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

Scan me for the how to use video

For further support call +61 2 9986 2252

For additional language instructions please visit https://apacsecurity.com/covid-19-antigen-test-resources/

Please read this 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 or influenza within the first 5 days of symptom onset. This test is intended for self-use by persons aged 15 years or above and also for an adult testing another person under 15 years of age. Individuals over 65 years of age should consider to seek assistance in performing the test.

The test is an aid for diagnosis of COVID-19/Influenza A+B and only provides a presumptive screening 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. Confirmation of positive results is required by contacting your State or Territory Coronavirus testing services to get a laboratory PCR test. A negative result does not mean a person does not have COVID-19/Influenza A+B. If you have symptoms, you should have a laboratory PCR test and follow medical advice.

[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.

✓ If you are concerned that you have been exposed to COVID-19 or Influenza.

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. Please consult your State or Territory Coronavirus testing services to get a laboratory PCR test for positives results or, if your symptoms are persisting or worsening, or if you are concerned at any time.
3. A positive result can only be validated through a PCR confirmatory test.
4. The test is less reliable in the later phase of infection and in asymptomatic individuals.
5. Within the first 5 days of symptom onset when viral shedding is highest, the detection effect is good during this period.
6. False negative results may occur if testing is not performed within the first 5 days of symptom onset.
7. If the test is to be used on a person under 15 years of age, the test must be undertaken by an adult.
8. 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.
9. Do not use this product after the expiration date.
10. 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.
11. Do not undertake testing in direct sunlight.
12. 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.
13. 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.
14. The test cassette should remain in the sealed pouch until use.
15. Wash hands thoroughly before and after testing.
16. 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 get a positive result, you must immediately seek a laboratory PCR test and follow-up with a clinical care facility.
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 after 1-2 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. Negative results may not mean that a person is not infectious and if symptoms are present the person must seek immediate further testing by PCR.
6. A Negative result does not rule out infection with another type of respiratory virus.
7. A positive result cannot determine whether a person is infectious.
8. Positive results do not rule out co-infections with other pathogens.
9. Positive results may occur, particularly in areas with low numbers of COVID-19 and Influenza A/B infections and confirmation with a PCR testing should be considered.

[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 554 individual patients (within 5 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 97.2% (95% confidence interval: 93.0%-98.9%, N=142) and a specificity of 99.8% (95% confidence interval: 98.6%-100%, N=412). Sensitivity according to days post-onset of symptoms as below:

Days post-onset of symptoms	SARS-CoV-2 RT-PCR positive	CLUNGENE® Rapid Test positive (SARS-CoV-2)	PPA	95%CI
0	12	12	100%	75.8%-100%
0~1	40	40	100%	91.2%-100%
0~2	86	86	100%	95.7%-100%
0~3	119	119	100%	96.9%-100%
0~4	132	131	99.2%	95.8%-99.9%
0~5	142	138	97.2%	93.0%-98.9%
Total	142	138	97.2%	93.0%-98.9%

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 92.7% (95% confidence interval: 85.7%-96.4%, N=96) and a specificity of 99.8% (95% confidence interval: 98.8%-100%, N=458). Sensitivity according to days post-onset of symptoms as below:

Days post-onset of symptoms	Influenza A RT-PCR positive	CLUNGENE® Rapid Test positive (Influenza A)	PPA	95%CI
0	12	12	100%	75.8%-100%
0~1	32	32	100%	89.3%-100%
0~2	61	61	100%	94.1%-100%
0~3	82	80	97.6%	91.5%-99.3%
0~4	90	86	95.6%	89.1%-98.3%
0~5	96	89	92.7%	85.7%-96.4%
Total	96	89	92.7%	85.7%-96.4%

Compared with RT-PCR, the Influenza A+B Antigen Rapid Test of influenza B showed a sensitivity of 90.4% (95% confidence interval: 79.4%-95.8%, N=52) and a specificity of 99.6% (95% confidence interval: 98.6%-99.9%, N=502). Sensitivity according to days post-onset of symptoms as below:

Days post-onset of symptoms	Influenza B RT-PCR positive	CLUNGENE® Rapid Test positive (Influenza B)	PPA	95%CI
0	5	5	100%	56.6%-100%
0~1	16	16	100%	80.6%-100%
0~2	29	29	100%	88.3%-100%
0~3	39	39	100%	91.0%-100%
0~4	47	44	93.6%	82.8%-97.8%
0~5	52	47	90.4%	79.4%-95.8%
Total	52	47	90.4%	79.4%-95.8%

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 Influenza A (H1N1, H3N2, H1N1pdm09) and Influenza B (Victoria, Yamagata) 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. Testing showed no evidence of cross-reactivity at the concentrations tested.

