COVID-19/Influenza A+B Antigen Combo Rapid Test

English (For Self-testing)

REF	Σ
ISrIDu325-B001	1
ISrIDu325-B002	2
ISrIDu325-B005	5
ISrIDu325-B020	20

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Please read these instructions for use before using the test.

[Intended use]

The COVID-19/Influenza A+B Antigen Combo Rapid Test is a lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2, influenza A and influenza B viral nucleocapsid protein antigens in nasal swab from individuals suspected of being infected with COVID-19 within the first 7 days of symptom onset or influenza within the first 4 days of symptom onset. This test is intended for self-use by persons aged 15 years or above and for an adult testing another person under 15 years of age. Individuals over 65 years of age should consider seeking assistance in performing the test.
The test is an aid for diagnosis of COVID-19/Influenza A+B and only provides a presumptive test result for the SARS-CoV-2, influenza A and influenza B virus. It is intended to be used in the home or similar environment by a lay person.

- A negative result does not mean a person does not have COVID-19/Influenza A/Influenza B. If symptoms persist or if you feel unwell, please consult a medical practitioner for follow-up clinical care.
- For POSITIVE COVID-19 results: 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. For details, please visit https://www.health.gov.au/topics/covid-19/testing-positive.
- For POSITIVE INFLUENZA results: If you have a positive result or are unwell, contact a medical practitioner for follow up clinical care.
- If you are unwell, you should contact a medical practitioner for consultation.
- If you have invalid results, you need to retest with a new test cassette and extraction reagent with a freshly collected sample and contact the sponsor.

[When to use the test kit]

Use this test:

✓ If you have COVID-like or Influenza-like symptoms including headache, fever, a cough, sore throat, loss of sense of smell or taste, shortness of breath, etc.

Do not use this test:

X If you are prone to nosebleeds.

[Warnings and precautions]

1. For *in vitro* diagnostic use only.
2. Do not use this test as the only guide to manage the test result(s) or your illness. For POSITIVE COVID-19 results: 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. For details, please visit https://www.health.gov.au/topics/covid-19/testing-positive. For POSITIVE INFLUENZA results: If you have a positive result or are unwell, contact a medical practitioner for follow up clinical care.
3. A negative result does not mean a person does not have COVID-19/Influenza A/Influenza B. If symptoms persist or if you feel unwell, please consult a medical practitioner for follow-up clinical care.
4. If you have invalid results, you need to retest with a new test cassette and extraction reagent with a freshly collected sample and contact the sponsor.
5. The test is less reliable in the later phase of infection and in asymptomatic individuals.
6. Within the first 7 days of symptom onset for COVID-19 and within the first 4 days of symptom onset for Influenza when viral shedding is highest, the detection effect is good during this period.
7. False negative results may occur if testing is not performed within the first 7 days of symptom onset for COVID-19 and within the first 4 days of symptom onset for Influenza.
8. Repeat testing within 1-3 days is recommended if there is an ongoing suspicion of infection, high risk setting, occupational risk, or other requirement.
9. The device cannot differentiate between SARS-CoV-2 (COVID-19) and SARS-CoV-1 (SARS-coronavirus).
10. If the test is to be used on a person under 15 years of age, the test must be undertaken by an adult.
11. The test is not suitable for use in children aged < 2 years of age.
12. Keep out of reach of children to reduce the risk of accidents e.g drinking the extraction reagent or swallowing parts of the test kit.
13. Do not use this product after the expiration date.
14. Only use the test once and only with the provided parts. The kit components cannot be used interchangeably in different batches to avoid inaccurate test result.
15. Do not undertake testing in direct sunlight.
16. Avoid contact with Extraction Reagent. If the extraction reagent is accidentally exposed to a person's skin or eye, rinse with plenty of running water immediately. If irritation persists, seek medical assistance.
17. This test involves taking a sample from deep inside your nose. When undertaking the test, pay particular attention to the instructions on how to swab your nose. Incorrect swabbing may lead to an inaccurate test result or damage to the donor.
18. The test cassette should remain in the sealed pouch until use.
19. Wash hands thoroughly before and after testing.
20. Dispose all parts of the used test kit into the waste bag, then discard the waste bag in the general waste.

