SARS-COV-2 and Influenza A+B Antigen Combo RapidTest (Nasal Swab)

REF ACO-1004

User instructions
For Self-testing
English

Plus Daily

FOR HOME-TESTING ONLY

Note: Use test only one time. Test within first 7 days of symptoms. Testing By adult or under adult supervision.
Customer Support Helpline: 1300 898 958 Available 24 hours, 7 days

Instruction Video

Before testing, scan the QR code to watch the How to Use video, or visit https://plusdaily.com.au/sars-cov-2-antigen-home-test-oral-fluid/

TEST KIT

Materials provided:

1 x Test cassette (packaged in foil pouch)
1 x Instructions for use
1 x Sterile swab
1 x Extraction buffer
1 x Biohazard Specimen Bag

Materials required but not provided:

Timer

BEFORE TESTING:

Important:

Wash your hands with soap and water for at least 20 seconds before and after test. If soap and water are not available, use hand sanitizer with at least 60% alcohol

1. Check the expiration date on the box.
• Do not use if the kit has expired.

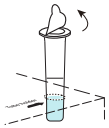
2. Ensure the kit is at room temperature for at least 30 minutes prior to use.

• Open the box carefully as it will be used in a later step.
• Do not open individual components until instructed.
• Note: A timing device (clock, timer, phone etc.) is required, but not provided.

3. Remove the cover of the tube with Extraction buffer

4. Put the Tube in the tube holder in the box.

• Note: Being careful not to spill the Tube contents.



NASAL SWAB SPECIMEN COLLECTION

Step 1: Open Swab protective pouch

• Open Swab protective pouch.
• Remove the sterile swab from the pouch

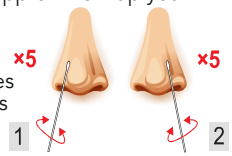
• Keep fingers away from the Swab end.

• Touch the stick end only.

Step 2: Swabbing both nostrils

• Insert the soft end of the Swab into your nostril until you feel resistance (Approx. 2cm up your nose).

• Slowly twist the swab, rubbing it along the insides of your nostril, 5 - 10 times against the nasal wall.



• Gently remove Swab from nostril.

Step 3: repeat step 2, in your other nostril

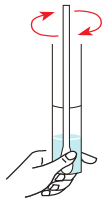
• Using the same Swab, repeat step 2, in your other nostril then withdraw the swab.

Note:
• This may feel uncomfortable. Do not insert the swab any deeper if you feel strong resistance or pain.
• When the nasal mucosa is damaged or bleeding, nasal swab collection is not recommended.
• If you are swabbing others, please wear a face mask. With children, you may not need to insert the swab as far into the nostril.
• For very young children, you may need another person to steady the child's head while swabbing.

Step 4: Insert the Swab into the extraction Tube

• Ensure it is touching the bottom and stir the swab to mix well.

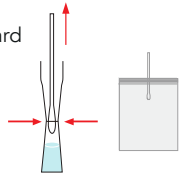
• Press the swab head against the tube and rotate the swab for 10 - 15 seconds.



Step 5: Hold the Tube firmly with one hand.

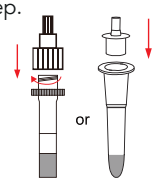
• Remove the swab while squeezing the swab head against the inside of the Extraction tube.

• Place the swab in the biohazard specimen bag provided and seal accordingly.



Step 6: Close the cap of the extraction tube

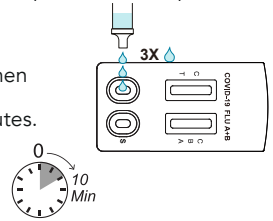
• Return the Tube to the Kit Box tube holder before proceeding to the next step.



PERFORM THE TEST

Remove the test cassette from the sealed foil pouch and use it within one (1) hour.
Note: Best results will be obtained if the test is performed immediately after opening the foil pouch.

