English

COVID-19 / RSV / Influenza A&B / AdV Antigen Test Kit

(For Self-Testing)

REF	Σ
ISHFDu535-B001	1
ISHFDu535-B002	2
ISHFDu535-B005	5
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ISHFDu535-B020	20

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For additional instructions please visit

https://tlchealthsupplies.store.unleashedsoftware.com/products/18221931

Carefully read the instructions for use before testing. Failure to follow the instructions may result in inaccurate test results.

[Intended use]

The COVID-19 / RSV / Influenza A&B / AdV Antigen Test Kit is a lateral flow immunoassay intended for the qualitative detection and differentiation of respiratory syncytial virus (RSV), influenza A (Flu A) and influenza B (Flu B) nucleoprotein antigens, SARS-CoV-2 nucleocapsid protein antigen and adenovirus (AdV) hexon protein antigen in nasal swab specimens from individuals with symptoms of respiratory viral infection. It is intended for individuals within the first 7 days of symptom onset as an aid for diagnosis of COVID-19, and within the first 4 days of symptom onset as an aid for diagnosis of influenza A/B, RSV and AdV infection.

This test is intended for self-use by persons aged 14 years of age or older. For individuals under 14 years of age, the test must be performed by an adult. It is intended to be used in the home or similar environment by a lay person.

The test only provides a preliminary test result. Test results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2, influenza, RSV and AdV. You should not take any decision of medical relevance without first consulting your doctor.

[When to use the test kit]

Use this test:

✓ If you have symptoms of respiratory viral infection including headache, fever or chills, cough, sore throat, congestion or runny nose, loss of smell or taste, fatigue, muscle or body aches, 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 sole guide to manage your illness.
3. The test is less reliable in the later phase of infection and in asymptomatic individuals.
4. False negative results may occur if testing is not performed within the first 7 days of symptom onset for COVID-19 or within the first 4 days of symptom onset for influenza, RSV and AdV infection.
5. If the test is to be used on a person under 14 years of age, the test must be undertaken by an adult.
6. Test components can only be used once. DO NOT REUSE.
7. Do not use this product after the expiration date.
8. Keep out of reach of children to reduce the risk of accidentally drinking the buffer or swallowing parts.
9. Avoid contact with buffer liquid. If the buffer is accidentally exposed to a person's skin or eye, immediately rinse with plenty of running water. If irritation persists, seek medical assistance.
10. The test cassette should be used within one hour after opening. It is recommended to use it immediately under high humidity conditions.
11. Do not dip the swab into provided solution or other liquid before inserting the swab into the nose.
12. Incorrect test results may occur if a specimen is incorrectly collected or handled.
13. If an invalid result is produced, the user should retest with a new test.
14. Dispose all parts of the used test kit into the waste bag, then discard the waste bag in general waste.

[What is included in the test kit]

Components	ISHFDu535-B001	ISHFDu535-B002	ISHFDu535-B005	ISHFDu535-B010	ISHFDu535-B020
1. Test Cassette	1x	2x	5x	10x	20x
2. Buffer Tube	1x	2x	5x	10x	20x
3. Swab	1x	2x	5x	10x	20x
4. Waste Bag	1x	2x	5x	10x	20x
5. Instructions for Use	1x	1x	1x	2x	4x
6. Work Station	/	/	/	/	1x

[Storage and stability]

- **Store the test kit at 4–30℃**. The kit is stable until the expiration date printed on the outer packaging.
- The test cassette must remain in the sealed pouch until use. **Once opened, the test cassette should be used within one hour.**

[Limitations]

1. This test does not distinguish between SARS-CoV and SARS-CoV-2.
2. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance of this test will give a false negative result in an individual with COVID-19, influenza, RSV and AdV infection as compared to a molecular test, especially in samples with low viral load.
3. A false negative result can occur if the level of viral antigens in the specimen is below the detection limit of this test. It is recommended to repeat the test 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 have a known exposure to influenza, COVID-19, RSV or AdV.
4. A negative result does not mean a person is not infectious. If symptoms persist, the person must seek medical attention and further testing.
5. A negative result does not rule out infection with another type of respiratory virus.
6. A positive result cannot necessarily determine whether a person is infectious.
7. Positive results indicate a presence of viral antigens, but clinical correlation with patient history and other diagnostic information are necessary to determine infection status.
8. Positive results do not rule out co-infections with other pathogens.

