COVID-19 and Flu A/B Multiplex Panel for Home Use (Nasal Swab) Package Insert

For Self-testing

REF COF-CT525H	English

Before testing, scan the QR code to watch the "how to use" video.
For more information, please refer to https://www.citestdiagnostics.com/Home/ProductInfo/391.
This rapid test is applied to people of different ages. Children should be tested with the help of an adult.

A rapid test for the qualitative detection of SARS-CoV-2 nucleocapsid protein, Influenza A and Influenza B nucleoproteins antigens present in nasal swab specimen. For self-testing in vitro diagnostic use.

INTENDED USE

The COVID-19 and Flu A/B Multiplex Panel for Home Use (Nasal Swab) is a single-use test kit intended to be used as an aid in the diagnosis of 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 within 7 days of symptom onset and/or with Influenza A+B within 4 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 contact your State or Territory Coronavirus testing services to get a laboratory PCR test. 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.
Testing for children and young people should be performed by an adult.
The COVID-19 and Flu A/B Multiplex Panel for Home Use (Nasal Swab) provides a preliminary result only. The final confirmation should be based on clinical diagnostic results.

BACKGROUND

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 cases.
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 virus. 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.

TEST PRINCIPLE

The COVID-19 and Flu A/B Multiplex Panel for Home Use (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 nasal swab specimen.

REAGENTS

The test contains monoclonal anti-SARS-CoV-2 antibody, anti-Influenza A antibody, anti-Influenza B antibody and goat anti-mouse IgG as the capture reagent, and monoclonal anti-SARS-CoV-2 antibody, anti-Influenza A antibody, anti-Influenza B antibody and mouse IgG as the detection reagent.

WARNINGS AND PRECAUTIONS

Please read all the information in this package insert before performing the test.

1. For self-testing *in vitro* diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. **Do not drink the buffer in the kit.** Test kit solutions should only be used as directed. Carefully handle the buffer and avoid it contacting skin or eyes, rinse with plenty of running water immediately if contacting.
4. Store the test kit 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.
5. This test kit is intended to be used as a preliminary test only. 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.
6. Follow the indicated time strictly.
7. Use the test only once. Do not dismantle and touch the test window of the test cassette.
8. The kit must not be frozen or used after the expiration date printed on the package.
9. Keep out of the reach of children.
10. Test for children should be under the guidance of an adult.
11. Wash hands thoroughly before and after handling.
12. Small children and young people under the age of 16 should be swabbed with the help of an adult.
13. Testing for children under the age of 2 must not be performed.
14. Please ensure that 3 drops of solution to each specimen are used for testing. Too much or too little sample may lead to deviation of results.

STORAGE

Store the test kit as packaged in the sealed pouch at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date. Keep it dry.

MATERIALS

Materials Provided

	Kit size	25T/kits
Components	Test cassette	25
	Sterile swab	25
	Extraction buffer	25
	Package insert	25
	Tube holder	1

Materials required but not provided

• Timer
• Biosafety bag (optional)

LIMITATIONS

1. Performance was evaluated with nasal swab specimens only, using the procedures provided in this package insert. Failure to follow these procedures may alter test performance.
2. The COVID-19 and Flu A/B Multiplex Panel for Home Use (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, it is because the very early infection virus may not be detected. **It is recommended to test again with a new kit within 1-3 days.**
4. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance
5. A negative result does not mean a person is not infectious or does not have influenza. If symptoms persist the person should seek medical attention and further testing if required.
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. False negative results may occur if a specimen is improperly collected or handled.
8. False negative results may occur if inadequate levels of viruses are present in the specimen.
9. **The COVID-19 and Flu A/B Multiplex Panel for Home Use (Nasal Swab) may give false negative results in the later phase of infection, it is recommended to use the test within the first 7 days of symptom onset for COVID-19 and within 4 days of symptom onset for Influenza A+B.**
10. **Tests are less reliable in asymptomatic individuals.**
11. **A negative result does not rule out infection with another type of respiratory virus.**
12. **A positive result cannot necessarily determine whether a person is infectious. It needs to check local state or territory requirements for reporting positive results.**
13. The COVID-19 and Flu A/B Multiplex Panel for Home Use (Nasal Swab) is a presumptive test only and **follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.**

Clinical performance

The COVID-19 and Flu A/B Multiplex Panel for Home Use (Nasal Swab) has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for the COVID-19 and Flu A/B Multiplex Panel for Home Use (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:

The COVID-19 and Flu A/B Multiplex Panel for Home Use		RT-PCR (Nasopharyngeal swab)		Total
		Positive	Negative	
SARS-CoV-2 Antigen	Positive	393	3	396
	Negative	13	486	499
Total		406	489	895
Relative Sensitivity		96.80% (95%CI: 94.59%~98.28%)		
Relative Specificity		99.39% (95%CI: 98.22%~99.87%)		
Accuracy		98.21% (95%CI: 97.11%~99.15%)		

Influenza A+B Test:

The COVID-19 and Flu A/B Multiplex Panel for Home Use		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%)		

The COVID-19 and Flu A/B Multiplex Panel for Home Use		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%)		

Limitation of Detection

The COVID-19 and Flu A/B Multiplex Panel for Home Use can detect SARS-CoV-2 virus of as low as 78 $TCID_{50}$/mL, Influenza A virus of as low as 10 $TCID_{50}$/mL, Influenza B virus of as low as 50 $TCID_{50}$/mL.

Variants

Variants the device can detect are as follows.

Variants	Lineage
Alpha	B.1.1.7
Beta	B.1.351
VUI-21ARP-03	B.1.617.3
Gamma	P.1.2
Delta	B.1.617.2
	B.1.617.3
	AY Sub-lineages
Omicron	B.1.1.529

Usability

For lay-user study, 239 lay-users were recruited. All lay-users gave the same results as those from professional. Comparing with PCR, the COVID-19 and Flu A/B Multiplex Panel for Home Use (Nasal Swab) has a sensitivity of 86.11%, 92.11% and 93.02% and a specificity of 100%, 100% and 99.49% in detecting COVID-19, Flu A and Flu B respectively.

Specificity Testing with Various Viral Strains

The COVID-19 and Flu A/B Multiplex Panel for Home Use (Nasal Swab) was tested with the following viral strains. No discernible line was observed at the test-line region.

Description	Description
Adenovirus type 3	Human Rhinovirus 2
Adenovirus type 7	Human Rhinovirus 14
Human coronavirus OC43	Human Rhinovirus 16
Human coronavirus 229E	Measles
Human coronavirus NL63	Mumps
Human coronavirus HKU1	Parainfluenza virus 2
MERS COV Florida	Parainfluenza virus 3
Enterovirus Type 68 (2007 Isolate)	Respiratory syncytial virus
Chlamydia pneumoniae	Bordetella pertussis A639
Haemophilus influenza type b	Mycoplasma pneumonia M129
Legionella pneumophila Philadelphia	/

Cross-reactivity

The organisms in the table below were tested negative with the COVID-19 and Flu A/B Multiplex Panel for Home Use (Nasal Swab). There exists cross reactivity of SARS-CoV-1 with SARS-CoV-2 for this rapid test.

Arcanobacterium	*Pseudomonas aeruginosa*
Candida albicans	*Staphylococcus aureus subspaureus*
Corynebacterium	*Staphylococcus epidermidis*
Escherichia coli	*Streptococcus pneumoniae*
Moraxella catarrhalis	*Streptococcus pyogenes*
Neisseria lactamica	*Streptococcus salivarius*
Neisseria subflava	*Streptococcus sp group F*

Interfering Substances

Test results are not interfered by following substances at certain concentrations.

Substance	Substance
Whole Blood	Oxymetazoline
Mucin	Phenylephrine
Budesonide Nasal Spray	Rebetol
Dexamethasone	Relenza
Fluni solide	Tamiflu
Mupirocin	Tobramycin
HAMA	Biotin

EXTRA INFORMATION

1. How does the COVID-19 and Flu A/B Multiplex Panel for Home Use (Nasal Swab) work?

The test is for the qualitative detection of SARS-CoV-2 and/or Influenza A/Influenza B antigens in self-collected swab specimens. A positive result indicates SARS-CoV-2 and/or Influenza A/Influenza B antigens present in the specimen.

2. When should the test be used?

SARS-CoV-2 and/or Influenza A/Influenza B antigen can be detected in acute respiratory tract infection. It is recommended to run the test when you are suspected of being infected with COVID-19 and/or Influenza A/Influenza B.