[What is included in the test kit]

Components	ISrIDu325-B001	ISrIDu325-B002	ISrIDu325-B005	ISrIDu325-B020
1. Test Cassette	1x	2x	5x	20x
2. Extraction Reagent Tube	1x	2x	5x	20x
3. Swab	1x	2x	5x	20x
4. Waste Bag	1x	2x	5x	20x
5. Instructions for Use	1x	1x	1x	4x
6. Work Station	/	/	/	1x

[Storage and stability]

- Store as packaged in the sealed pouch between **4–30℃**.
- The LOT and the expiration date are displayed on the foil packaging and box.

[Limitations]

1. The product is limited to provide a qualitative detection. The intensity of the test line does not necessarily correlate to the concentration of the antigens in the specimens.
2. Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result.
3. The test is a presumptive test only. 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. For details, please visit https://www.health.gov.au/topics/covid-19/testing-positive. If you have positive result for Influenza or are unwell, you are advised to consult a medical practitioner for follow-up clinical care.
4. A false negative result can occur if the quantity of antigens present in the specimen is below the detection threshold of the assay, or the virus has undergone minor amino acid mutation(s) in the target epitope region recognized by the monoclonal antibodies utilized in the test. Repeat testing within 1-3 days is recommended, if there is an ongoing suspicion of infection, being in a high risk setting or where there is an occupational risk or have a known exposure to COVID-19 or Influenza.
5. A false negative result may occur, particularly if testing is not performed within the first 4 days of symptom onset, for Influenza.
6. Negative results may not mean that a person is not infectious and if symptoms persist or if you feel unwell, please consult a medical practitioner for follow-up clinical care.
7. A Negative result does not rule out infection with another type of respiratory virus.
8. A positive result cannot determine whether a person is infectious.
9. Positive results do not rule out co-infections with other pathogens.

[Frequently asked questions (FAQ)]

How does the COVID-19/Influenza A+B Antigen Combo Rapid Test work?

The COVID-19/Influenza A+B Antigen Combo Rapid Test is a type of test called an antigen test. When you have COVID-19 or Influenza, the SARS-CoV-2 virus or Influenza virus can be present in your nasal secretions. The COVID-19/Influenza A+B Antigen Combo Rapid Test can detect small parts of SARS-CoV-2 virus or Influenza virus in your nasal secretions. These small parts of the SARS-CoV-2 virus or Influenza virus are known as proteins or antigens.

Will this test hurt?

No, the nasal swab is not sharp and it should not hurt. Sometimes the swab can feel slightly uncomfortable or tickly. If you feel pain, please stop the test and seek advice from a doctor.

What are the potential benefits and risks of this test?

Potential risks include:

- Discomfort during sample collection.
- Incorrect test results (see Limitations section).

Potential benefits include:

- The results, along with other information, can help your doctor make informed recommendations about your treatment/care.
- The results of this test may help limit the spread of illness to your family and others in your community.

[Performance characteristics]

Clinical Performance

The clinical performance of COVID-19/Influenza A+B Antigen Combo Rapid Test was established in prospective studies with nasal swabs collected from 918 individual patients (within 7 days post symptoms onset). For comparison, to each of the participants, an RT-PCR testing was performed by professional sampling with nasopharyngeal swab for detection of SARS-CoV-2, Influenza.

For COVID-19 Antigen Rapid Test:

Compared with RT-PCR, the COVID-19 Antigen Rapid Test showed a sensitivity of 95.3% (95% confidence interval: 92.0%-97.3%, N=256) and a specificity of 99.8% (95% confidence interval: 99.2%-100%, N=662), when testing symptomatic subjects within the first seven days after symptom onset.