[Frequently asked questions (FAQ)]

1. How does the COVID-19 / RSV / Influenza A&B / AdV Antigen Test Kit work?

The COVID-19 / RSV / Influenza A&B / AdV Antigen Test Kit is a type of test known as an antigen test. It contains antibodies that react specifically with the SARS-CoV-2 nucleocapsid protein antigen, the adenoviral hexon protein antigen, the nucleoprotein antigens from RSV, Flu A and Flu B. It can detect these viral proteins in a nasal swab specimen during the acute phase of infection.

After collecting a nasal swab specimen, the swab is transferred to a buffer tube to extract the viral proteins. Three (3) drops of the extracted sample are applied to each sample well (S) on the test cassette. Three result windows will display a control (C) line if the test is performed correctly. Additionally, coloured lines will appear at the location of 'CoV', 'RSV', 'A', 'B' and/or 'AdV' if viral proteins are detected. The presence of only the control (C) line indicates that viral proteins are not detected.

2. 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.

3. What are the potential benefits and risks of this test?

Potential risks include:

- Discomfort during sample collection.
- Incorrect test results (see Warnings and Limitations sections for more information).

Potential benefits include:

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

[Performance characteristics]

Clinical Performance

The clinical performance of COVID-19 / RSV / Influenza A&B / AdV Antigen Test Kit was established in prospective studies with nasal swabs collected from 1260 individuals with symptoms of respiratory viral infection. For comparison, to each of the participants, a RT-PCR testing was performed by sampling with a nasopharyngeal swab.

For COVID-19, the test correctly identified **95.1%** (156 out of 164) of SARS-CoV-2 positive samples with a confidence interval of 90.7% to 97.5% (known as sensitivity), and correctly identified **99.7%** (1093 out of 1096) of SARS-CoV-2 negative samples with a confidence interval of 99.2% to 99.9% (known as specificity).

For RSV, the test showed a sensitivity of **96.0%** (95 out of 99, with a confidence interval of 90.1% to 98.4%) and a specificity of **99.6%** (776 out of 779, with a confidence interval of 98.9% to 99.9%).

For Flu A, the test showed a sensitivity of **95.4%** (125 out of 131, with a confidence interval of 90.4% to 97.9%) and a specificity of **99.6%** (744 out of 747, with a confidence interval of 98.8% to 99.9%).

For Flu B, the test showed a sensitivity of **94.8%** (55 out of 58, with a confidence interval of 85.9% to 98.2%) and a specificity of **99.4%** (815 out of 820, with a confidence interval of 98.6% to 99.7%).

For AdV, the test showed a sensitivity of **94.1%** (80 out of 85, with a confidence interval of 87.0% to 97.5%) and a specificity of **99.5%** (789 out of 793, with a confidence interval of 98.7% to 99.8%).

Usability Study

In a usability study involving 256 lay users taking place in the self-testing environment, the test correctly identified 97.2% (35 out of 36) of positive samples and 100% (220 out of 220) of negative samples for COVID-19. For RSV, 96.9% (31 out of 32) of positive samples and 99.6% (223 out of 224) of negative samples were correctly identified. For Flu A, 95.2% (40 out of 42) of positive samples and 100% (214 out of 214) of negative samples were correctly identified. For Flu B, 93.5% (29 out of 31) of positive samples and 99.6% (224 out of 225) of negative samples were correctly identified. For AdV, 93.5% (29 out of 31) of positive samples and 100% (225 out of 225) of negative samples were correctly identified. All samples were confirmed as positive and negative by RT-PCR, respectively.

Limit of Detection

Limit of detection (LoD) studies determine the lowest detectable concentration of SARS-CoV-2, RSV, influenza A, influenza B, AdV at which ≥95% of all (true positive) replicates test positive.

Virus	Strain	LoD ($TCID_{50}$/mL)
SARS-CoV-2	Hong Kong/VM20001061/2020	315
RSV	2013 Isolate (type A)	550
	3/2015 Isolate 2 (type B)	379
Influenza A	A/Wisconsin/588/2019 (H1N1pdm09)	700
	A/Singapore/INFIMH-16-0019/2016 (H3N2)	755
Influenza B	B/Brisbane/60/2008 (Victoria lineage)	585
	B/Utah/9/2014 (Yamagata lineage)	390
AdV	Species B, type 3	160
	Species C, type 1	890
	Species E, type 4	210

This test can detect SARS-CoV-2 antigen as low as 400 IU/mL, as determined by using the 1st WHO International Standard for SARS-CoV-2 antigen (NIBSC code: 21/368).