Potential Cross-Reactant	Concentration Tested	SARS-CoV-2 (Yes/No)	Influenza A (Yes/No)	Influenza B (Yes/No)
Recombinant MERS-CoV NP protein	50 μg/mL	No	No	No
SARS-CoV-2	1×10^6 $TCID_{50}$/mL	N/A	No	No
Influenza A（H1N1）	1.0×10^6 PFU/mL	No	N/A	No
Influenza A (H1N1pdm09)	1.0×10^6 PFU/mL	No	N/A	No
Influenza A（H3N2）	1.0×10^6 PFU/mL	No	N/A	No
Influenza B（Victoria）	1.0×10^6 PFU/mL	No	No	N/A
Influenza B（Yamagata）	1.0×10^6 PFU/mL	No	No	N/A
Adenovirus type 1	1.0×10^6 PFU/mL	No	No	No
Adenovirus type 2	1.0×10^6 PFU/mL	No	No	No
Adenovirus type 3	1.0×10^6 PFU/mL	No	No	No
Adenovirus type 5	1.0×10^6 PFU/mL	No	No	No
Adenovirus type 7	1.0×10^6 PFU/mL	No	No	No
Adenovirus type 55	1.0×10^6 PFU/mL	No	No	No
Human metapneumovirus	1.0×10^6 PFU/mL	No	No	No
Parainfluenza virus type 1	1.0×10^6 PFU/mL	No	No	No
Parainfluenza virus type 2	1.0×10^6 PFU/mL	No	No	No
Parainfluenza virus type 3	1.0×10^6 PFU/mL	No	No	No
Parainfluenza virus type 4	1.0×10^6 PFU/mL	No	No	No
Respiratory syncytial virus	1.0×10^6 PFU/mL	No	No	No
Enterovirus	1.0×10^6 PFU/mL	No	No	No
Rhinovirus	1.0×10^6 PFU/mL	No	No	No
Human coronavirus 229E	1.0×10^6 PFU/mL	No	No	No
Human coronavirus OC43	1.0×10^6 PFU/mL	No	No	No
Human coronavirus NL63	1.0×10^6 PFU/mL	No	No	No
Human coronavirus HKU1	1.0×10^6 PFU/mL	No	No	No
Mycoplasma pneumoniae	1.0×10^7 CFU/mL	No	No	No
Chlamydia pneumoniae	1.0×10^7 CFU/mL	No	No	No
Legionella pneumophila	1.0×10^7 CFU/mL	No	No	No
Haemophilus influenzae	1.0×10^7 CFU/mL	No	No	No
Streptococcus pyogenes (group A)	1.0×10^7 CFU/mL	No	No	No
Streptococcus pneumoniae	1.0×10^7 CFU/mL	No	No	No
Staphylococcus aureus	1.0×10^7 CFU/mL	No	No	No
Candida albicans	1.0×10^7 CFU/mL	No	No	No

Interference

The following potential interference substances were evaluated with the COVID-19/Influenza A+B Antigen Combo Rapid Test at the concentrations listed below and were found not to affect test performance.

Substance	Concentration	Substance	Concentration
Mucin	2 mg/mL	Fluticasone propionate	5 mg/mL
Whole blood	4%	Dexamethasone	5 mg/mL
Zanamivir	5 mg/mL	Tobramycin	5 μg/mL
Ribavirin	5 mg/mL	Mupirocin	10 mg/mL
Arbidol	5 mg/mL	Triamcinolone	10 mg/mL
Oseltamivir phosphate	10 mg/mL	Histamine dihydrochloride	10 mg/mL
Saline nasal spray	15%	Benzocaine	5 mg/mL
Oxymetazoline	15%	Menthol	10 mg/mL
Phenylephrine	15 mg/mL		

[Contact information]

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

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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@tga.gov.au or call 1800 809 361.

To contact your local state/territory health department click on the following link:
https://www.health.gov.au/about-us/contact-us/local-state-and-territory-health-departments

Local state and territory health departments

Contact details and websites of the local state and territory health departments.

Australian Capital Territory Department of Health	Business hours: 02 5124 9213 Coronavirus helpline (8am to 8pm daily): 02 6207 7244 https://health.act.gov.au
New South Wales Department of Health	General enquiries: 1300 066 055 Coronavirus hotline (Service NSW, 24/7): 137 788 https://www.health.nsw.gov.au
Northern Territory Department of Health	General enquiries: 08 8922 8044 Coronavirus hotline (National helpline): 1800 020 080 https://health.nt.gov.au
Queensland Department of Health	13HEALTH: 13 432 584 Coronavirus hotline: 134COVID, 134 268 https://www.health.qld.gov.au
South Australian Department of Health	General enquiries: 1300 232 272 Coronavirus hotline (9am to 5pm daily): 1800 253 787 https://www.sahealth.sa.gov.au/
Tasmanian Department of Health	General enquiries: 1300 135 513 Public Health Hotline (coronavirus): 1800 671 738 https://www.health.tas.gov.au
Victorian Department of Health	Department of Health and Human Services: 1300 650 172 Victorian coronavirus hotline (24/7): 1800 675 398 https://www.dhhs.vic.gov.au
Western Australian Department of Health	General enquiries: 08 9222 4222 Coronavirus hotline: 13COVID (8am to 6pm, Mon–Fri), 1800 595 206 https://www.healthywa.wa.gov.au

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.: 1.0
Effective Date: May 25, 2022

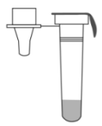
Turn page

[Preparing to do 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

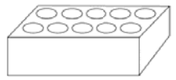


Extraction Reagent Tube

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)

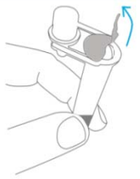
[Before starting]

Wash your hands in soapy water and dry thoroughly.

