within the first 7 days symptom onset, false SARS-CoV-2 negative results may occur.If testing is not performed within the first 4 days symptom onset, false influenza negative results may occur.
8.A negative result does not mean a person is not infectious or does not have influenza. If symptoms persist the person should seek medical attention.A negative result does not rule out infection with another type of respiratory virus
9.A positive result cannot necessarily determine whether a person is infectious.SARS-CoV-2 and Influenza self-testing are for use as an aid for diagnosis only and 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)
SARS-CoV-2	BetaCoV/JS12/human/2022	10
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/Colorado/06/2017 (Victoria)	10^0
	B/Phuket/3073/2013 (Yamagata)	10^2
	B/Chaoyang Beijing/12977/2017 (Yamagata)	10^4

	Virus Strain	LoD($TCID_{50}$/mL)
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

Customer Support
For assistance regarding to the use of the test kit and interpretation of test results, call 1800 517 206,The service is available between 9 am to 7 pm (AEST), or 9 am to 8 pm (AEDT), 7 days per week.

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

• Cross Reactivity
Cross reactivity of SARS-CoV-2/FluA/FluB+ADV/RSV Antigen Combo Rapid Test Kit (LFIA) was evaluated by testing commensall and pathogenic microorganisms listed below that may be present in the clinical samples. The substance below are no Cross Reactivity with test result,which the each assay marker is active on itself and does not cross-react with the other marker(For example, the SARS-CoV-2 is active against SARS-CoV-2, but has no cross-reactivity against H1N1 (2009), Influenza A H1N1, Seasonal Influenza A H3N2, Influenza A H5N1, etc).
List of cross reactivity sustances tested:(The test concentration is 1×10^6 CFU/mL or 1×10^6 $TCID_{50}$/mL). Human coronavirus OC43, Human coronavirus NL63, Human coronavirus HKU1, Human coronavirus 229E, MERS-coronavirus, SARS-coronavirus, SARS-COV-2, H1N1(2009), Influenza A H1N1, Seasonal Influenza A H3N2, Influenza A H5N1, Influenza A H7N9, Influenza B Victoria, Influenza B Yamagata, Parainuenza virus Type 1,Respiratory syncytial virus,Enterovirus CA16e, ADV-1, ADV-2, ADV-3, ADV-4, ADV-7, ADV-55, RSV-A, RSV-B, Mycoplasma pneumoniae, Staphylococcus aureus, Staphylococcus epidermidis, Bordetella pertussis, Legionella pneumophila, Streptococcus pneumoniae, Haemophilus Influenzae, Mycobacterium tuberculosis, Candida albicans,Streptococcus pyogenes,Streptococcus dysgalactiae subspecies equisimilis. Pneumocystis jirovecii (PJP), Chlamydia pneumoniae, Mycobacterium tuberculosis, Streptococcus salivarius, Pseudomonas aeruginosa, Parainfluenza virus Type2, Parainfluenza virus Type3, Parainfluenza virus Type4, Rhinovirus Human Metapneumovirus (hMPV).

• 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 SARS-CoV-2/Flu A/Flu B+ADV/RSV Antigen Combo Rapid Test Kit (LFIA) at the concentrations listed below.
Endogenous Substance: Mucin, whole blood, icteric (bilirubin) rheumatoid factor, triglycerides, hemoglobin, anti-nuclear antibody, total IgG, total IgM, total IgA.
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, 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

1. SARS-CoV-2 Test
The performance of SARS-CoV-2/FluA/FluB+ADV/RSV Antigen Combo Rapid Test Kit (LFIA) were evaluated with 1173 anterior nasal swabs and 1173 Throat swabs. Two swabs were collected with the same people, an anterior nasal swab tested directly using SARS-CoV-2/FluA/FluB+ADV/RSV Antigen Combo Rapid Test Kit (LFIA) and a Throat swab tested by the RT-PCR Test Kit.

SARS-CoV-2/FluA/FluB+ 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%)		Positive predictive value: 100.00% (96.45%~100.00%)	
Diagnostic specificity: 100.00% (99.65%~100.00%)		Negative predictive value:99.53% (98.91%~99.85%)	
Accuracy:99.57%(99.01%~99.86%)		Kappa:0.9737 95%CI: 0.9508~0.9967	

2. Influenza A Test
The performance of SARS-CoV-2/FluA/FluB+ADV/RSV Antigen Combo Rapid Test Kit (LFIA) were evaluated with 1173 anterior nasal swabs and 1173 Throat swabs. Two swabs were collected with the same people, an anterior nasal swab tested directly using SARS-CoV-2/FluA/FluB+ADV/RSV Antigen Combo Rapid Test Kit (LFIA) and a Throat swab tested by the RT-PCR Test Kit.