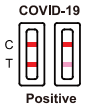
• Place the test cassette on a flat and level surface.
• Do not move the test cassette during test developing.
• Invert the specimen extraction tube and add 3 drops of extracted specimen to the sample well (S) of the test cassette.
• Start the timer.Secure tube cap back on extraction tube and wait 10 minutes.
• Do not touch the Test Device during this period.
• Read the result at 10 minutes.
• Keep Test Device flat on table.
• Do not read the result earlier than 10 minutes or after 20 minutes.



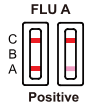
READING YOUR TEST RESULT

POSITIVE

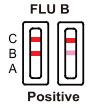
POSITIVE SARS-CoV-2:* Two colored lines appear in the left window. One colored line should be in the control region (C) and another colored line should be in the Test region (T).



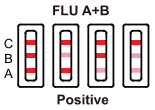
POSITIVE Influenza A:* Two colored lines appear in the right window. One colored line should be in the control region (C) and another colored line should be in the Influenza A region (A).



POSITIVE Influenza B:* Two colored lines appearin the right window. One colored line should be in the control region (C) and another colored line should be in the Influenza B region (B).



POSITIVE Influenza A and Influenza B:*
Three colored lines appear in the right window. One colored line should be in the control region (C) and two colored line should be in the Influenza A region (A) and Influenza B region (B).

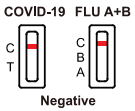


*NOTE: The intensity of the color in the test line region (T/B/A) will vary based on the amount of SARS-CoV-2 and / or Influenza A+B antigen present in the sample. So any shade of color in the test region (T/B/A) should be considered positive.

A positive results means it is very likely you have COVID-19 and / or Influenza A/Influenza B, A positive, please 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

NEGATIVE: One colored line appears in the control region (C).

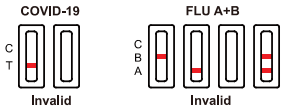


No apparent colored line appears in the test line region (T/B/A). You are unlikely to have COVID-19 and / or Influenza A/Influenza B. However, it is possible for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19 and / or Influenza A/Influenza B. This means you could possibly still have COVID-19 and / or Influenza A/Influenza B even though the test is negative.

In addition, you can repeat the test with a new test kit. In case of suspicion, repeat the test after 1-2 days, as the coronavirus/Influenza virus cannot be precisely detected in all phases of an infection.

INVALID

INVALID: Control line fails to appear.



Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test or contact our COVID-19 and / or Influenza helpline.

Disposing of your test kit

After completing your test, place all components into the plastic biohazard specimen bag provided and seal. You can then dispose of this sealed bag in your household waste (not recycling) or according to your local guidelines.

Warning:

There is a risk of a false negative result, particularly if testing is not performed within the first 7 days of symptom onset. The test is less reliable in the later phase of infection and in asymptomatic individuals. A negative result does not rule out infection with another type of respiratory virus. If you experience symptoms such as headaches, migraines, fever, loss of sense of smell or taste, contact the nearest medical facility according to guidelines provided by your local authority. Even with a negative test result, distance yourself and observe hygiene rules. In relation to migration/traveling, attending events, etc, you should follow your local COVID guidelines/ requirements.

Precautions

Please read all the information in this package insert before performing the test.
- For self-testing in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not drink the buffer in the kit. Carefully handle the buffer and avoid it contacting skin or eyes, rinse with plenty of running water immediately if contacting.
- Store in a dry place at 2-30 °C (36-86 °F), avoiding areas of excess moisture. If the foil packaging is damaged or has been opened, please do not use.
- This test kit is intended to be used as a preliminary test only and repeatedly abnormal results should follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance".
- Follow the indicated time strictly.
- Use the test only once. Do not dismantle and touch the test window of the test cassette.
- The kit must not be frozen or used after the expiration date printed on the package.
- Test for children should be under the guidance of an adult.
- Wash hands thoroughly before and after handling.
- Please ensure that an appropriate amount of samples are used for testing. Too much or too little sample size may lead to deviation of results.