Inclusivity

Analytical reactivity of the COVID-19 / RSV / Influenza A&B / AdV Antigen Test Kit was demonstrated using the following inactivated viruses, and it confirmed that the performance of the product was not affected.

COVID-19: Alpha, Beta, Gamma, Delta, Omicron (BA.1, BA.2.3, BA.4.6, BA.5, BA.2.86) variants

RSV:

RSV type A strains	RSV type B strains
12/2014 Isolate 12	ATCC-2012-11
2/2015 Isolate 2	11/2014 Isolate 2
A2023/06-12NSMM	CH93(18)-18

Flu A:

H1N1 strains	H3N2 strains
A/Michigan/45/2015	A/South Australia/34/2019
A/Brisbane/02/2018	A/Hong Kong/45/2019
A/Victoria/2570/2019	A/Hong Kong/2671/2019
A/Sydney/5/2021	A/Darwin/6/2021
A/Victoria/4897/2022	A/Darwin/9/2021
A/Wisconsin/67/2022	A/Massachusetts/18/2022
	A/Thailand/8/2022

Flu B:

Victoria lineage strains	Yamagata lineage strains
B/Colorado/06/2017	B/Phuket/3073/2013
B/Washington/02/2019	B/Brisbane/9/2014
B/Austria/1359417/2021	

AdV:

Species B	Species C	Species E
Adenovirus type 3	Adenovirus type 1	Adenovirus type 4
Adenovirus type 7	Adenovirus type 2	
Adenovirus type 14	Adenovirus type 5	
Adenovirus type 21	Adenovirus type 6	
Adenovirus type 55		

Cross-Reactivity

Cross-reactivity and microbial interference of the COVID-19 / RSV / Influenza A&B / AdV Antigen Test Kit were evaluated by testing a panel of related respiratory pathogens and other microorganisms that could be present in the nasal cavity. The following pathogens and other microorganisms have no effect on the test results, which the each target analyte is active on itself and does not cross-react with the other analyte:
SARS-CoV-2 (wild-type, Alpha, Beta, Gamma, Delta, Omicron), Respiratory syncytial virus (type A, B), Influenza A (H1N1pdm09, H3N2), Influenza B (Victoria, Yamagata), Adenovirus (type 1, 2, 3, 4, 5, 6, 7, 14, 21, 55), Human coronavirus (229E, HKU1, NL63, OC43), MERS-coronavirus, Cytomegalovirus, Enterovirus (A71, D68), Epstein-Barr virus, Parainfluenza virus (type 1, 2, 3, 4A), Measles virus, Human metapneumovirus, Mumps virus, Rhinovirus, *Bordetella pertussis, Candida albicans*, *Chlamydia pneumoniae*, *Corynebacterium diphtheriae*, *Escherichia coli*, *Haemophilus influenzae*, *Lactobacillus sp.*, *Legionella pneumophila*, *Moraxella catarrhalis*, *Mycobacterium tuberculosis*, *Mycoplasma pneumoniae*, *Neisseria meningitidis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Streptococcus salivarius*, Pooled human nasal wash.

Cross-reactivity was observed for SARS-CoV.

Interference

No interference was observed with the following substances:
Human whole blood; Mucous (Mucin); Human anti-mouse antibody (HAMA); Common nasal sprays or drops (Oxymetazoline HCl, Phenylephrine HCl, Saline nasal spray); Nasal gel (NeilMed NasoGel); Zinc throat spray; Throat lozenges (Benzocaine, Menthol); Nasal corticosteroids (Beclomethasone, Budesonide nasal spray, Dexamethasone, Flunisolide, Fluticasone propionate, Mometasone furoate, Triamcinolone acetonide); Anti-viral drugs (Arbidol, Oseltamivir phosphate, Ribavirin, Zanamivir); Other common medicines (Azithromycin, Ceftriaxone, Chlorpheniramine maleate, Mupirocin, Tobramycin); Biotin.