For Influenza A+B Antigen Rapid Test:

Compared with RT-PCR, the Influenza A+B Antigen Rapid Test of influenza A showed a sensitivity of 94.4% (95% confidence interval: 88.3%-97.4%, N=107) and a specificity of 99.8% (95% confidence interval: 98.9%-100%, N=528), when testing symptomatic subjects within the first four days after symptom onset. Compared with RT-PCR, the Influenza A+B Antigen Rapid Test of influenza B showed a sensitivity of 92.6% (95% confidence interval: 82.5%-97.1%, N=54) and a specificity of 99.7% (95% confidence interval: 98.8%-99.9%, N=581), when testing symptomatic subjects within the first four days after symptom onset.

Limit of Detection (Analytical Sensitivity)

Virus Linea	LoD Titer ($TCID_{50}$/mL)	Virus Linea	LoD Titer ($TCID_{50}$/mL)
SARS-CoV-2 wild type	5.70×10^{2}	Flu B (Yamagata) B/Phuket/3073/2013	1.23×10^{4}
Flu A (H1N1) A/Singapore/63/04	1.04×10^{3}	Flu A (H3N2) A/Victoria/361/11	1.90×10^{4}
Flu A (H1N1) pdm09 A/Canada/6294/09	2.05×10^{3}	Flu B (Victoria) B/Victoria/504/00	1.05×10^{3}
Flu B (Yamagata) B/Yamagata/16/88	1.55×10^{4}	Flu A (H1N1) pdm09 A/Victoria/2570/2019	2.40×10^{3}
Flu A (H3N2) A/Darwin/6/2021	1.10×10^{3}	Flu B (Victoria) B/Austria/1359417/2021	1.89×10^{3}

Variants

The SARS-CoV-2 variant Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1), Delta (B.1.617.2) and Omicron (B.1.1.529) could be detected out by the device at specific concentrations.
The influenza strain H1N1 (Brisbane/59/07, New Caledonia/20/99, Solomon Island/03/06), H3N2 (Wisconsin/67/05, Hong Kong/8/68, Brisbane/10/07, Texas/50/12, Darwin/9/2021, Hong Kong/2671/2019, Hong Kong/45/2019, South Australia/34/2019, Switzerland/8060/2017, Singapore/INFIMH-16-0019/2016), H1N1pdm09 (Mexico/4108/09, NY/02/09, California/07/09, Wisconsin/588/201, Brisbane/02/2018, Michigan/45/2015), Victoria (Malaysia/2506/04, Lee/40, Washington/02/2019, Colorado/06/2017), and Yamagata (Florida/02/06, Massachusetts/2/12, Panama/45/90) could be detected out by the device at specific concentrations.

Usability Study

154 lay users in different age distribution, different education level and different gender participated in usability study conducted in the self-testing environment. Compared to RT-PCR, the clinical performance of COVID-19/Influenza A+B Antigen Combo Rapid Test in hands of lay persons showed a sensitivity of 95.5% (95% confidence interval: 84.9%-98.7%, N=44) and a specificity of 100% (95% confidence interval: 96.6%-100%, N=110) for COVID-19 antigen, a sensitivity of 90.9% (95% confidence interval: 76.4%-96.9%, N=33) and a specificity of 100% (95% confidence interval: 96.9%-100%, N=121) for influenza A antigen and a sensitivity of 89.5% (95% confidence interval: 68.6%-97.1%, N=19) and a specificity of 99.3% (95% confidence interval: 95.9%-99.9%, N=135) for influenza B antigen.

Cross Reactivity (Analytical Specificity)

Cross-reactivity of COVID-19/Influenza A+B Antigen Combo Rapid Test was evaluated by testing a panel of respiratory pathogens that could potentially cross-react with the analyte detection reagents in the test device.