Storage and Stability

Store the SARS-COV-2 Antigen Home Test (Oral Fluid) device at 2-30°C. Do not freeze. All reagents are stable until the expiration dates marked on their outer packaging.

Intended use

The SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab) is a single-use test kit intended to detect the SARS-CoV-2, Influenza A and Influenza B virus that causes COVID-19 and / or Influenza with self-collected nasal swab specimen. The test is intended for use in symptomatic individuals who are suspected of being infected with COVID-19 and / or Influenza A+B within the first 7 days of symptom onset. Results are for the detection of SARS-CoV-2 Nucleocapsid protein, Influenza A and Influenza B nucleoproteins antigens. An antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results are indicative of the presence of SARS-CoV-2 and / or Influenza A+B. Individuals who test positive should self-isolate and seek additional care from their healthcare provider. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 and / or Influenza A+B infection. Individuals who test negative and continue to experience COVID-like or flu-like symptoms should seek follow up care from their healthcare provider. The SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab) obtain a preliminary result only, the final confirmation should be based on clinical diagnostic results.

Summary

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus 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 main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases1.
Influenza (commonly known as 'flu') is a highly contagious, acute viral infection of the respiratory tract. It is a communicable disease easily transmitted through the coughing and sneezing of aerosolized droplets containing live virus2.
Influenza outbreaks occur each year during the fall and winter months. Type A viruses are typically more prevalent than type B viruses and are associated with most serious influenza epidemics, while type B infections are usually milder.

Principle

The SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 nucleocapsid protein, Influenza A and Influenza B nucleoproteins antigens in human swab specimen.

Reagents

The test device contains anti-SARS-CoV-2 antibodies and Influenza A+B antibodies.

Limitations

1. Performance was evaluated with nasal swab specimens only, using the procedures provided in this package insert.
2. The SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab) will only indicate the presence of SARS-CoV-2 and / or Influenza A/Influenza B antigens in the specimen.
3. If the test result is negative or non-reactive and clinical symptoms persist or being in a high risk setting or where there is an occupational risk or other requirement, it is because the very early infection virus may not be detected, It is recommended to test again with a new test 1-2 days later or contact the nearest Covid test centre for a PCR test, using the rules of your local authority.
4. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
5. A negative result for Influenza A or Influenza B obtained from this kit should be confirmed by RT-PCR/culture.
6. Positive results of COVID-19 may be due to infection with non- SARS-CoV-2 coronavirus strains or other interference factors. A positive result for influenza A and/or B does not preclude an underlying co-infection with another pathogen, therefore the possibility of an underlying bacterial infection should be considered.
7. Failure to follow these procedures may alter test performance.
8. False negative results may occur if a specimen is improperly collected or handled.
9. False negative results may occur if inadequate levels of viruses are present in the specimen.
10. If testing is not performed within the first 7 days of symptom onset, it is possible for this test to give a negative result that is incorrect (a false negative).
11. Tests are less reliable in the later phase of infection and in asymptomatic individuals.
12. The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations.
13. A negative result does not rule out infection with another type of respiratory virus

Performance Characteristics

Clinical performance

The SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab) has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for the SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab). Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result.

SARS-CoV-2 Test:

SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test		RT-PCR		TOTAL
		Positive	Negative	
SARS-CoV-2 Antigen	Positive	161	2	163
	Negative	5	482	487
Total		166	484	650
Relative Sensitivity		96.99% (95% CI: 93.11%~99.01%)		
Relative Specificity		99.59% (95% CI: 98.52%~99.95%)		
Accuracy		98.92% (95% CI: 97.79%~99.57%)		

Influenza A+B Test:

SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test		RT-PCR		TOTAL
		Positive	Negative	
Influenza A Antigen	Positive	68	2	70
	Negative	3	485	488
Total		71	487	558
Relative Sensitivity		95.77% (95% CI: 88.14%~99.12%)		
Relative Specificity		99.59% (95% CI: 98.52%~99.95%)		
Accuracy		99.10% (95% CI: 97.92%~99.71%)		

SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test:

SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test		RT-PCR		TOTAL
		Positive	Negative	
Influenza B Antigen	Positive	48	3	51
	Negative	3	504	507
Total		51	507	558
Relative Sensitivity		94.12% (95% CI: 83.76%~98.77%)		
Relative Specificity		99.41% (95% CI: 98.28%~99.88%)		
Accuracy		98.92% (95% CI: 97.67%~99.60%)		

A usability study was performed with 131 lay people. The test results showed that laymen can read a range of results from negative over weak positive to positive and that they can identify results as well. The results show that the instructions provided with the test kit made it easy for the user to understand. The test is therefore suitable for lay user.

Limitation of Detection

The LOD for the SARS-CoV-2 variants was 78 $TCID_{50}$/ml, for the Influenza A virus was 10 $TCID_{50}$/ml and for the Influenza B virus was 50 $TCID_{50}$/ml.

Sensitivity Performance

The following SARS-CoV-2 variants can detect:
Alpha, Beta, VUI-21ARP-03, Gamma, Delta & Omicron.

Specificity Testing with Various Viral Strains
The SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test was tested with the following viral strains. No discernible line at either of the test-line regions was observed at these concentrations listed.

SARS-CoV-2 Test:
Adenovirus type 3, Adenovirus type 7, Human coronavirus OC43, Human coronavirus 229E, Human coronavirus NL63, Human coronavirus HKU1, MERS COV Florida, Influenza A H1N1, Influenza A H3N2, Influenza B, Human Rhinovirus 2, Human Rhinovirus 14, Human Rhinovirus 16, Measles, Mumps, Parainfluenza virus 2, Parainfluenza virus 3, Respiratory syncytial virus.

Influenza A+B Test:
Adenovirus type 3, Adenovirus type 7, Human coronavirus OC43, Human coronavirus 229E, Human coronavirus NL63, Human coronavirus HKU1, MERS COV Florida, Human Rhinovirus 2, Human Rhinovirus 14, Human Rhinovirus 16, Measles, Mumps, Parainfluenza virus 2, Parainfluenza virus 3, Respiratory syncytial virus.

Cross-reactivity

The following organisms were negative when tested with the SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab):
Arcanobacterium, Candida albicans,Corynebacterium, Escherichia coli, Moraxella catarrhalis, Neisseria lactamica, Neisseria subflava, Pseudomonas aeruginosa, Staphylococcus aureus subspaureus, Staphylococcus epidermidis, Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus salivarius, Streptococcus sp group F.

Interfering Substances

Test results will not be interfered by following substances at certain concentrations:
Whole Blood, Mucin, Budesonide Nasal Spray, Dexamethasone, Flunisolide, Mupirocin, Oxymetazoline, Phenylephrine, Rebetol, Relenza, Tamiflu, Tobramycin.

Important Contact

In the event you are experiencing problems with the test, please contact Plus Daily Ltd. Additionally, you may wish to report poor performance or usability issues directly to the Therapeutic Goods. Administration (TGA) via the Medical Device Incident Reporting scheme, email iris@tga.gov.au or call 1800 809 361. To contact your local state/territory health department go to the following link:
https://www.health.gov.au/about-us/contact-us/local-state-and-territory-health-departments

Contact details and websites of the local State or Territory Health Department:
Australian Capital Territory Department of Health, General Enquiries: 02 5124 9213
Coronavirus helpline (8am to 8pm) : 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, General enquiries: 13HEALTH or 13 432 584
Coronavirus hotline: 134COVID or 134 268 https://www.health.qld.gov.au/
South Australian Department of Health, General enquiries: 1300 232 272
Coronavirus hotline (9am to 5pm): 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, General enquiries: 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, M-F) https://www.healthywa.wa.gov.au/

Index of Symbols

IVD	For in vitro diagnostic use only	Σ	Tests per kit		Do not reuse
2°C 30°C	Store between 2-30°C		Use by	REF	Catalog #
	Do not use if package is damaged	LOT	Lot Number		
	Manufacturer		Consult Instructions For Use		

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