3. Can the result be incorrect?

The results are accurate as far as the instructions are carefully respected.
Nevertheless, the result can be incorrect if inadequate sampling volume or the COVID-19 and Flu A/B Multiplex Panel for Home Use (Nasal Swab) gets wet before test performing, or if the number of extraction specimen drops are less than 3 or more than 4.
Besides, due to immunological principles involved, there exist chances of false result in rare cases. Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

4. How to interpret the test if the color and the intensity of the lines are different?

The color and intensity of the lines have no importance for result interpretation. The lines should only be homogeneous and clearly visible. The test should be considered as positive whatever the color intensity of the test line is.

For CUSTOMER SUPPORT HELPLINE: Call (+61) 2-9959-2400 9am-7pm (AEST)/9am-8pm (AEDT), 7 days per week for information on the correct use of this test and for interpretation of the test results.

LOCAL CONTACT DETAILS

Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance

TO LOCATE YOUR NEAREST COVID TESTING CENTRE AND LABORATORY PLEASE CONTACT

STATE AND TERRITORY CONTACT NUMBERS

Australian Capital Territory Coronavirus Helpline (8am-8pm daily)	02 6207 7244 https://health.act.gov.au/
New South Wales Coronavirus Helpline (Service NSW 24/7)	137 788 https://www.health.nsw.gov.au/
Northern Territory Coronavirus National Hotline (National Helpline)	1800 020 080 https://health.nt.gov.au/
Queensland Coronavirus Helpline (134COVID)	134 268 https://www.health.qld.gov.au/
South Australia Coronavirus Helpline (9am -5 pm Daily)	1800 253 787 https://www.sahealth.sa.gov.au/
Tasmanian Public Health Hotline (Coronavirus)	1800 671 738 https://www.health.tas.gov.au/
Victoria Coronavirus Hotline (24/7)	1800 675 398 https://www.dhhs.vic.gov.au/
Western Australia Coronavirus Hotline 13COVID (8am- 6pm Mon-Fri)	1800 595 206 https://www.healthywa.gov.au/

Contact the 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)

LITERATURE REFERENCES

1. Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia (Trial Version 7). National Health Commission & National Administration of Traditional Chinese Medicine.2020.
2. Williams, KM, Jackson MA, Hamilton M. (2002) Rapid Diagnostic Testing for URIs in Children; Impact on Physician Decision Making and Cost. Infec. Med. 19(3): 109-111.

INDEX OF SYMBOLS

IVD	*In vitro* diagnostic medical device		Tests per kit
2°C 30°C	Temperature limit 2-30 °C		Use by
	Do not use if package is damaged	LOT	Batch code
	Manufacturer		Consult Instructions For Use
	Keep dry	REF	Catalog #
	Do not reuse		

CITEST DIAGNOSTICS INC.
170-422 Richards Street
Vancouver BC, V6B 2Z4, Canada

Sponsor by:
LC & Partners Pty Ltd.
Add: Level 32, 101 Miller Street,
North Sydney NSW 2060, Australia
Tel: (61) 2-99592400

Statement: Information about manufacturer of sterile swab is placed on the packaging.

Number: 146815400
Revision date: 2023-11-24

Before testing, scan the QR code to watch the "how to use" video.

BEFORE STARTING

Wash hands thoroughly before testing.

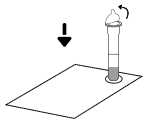
1. PREPARE FOR THE TEST

1A. Check the expiration date on the box.
Do not use if the kit has been damaged or has expired

1B. Ensure the kit is at room temperature for at least 30 minutes prior to use.
Open the box carefully.
Do not open individual components until instructed.
Note: A timing device (clock, timer, phone etc.) is required, but not provided.

1C. Remove the cover of the tube containing the extraction buffer.

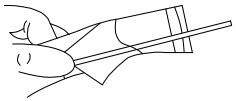
1D. Place the tube in the tube holder.
Note: Being careful not to spill the Tube contents.



2. NASAL SWAB SPECIMEN COLLECTION

2A. Open Swab protective pouch.

Remove the sterile swab from the pouch



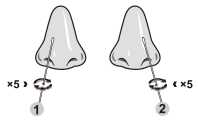
! **Do not touch the "cotton" tip.**

2B. Swabbing.

Insert the swab into one nostril. Do not exceed 2 cm.

Firmly rub the swab in a circular motion around the inside wall of the nostril for 5-10 times.

Gently remove the swab from the nostril.