Potential Cross-Reactant	SARS-CoV-2 (Yes/No)	Influenza A (Yes/No)	Influenza B (Yes/No)
Recombinant MERS-CoV NP protein	No	No	No
Recombinant SARS-CoV-1 N-protein	Yes	No	No
SARS-CoV-2	N/A	No	No
Influenza (AH1N1)	No	N/A	No
Influenza A (H1N1pdm09)	No	N/A	No
Influenza A (H3N2)	No	N/A	No
Influenza B (Victoria)	No	No	N/A
Influenza B (Yamagata)	No	No	N/A
Adenovirus type 1	No	No	No
Adenovirus type 2	No	No	No
Adenovirus type 3	No	No	No
Adenovirus type 5	No	No	No
Adenovirus type 7	No	No	No
Adenovirus type 55	No	No	No
Human metapneumovirus	No	No	No
Parainfluenza virus type 1	No	No	No
Parainfluenza virus type 2	No	No	No
Parainfluenza virus type 3	No	No	No
Parainfluenza virus type 4	No	No	No
Respiratory syncytial virus	No	No	No
Enterovirus	No	No	No
Rhinovirus	No	No	No
Human coronavirus 229E	No	No	No
Human coronavirus OC43	No	No	No
Human coronavirus NL63	No	No	No
Human coronavirus HKU1	No	No	No
Mycoplasma pneumoniae	No	No	No
Chlamydia pneumoniae	No	No	No
Legionella pneumophila	No	No	No
Haemophilus influenzae	No	No	No
Streptococcus pyogenes (group A)	No	No	No
Streptococcus pneumoniae	No	No	No
Staphylococcus aureus	No	No	No
Candida albicans	No	No	No
Mycobacterium tuberculosis	No	No	No
Bordetella pertussis	No	No	No
Pneumocystis jirovecii (PJP)	No	No	No
Staphylococcus epidermis	No	No	No
Streptococcus salivarius	No	No	No
Pseudomonas aeruginosa	No	No	No

Interference

The following potential interference substances were evaluated with the COVID-19/Influenza A+B Antigen Combo Rapid Test were found not to affect test performance: Mucin, Whole blood, Zanamivir, Ribavirin, Arbidol, Oseltamivir phosphate, Saline nasal spray, Oxymetazoline, Phenylephrine, Fluticasone propionate, Dexamethasone, Tobramycin, Mupirocin, Triamcinolone, Histamine dihydrochloride, Benzocaine, Menthol.

[Contact information]

Hangzhou Clongene Biotech Co., Ltd.
No.1 Yichuang Road, Yuhang Sub-district, Yuhang District, 311121 Hangzhou, China
https://en.clongene.com/

AU REP APAC Security Pty Ltd
Unit 28, 19 Narabang Way, Belrose, NSW, 2085, Australia
Tech support: +61 2 9986 2252, hours: 9am-7pm (AEST), 7 days per week
Email: support@apacsecurity.com
https://www.apacsecurity.com

In the event you are experiencing problems with the test, please contact our authorized representative in Australia as above.

Additionally, you may wish to report poor performance or usability issues to the Therapeutic Goods Administration (TGA) via the Users Medical Device Incident Report, email iris@health.gov.au or call 1800 809 361.

Index of Symbol

Do not reuse	In vitro diagnostic medical device	Lot number	Use by
Store between 4-30 ℃	Consult instructions for use	Keep away from sunlight	Caution
Catalogue number	Contains sufficient for <n> tests	Keep dry	Manufacturer
Do not use if package is damaged			

Version No.: 4.0
Effective Date: July 29, 2024

Turn page

Scan the QR code to watch how to use the device and access other resources.
For further support call +61 2 9986 2252
hours: 9am-7pm (AEST), 7days per week

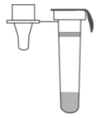
Contact TGA to report poor performance or usability issues in the self-test environment
Report an issue via the Users Medical Device Incident Report, email iris@health.gov.au or call 1800 809 361

[Preparing the test]