SARS-CoV-2/FluA/FluB+ 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%)		Positive predictive value: 100.00% (95.80%~100.00%)	
Diagnostic specificity: 100.00% (99.66%~100.00%)		Negative predictive value:99.63% (99.06%~99.90%)	
Accuracy:99.66% (99.13%~99.91%)		Kappa:0.9754 95%CI: 0.9514~0.9995	

3. Influenza B Test
The performance of SARS-CoV-2/FluA/FluB+ADV/RSV Antigen Combo Rapid Test Kit (LFIA) were evaluated with 1173 anterior nasal swabs and 1173 Throat swabs. Two swabs were collected with the same people, an anterior nasal swab tested directly using SARS-CoV-2/FluA/FluB+ADV/RSV Antigen Combo Rapid Test Kit (LFIA) and a Throat swab tested by the RT-PCR Test Kit.

SARS-CoV-2/FluA/FluB+ 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%)		Positive predictive value: 100.00% (96.15%~100.00%)	
Diagnostic specificity: 100.00% (99.66%~100.00%)		Negative predictive value:99.54% (98.92%~99.85%)	
Accuracy:99.57% (99.01%~99.86%)		Kappa:0.9718 95%CI: 0.9471~0.9965	

4. ADV Test
The performance of SARS-CoV-2/FluA/FluB+ADV/RSV Antigen Combo Rapid Test Kit (LFIA) were evaluated with 1173 anterior nasal swabs and 1173 Throat swabs. Two swabs were collected with the same people, an anterior nasal swab tested directly using SARS-CoV-2/FluA/FluB+ADV/RSV Antigen Combo Rapid Test Kit (LFIA) and a Throat swab tested by the RT-PCR Test Kit.

SARS-CoV-2/FluA/FluB+ 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%)		Positive predictive value:100% (97.30%~100%)	
Diagnostic specificity:100% (99.64%~100%)		Negative predictive value:99.39% (98.62%~99.73%)	
Accuracy:99.39% (98.77%~99.76%)		Kappa:0.9713 95%CI: 0.9502~0.9925	

5. RSV Test
The performance of SARS-CoV-2/FluA/FluB+ADV/RSV Antigen Combo Rapid Test Kit (LFIA) were evaluated with 1173 anterior nasal swabs and 1173 Throat swabs. Two swabs were collected with the same people, an anterior nasal swab tested directly using SARS-CoV-2/FluA/FluB+ADV/RSV Antigen Combo Rapid Test Kit (LFIA) and a Throat swab tested by the RT-PCR Test Kit.

SARS-CoV-2/FluA/FluB+ 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%)		Positive predictive value:100% (98.26%~100%)	
Diagnostic specificity:100% (99.61%~100%)		Negative predictive value:99.17% (98.37%~99.64%)	
Accuracy:99.32% (98.66%~99.71%)		Kappa:0.9771 95%CI: 0.9614~0.9929	

Usability Study
Usability Study has been conducted in Poland.
SARS-CoV-2/FluA/FluB+ADV/RSV Antigen Combo Rapid Test Kit (LFIA) was used to compared with 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 for 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).

Warnings and Precautions

• This test kit is used for self-testing (Layman's test).
• This test kit is used for in vitro diagnosis 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 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.
• If ADV test result is positive: There is currently a suspicion of Adenovirus infection, individuals with a positive result or who are unwell are advised to consult a medical practitioner for follow up clinical care.
• If RSV test result is positive: There is currently a suspicion of Respiratory syncytial virus infection, individuals with a positive result or who are unwell are 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.
• Do not mix with kit components from other batches.
• The test cassette,sterile swab ,Lysis Buffer and Dropper after the test are placed in a biosafety bag to avoid the potential risk of sample infection.
• A negative result does not mean a person is not infectious or does not have influenza. If symptoms persist the person should seek medical attention and further testing by PCR if required.
• A negative result does not rule out infection with another type of respiratory virus.

Report Performance or Usability Issues:
Contact TGA for calling 1800 809 361 to report poor performance or usability issues in the self-test environment.
Report an issue via the Users Medical Device Incident Report, email: iris@health.gov.au

References

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