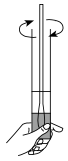
2C. Using the same Swab, repeat step 2B in your other nostril.
Withdraw the swab.

Note:
1. This may feel uncomfortable. Do not insert the swab any deeper if you feel strong resistance or pain.
2. When the nasal mucosa is damaged or bleeding, nasal swab collection is not recommended.
3. 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.
4. For very young children, you may need another person to steady the child's head while swabbing.

2D. Insert the Swab into the extraction Tube.

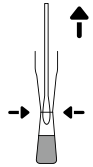
Ensure it is touching the bottom and stir the swab to mix well.

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



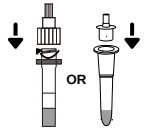
2E. Hold the Tube firmly with one hand.

Pull out the swab while pinching the tube. Release the sample on the swab in the tube as much as possible.



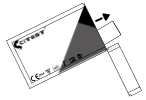
2F. Close the cap of the extraction tube

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



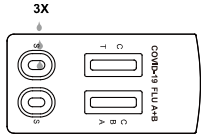
3. PERFORM THE TEST

3A. 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 clean and level surface.



! Do not move the test cassette during testing.

3B. Invert the tube and add **3 drops of solution** to each specimen well (S) of the test cassette and start the timer.



Start the timer. Secure tube cap back on extraction tube and **wait for 10 minutes.**

! Do not touch the Test Device during this period.

3C. Read the result at 10 minutes.

Keep the Test Device flat on the table.
Do not read the result earlier than 10 minutes or after 20 minutes.

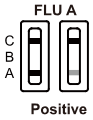
4. READING THE RESULTS

Please share your test result with your healthcare provider and carefully follow your local COVID guidelines/requirements.

POSITIVE

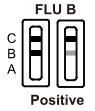
POSITIVE SARS-CoV-2:* Two colored lines appear in the COVID-19 window.

One colored line should be in the control region (C) and another colored line should be in the test region (T).



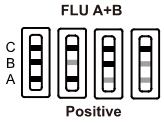
POSITIVE Influenza A:* Two colored lines appear in the Flu A+B window.

One colored line should be in the control region (C) and another colored line should be in the FLU A region (A).



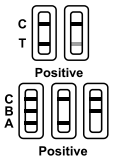
POSITIVE Influenza B:* Two colored lines appear in the Flu A+B window.

One colored line should be in the control region (C) and another colored line should be in the FLU B region (B).



POSITIVE Influenza A and Influenza B:* Three colored lines appear in the Flu A+B window.

One colored line should be in the control region (C) and two colored lines should be in the Flu A region (A) and Flu B region (B).

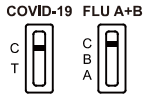


POSITIVE SARS-CoV-2 and Influenza A and/or Influenza B:* Four or five colored lines appear in the COVID-19 and Flu A+B window.

Two colored lines should be in the two control regions (C), two colored lines should be in the FLU A region (A) and FLU B region (B), and another colored line should be in the test region (T).

***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 antigens present in the sample. So any shade of color in the test region (T/B/A) should be considered positive.
A positive result means it is very likely you have COVID-19 and/or Influenza A/Influenza B, but the positive sample should be confirmed to reflect this. For a SARS-CoV-2 positive result, 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. For a Influenza A/Influenza B positive result, please consult a medical practitioner for follow-up clinical care if you feel unwell.

NEGATIVE



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

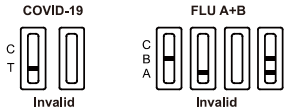
No colored line appears in the test line region (T/B/A).

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.

Even with a negative test result, distance and hygiene rules must be observed. When conducting activities such as migration/traveling, attending events please follow your local COVID/Influenza guidelines/requirements. If symptoms occur, please consult a medical practitioner for follow-up clinical care.

INVALID

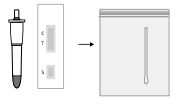


INVALID: Control line fails to appear.

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. If invalid result continues after repeating, please contact the sponsor.

5. DISPOSE OF THE TEST KIT

After the testing is completed, place all the components in a plastic bag (eg. biosafety bag) and seal it tightly, then dispose of it in a household waste or rubbish bin.



For Customer Support Helpline: Call (+61) 2-9959-2400 9am-7pm (AEST)/9am-8pm (AEDT), 7 days per week for information on the correct use of this test and for interpretation of the test results.