1. Keep a clock, timer or stopwatch at hand.
2. **Ensure that all test components are kept at room temperature (15–30 ℃).**
3. Ensure that the packaging is intact; Do not use the test if there is visible damage of the foil packaging.
4. Open the box and you will get the components shown below:

Instructions for Use

Swab

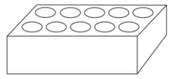


Extraction Reagent Tube

Waste Bag

Test Cassette

Note: *Only open the foil packaging of the test cassette when you are ready to carry out the test. Use the test cassette within one hour after opening.*



Work Station (For 20 Tests pack only)

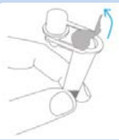
[Before starting]

Wash your hands in soapy water and dry thoroughly.

[Step-By-Step Instructions]

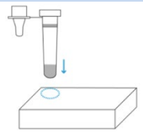
1. Open the Extraction Reagent Tube

Carefully tear off the sealed foil film on the extraction reagent tube.



2. Insert Tube into Box

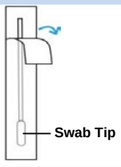
Gently press the tube through the perforated hole in the box (Or place the tube on the workstation).



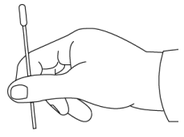
3. Remove the Swab

a. Open the swab package at the stick end.

Note*: Keep fingers away from swab tip.*

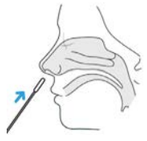


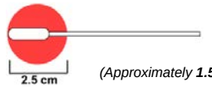
b. Take out the swab.



4. Swab the Left Nostril

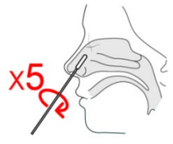
a. Gently insert the entire tip of the swab, app. **2.5 cm** into the left nostril.





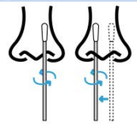
*(Approximately **1.5 times** the length of the swab tip)*

b. Firmly brush the swab against the inside of the nostril in a circular motion **5 times** or more.

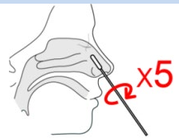


5. Swab the Right Nostril

a. Remove the swab from the left nostril and insert it into right nostril about **2.5 cm**.



b. Firmly brush the swab against the inside of the nostril in a circular motion **5 times** or more.

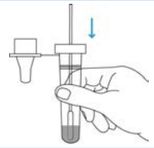


CHECK!
You should swab both nostrils.

Note: *A false negative result may occur if sample collection is not thoroughly undertaken.*

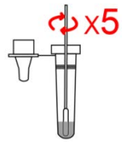
6. Insert the Swab into the Tube

Insert the nasal swab into the tube which contains extraction reagent.



7. Rotate the Swab 5 Times

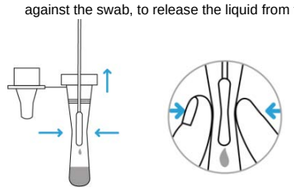
a. Rotate swab at least **5 times** while pressing the swab tip against the bottom and the sides of the tube.



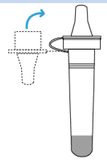
b. Let the tip of the swab soak in the tube for **1 minute**.

8. Remove the Swab

a. Remove the swab while squeezing the sides of the tube against the swab, to release the liquid from the swab.

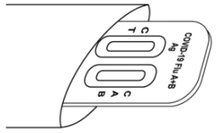


b. Cover the tube with the provided cap tightly and insert the tube back into the box.

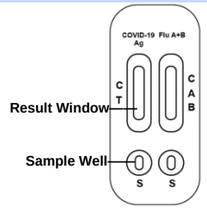


9. Take out the Test Cassette from the pouch

Open the sealed pouch and take out the test cassette.



Note*: Test cassette must lay **FLAT** on the table during the entire testing.*



10. Add Sample to the Sample Wells

a. Hold the tube vertically over the Sample Well - not at an angle.