[Step-By-Step Instructions]

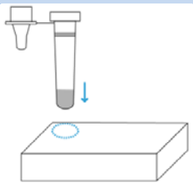
1. Open Extraction Reagent Tube

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



2. Insert Tube into Box

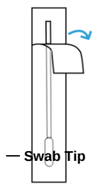
Gently press the tube through the perforated hole in the box. (Or place the tube on the work station.)



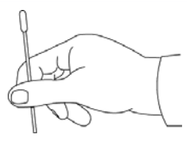
3. Remove the Swab

a. Open the swab package at the stick end.

Note*: Keep fingers away from swab tip.*

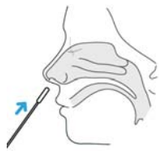


b. Take out the swab.

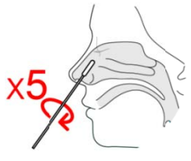


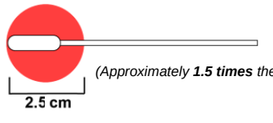
4. Swab the Left Nostril

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



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

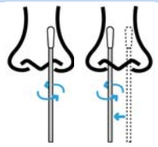




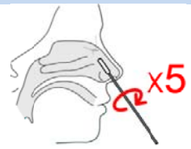
*(Approximately **1.5 times** the length of the swab tip)*

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.

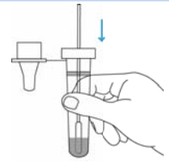


CHECK!
You should swab both nostrils.

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

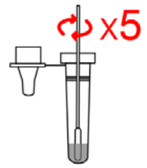
6. Insert the Swab into Tube

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



7. Rotate the Swab 5 Times

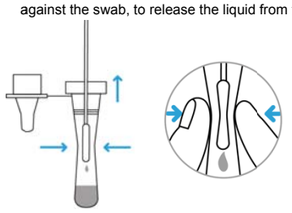
a. Rotate swab at least **5 times** while pressing the swab tip against the bottom and the sides of the tube.



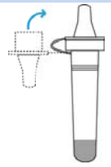
b. Let the tip of the swab soak in the tube for **1 minute**.

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.

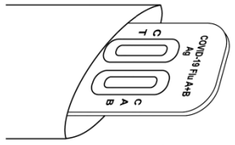


b. Cover the tube with the provided cap tightly and insert the tube back into the box.

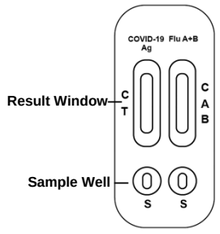


9. Take out the Test Cassette from the pouch

Open the sealed pouch and take out the test cassette.

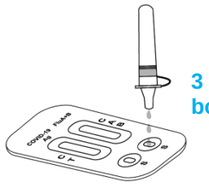


Note*: Test cassette must lay **FLAT** on the table during the entire testing.*



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 is 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. Timing

Start the clock / stopwatch or timer.

12. Wait 15 Minutes

Read test result at **15-20** minutes, **DO NOT** read more than 20 minutes.

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

[Read result]

Positive Result

For COVID-19 Antigen Rapid Test:

Two lines appear. One colored line appears at the control region (C), and another colored line appears at the test region (T).

Please look very closely!
The intensity of the T-line can be

A positive test result indicates that you are likely to carry the COVID-19 disease. If you have a **POSITIVE** result, follow the local State or Territory requirements for reporting positive results and confirmation testing if necessary. And if you are unwell, seek medical assistance.

For Influenza A+B Antigen Rapid Test:

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

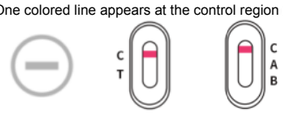
Influenza B positive result: One colored line appears at the control region (C), and another colored line appears at the B test region.

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.

A positive test result indicates that you are likely to carry the Influenza A/B disease. If you have a **POSITIVE** result, follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

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, Influenza A/B disease.

Even if you get a negative result, you still need to follow all public health advice on limiting the spread of COVID-19, Influenza A/B.

Please contact your State or Territory Health Department to get a laboratory PCR test if you develop symptoms or symptoms are persisting. If you suspect an infection, it is recommended that you repeat testing after 1-2 days, as the virus cannot be precisely detected in all phases of an infection.

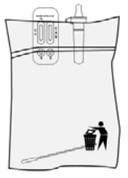
Invalid Result

Control line fails to appear.

Note: *If a C-line does not appear, the test result is invalid regardless of the appearance of a T-line or not.*

If a C-line does not appear, it shows an **INVALID** test result. You need to retest with a new test cassette or contact a doctor or a COVID-19 & Influenza A/B test center.

[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.

Scan the QR code to watch how to use the device and access other resources.

For additional language instructions please visit
https://apacsecurity.com/covid-19-antigen-test-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@tga.gov.au or call 1800 809 361