[Contact information]

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https://www.clongene.com

Sponsor: TLC Healthcare
Level 10, 468 St Kilda Road, Melbourne Victoria 3004, Australia
Part of the TLC Healthcare Group
Email: enquiries@tlcsupplies.com.au
Phone: +61 132 852
tlcsupplies.com.au

In the event you are experiencing problems with the test, please contact our sponsor 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
Unique device identifier		Biological risks	
Do not use if package is damaged			

Version No.: 2.0
Effective Date:

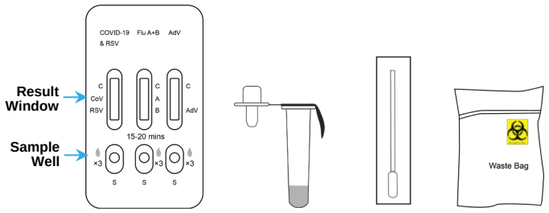
Turn page

Scan the QR code to watch how to use the device.
For additional instructions please visit
https://tlchealthsupplies.store.unleashedsoftware.com/products/18221931
For further support call **+61 132 852**,
hours: **9am-7pm** (AEST), **Mon-Fri**

Preparing for the test

1. Keep a clock, timer or stopwatch at hand.
2. Ensure that all test components are kept at room temperature (**10-30℃**).
3. Ensure that there is sufficient lighting for testing and interpretation.

4. Wash your hands in soapy water and dry thoroughly.
5. Check all kit components are present and have not been opened.
   DO NOT use if any of the components or sealed packaging is damaged.

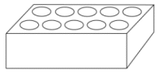


Test Cassette (inside foil pouch)

Buffer Tube

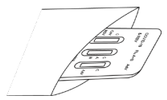
Swab

Waste Bag



Work Station (for 20 Tests pack only)

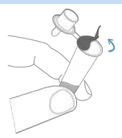
6. Remove the test cassette from the sealed pouch, and the test cassette must stay FLAT on a table during the entire testing.



Test Procedure

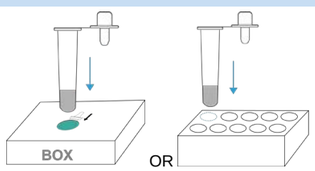
1. Open the Buffer Tube

Carefully tear off the sealed foil film on the buffer tube.



2. Insert Tube into Box

Gently press the tube through the perforated hole on the box, or insert the tube into the work station.

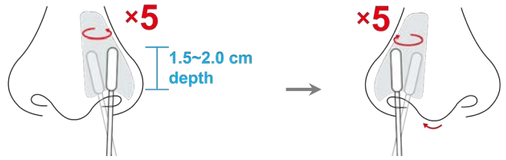


3. Remove the Swab

Open the swab package at stick end.
Take out the swab.
DO NOT touch the swab tip.

4. Swab Both Nostrils

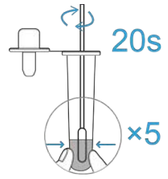
a. Gently insert the entire tip of the swab into one nostril about **1.5~2.0 cm**. **With children**, the maximum depth of insertion into the nostril may be **1.0~1.5 cm**.
b. Firmly brush the swab against the inside of the nostril in a circular motion **5 times** or more.
c. Remove the swab and repeat the step above in the **OTHER** nostril using the same swab.



***CHECK:** You should swab **both nostrils**.*
A false negative result may occur if the nasal swab is not properly collected.

5. Process Sample

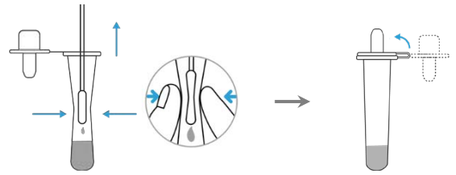
a. Insert the swab in the buffer tube to the bottom.
b. Rotate the swab in the liquid for at least **20 seconds** while pressing swab tip against the bottom and sides of the tube.
c. Squeeze the swab tip from the outside of the tube **5 times**.