3 drops in both wells

b. Add **3 drops** from the tube into both Sample Wells by gently squeezing the sides of the tube.

Note 1: *A false negative result may occur if less than 3 drops of sample are used.*

Note 2: *The result will not be affected if 1-2 more drops of sample are accidently added – as long as you can read a C-line (see Read result below).*

11. Timer

Start the clock / stopwatch or timer at 15 minutes

12. Wait for 15 Minutes

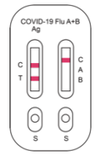
Read test result at **15-20** minutes, **DO NOT** read the result after 20 minutes.

Note: *False results can occur if the test results are read before 15 minutes or after 20 minutes.*

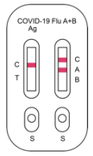
[Reading the result]

Positive Result [+]

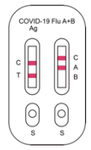
Please look very closely as the intensity of the line (T/A/B) can be very faint!



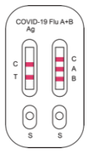
COVID-19 positive result:
One colored line appears at the control region (C), and a second colored line appears at the test region (T).



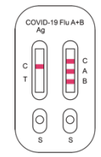
Influenza A positive result:
One colored line appears at the control region (C), and a second colored line appears at the A test region.



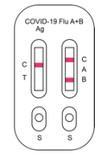
COVID-19 and Influenza A positive result:
Two colored lines appear at the control region (C), and both the T and A lines appear at the test region.



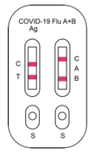
COVID-19 and Influenza A & B positive result:
Two colored lines appears at the control region (C), and all colored lines appears at the test region (T/A/B).



Influenza A & B positive result:
One colored line appears at the control region (C), and both the A and B lines appear at the test region.



Influenza B positive result:
One colored line appears at the control region (C), and a second colored line appears at the B test region.



COVID-19 and Influenza B positive result:
Two colored lines appear at the control region (C), and both the T and B lines appear at the test region.

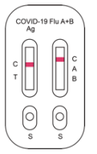
A **positive** test result for COVID-19 or Influenza indicates that you are likely to carry the COVID-19 or Influenza A/B disease.

For **POSITIVE COVID-19** results: 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. For details, please visit https://www.health.gov.au/topics/covid-19/testing-positive.

For **POSITIVE INFLUENZA** results: If you have a positive result or are unwell, contact a medical practitioner for follow up clinical care.

If you are unwell, you should contact a medical practitioner for consultation.

Negative Result [-]

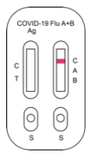


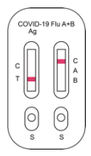
One colored line appears at the control region (C), and no line appears at the test region (T/A/B).

A **NEGATIVE** test result indicates that you are unlikely to carry the COVID-19 or Influenza A/B disease.
If symptoms persist or if you feel unwell, please consult a medical practitioner for follow-up clinical care. If you suspect an infection, it is recommended that you repeat testing within 1-3 days, as the virus cannot be precisely detected in all phases of an infection.

Invalid Result [?]

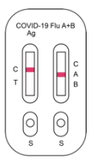
COVID-19 INVALID result: No colored line appears at the control region (C) for COVID-19.

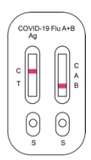


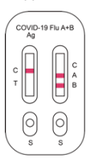


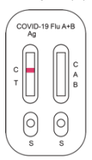
Note: *If a C-line does not appear, the test result is invalid regardless of the appearance of a coloured line at the test region (T/A/B) or not.*

Influenza A & B INVALID result: No colored line appears at the control region (C) for Influenza A/B.









If a C-line does not appear, it shows an **INVALID** test result. You need to retest with a new test cassette and extraction reagent with a freshly collected sample and contact the sponsor.

[Dispose the used test kit]

Collect all parts of the kit and swab specimens in a waste bag and dispose of them with general waste. Wash your hands thoroughly after handling.