Inadequate sample processing can result in a false negative result

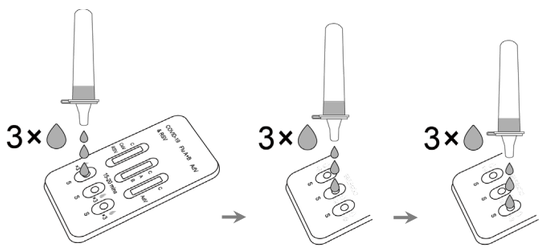
6. Remove the swab

Remove the swab while squeezing the sides of the tube. Then cover the tube with the dropper cap tightly.



7. Add Sample to Each Sample Well

Invert the buffer tube, and add **3 drops** from the tube into **each** Sample Well (S) by gently squeezing the sides of the tube.



Adding less than 3 drops of sample may result in inaccurate results.

8. Wait for 15 Minutes

Set a timer, and read the test result at **15-20 minutes**.
DO NOT read the result before 15 minutes or after 20 minutes.
Go to the Result Interpretation section below to read your test results.

9. Dispose of 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.

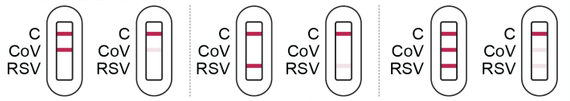
Result Interpretation

Positive Result

Three 'C' lines must be PRESENT

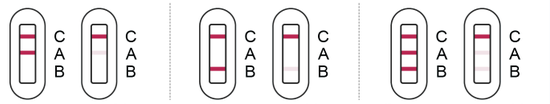
If three control (C) lines are visible, and any other line or multiple lines (no matter how faint) appear at 'CoV', 'RSV', 'A', 'B' and/or 'AdV', the test is **positive** for that virus.

For COVID-19 & RSV:



COVID-19 Positive | **RSV Positive** | **COVID-19 & RSV Positive**

For Flu A+B:



Influenza A Positive | **Influenza B Positive** | **Influenza A & B Positive**

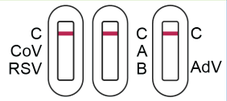
For AdV:

Adenovirus Positive

Negative Result

Three 'C' lines only

If three control (C) lines are visible, but no other lines appear, the test is **negative**.

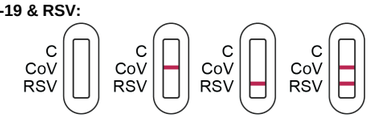


Invalid Result

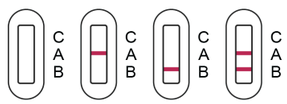
Missing 'C' line in either result window

If the control (C) line is not visible in either result window, the test is **invalid**.

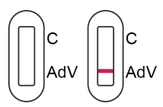
For COVID-19 & RSV:



For Flu A+B:



For AdV:



What to do if you test positive for COVID-19?

A positive test result means that the SARS-CoV-2 virus was detected in your sample. It is very likely that you have COVID-19 and are contagious.
If you test positive for COVID-19, you should: stay at home until your symptoms are gone; manage and treat your symptoms; see your doctor if your symptoms worsen; avoid people in high-risk settings like hospitals and residential aged care facilities; wear a face mask; keep physical distance from others. If you feel short of breath or have chest pain, call triple zero (000) immediately and ask for an ambulance. For further information on how to manage symptoms and protect those around you, please visit https://www.health.gov.au/topics/covid-19/testing-positive.

What to do if you test positive for RSV?

A positive test result means that the RSV virus was detected in your sample. It is very likely that you have RSV infection and are contagious.
You should seek follow-up care with your doctor.

What to do if you test positive for Flu A/B?

A positive test result means that the influenza A or influenza B virus was detected in your sample. It is very likely that you have influenza and are contagious.
You should seek follow-up care with your doctor.

What to do if you test positive for AdV?

A positive test result means that the adenovirus was detected in your sample. It is very likely that you have adenovirus infection and are contagious.
You should seek follow-up care with your doctor.

What to do if you test negative?

A negative test result means that SARS-CoV-2, RSV, influenza A, influenza B and AdV viruses were not detected in the sample. A negative result does not rule out COVID-19, influenza, RSV and AdV infection.
If your symptoms persist, please seek medical attention and further testing. It is recommended to test again within 1-3 days, as the virus may not be detectable in the very early phases of an infection.

What to do if you have a invalid result?

You should retest with a new swab, a new buffer tube, and a new test cassette, taking care to follow the instructions. If test still fails, please contact the distributor or the store, where you bought the product, with the lot number.