

**SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA)**

Self-testing

**FOR IN VITRO DIAGNOSTIC USE ONLY. FOR SELF-TESTING. PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST.**



Operation video

Test cassette: 1 pc/bag

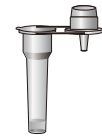
REF	Specification
1041-14-01	1 pc/Box
1041-24-01	2 pcs/Box
1041-34-01	5 pcs/Box
1041-54-01	20 pcs/Box

Display of the anterior nasal swab in original size.

**KIT CONTENTS**



Test cassette (individually in a foil pouch with desiccant)



Lysis Buffer and Dropper



Anterior Nasal Swab (CE0197)



Instructions for use (20pcs/Box, 4\*IFU)



Bio-Safety Bag

**PREPARATION**

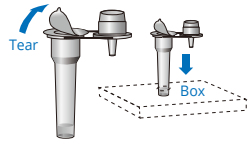
- 1 Prepare the timing tools and make sure a clean testing environment.
- 2 Carefully read IFU of SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA).
- 3 Check the expiry date on the foil pouch. Do not use kit components after their expiration date. Open the pouch and take out the test cassette, place it on a flat surface.



**Warning!**  
This test kit should be used within 1 hour after opening the foil pouch.

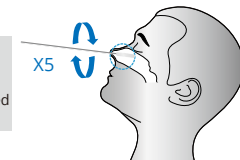
**ANTERIOR NASAL SECRETION TEST PROCEDURE**

- 1 Tear the seal of the lysis buffer and place it on the test-tube rack.
- 2 Insert the swab (stick with larger absorbent tip) into a nostril (2.5 cm). Be sure to collect any nasal drainage that may be present. Those ≥18 years old can sample on their own, while children aged 5-17 years old need to be sampled and tested with the assistance of an adult.
- 3 Insert the swab into the sampling tube and rotate the swab against the inner tube wall 10 times.

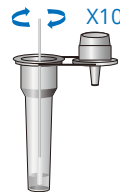


Carefully rotate the swab in a circular path against the inside of the nostril at least 5 times.

Using the same swab repeat the procedure in the other nostril.



Sample should be treated with lysis buffer provided in this kit as soon as possible after collection. If the sample cannot be processed immediately, it should be stored immediately in a dry, sterilized and strictly sealed plastic tube. It can be stored at room temperature for 1 hour, 2 C-8 C for 4 hours. Could be stored at -20 C for 1 months.

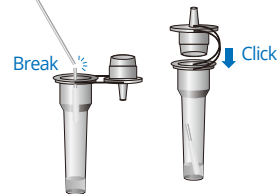
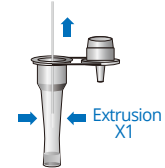
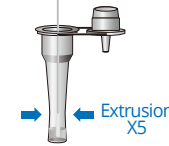


For specification of 1 pc/box - 2 pcs/box - 5 pcs/box, the package box can be used as test-tube rack by pushing the dotted holes on the box, For 20pcs/box please use the provided test-tube rack in the box.

**SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA)**

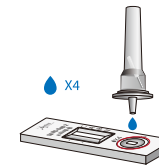
Self-testing

- 4 Squeeze the swab from the outer tube wall 5 times. Lift the swab above the buffer solution level, squeeze the swab from the outer tube wall one time to leave the sample in the tube as much as possible.
- 5 Break the swab and cover the tube with the dropper.



- 6 Add 4 drops processed sample extract into the sample well.

Open the foil pouch, then lay the test cassette on a clean flat surface



- 7 Read the results within 15-20 mins.

Result observed after 20 mins is invalid



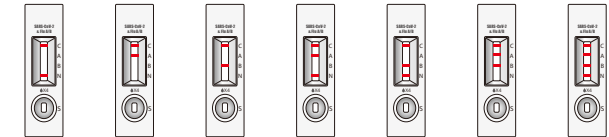
Remark: Additional required but not provided equipment: Timer

Place all used materials in a Bio-safety bag, seal it tightly, and dispose of it in a household waste bin.

**DISPLAY OF THE RESULT / EXPECTED VALUES**

"C": Control Line

Positive +



"A": Influenza A Test Line

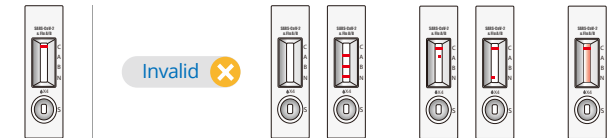
"B": Influenza B Test Line

"N": SARS-CoV-2 Test Line

"S": Sample Well

Negative -

Invalid X



**Positive result:**

- SARS-CoV-2 Positive result: If the control line (C line) and the test line (N line) appear at the same time, it means that the SARS-CoV-2 has been detected and the result is positive.
- Influenza A positive result: If both the control line (C line) and the Influenza A test line (A line) appear at the same time, it means that Influenza A antigen has been detected in the sample and the result of Influenza A is positive.
- Influenza B positive result: If both the control line (C line) and the Influenza B test line (B line) appear at the same time, it means that influenza B antigen has been detected in the sample and the result of influenza B is positive.

**Note:** The intensity of color that the test line area (N line/A line/B line) shows will vary according to the concentration of SARS-CoV-2 antigen, Influenza A antigen and Influenza B antigen. The result should be determined on whether the N line is formed or not, and is irrelevant to the color intensity. Therefore, any intensity of color in the test area (N line/A line/B line) should be considered positive.

**What you need to do:**

- There is currently a suspicion of a COVID-19, Influenza A or Influenza B infection.
- Individuals who have tested positive for SARS-CoV-2 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.
- Individuals who have tested positive for influenza or who are unwell are advised to consult a medical practitioner for follow-up clinical care.

**Negative result:**

If only the control line (C line) appears and the test line (N line, A line and B line) is invisible, the sample does not contain SARS-CoV-2 and Influenza A/B antigen or the antigen concentration is lower than the limit of detection, then the result is negative.

**What you need to do:**

- Continue to comply with all applicable rules regarding contact with others and protective measures.
- There may be an infection even if the test is negative.
- If symptoms develop persist or become more severe, follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
- If it is suspected, repeat the test after 1-3 days, as the coronavirus cannot be precisely detected in all phases of an infection.

**Invalid result:**

The test result is invalid if any of the following circumstances apply

1. No C line appears
2. The test line (A line / B line / N line) appears incompletely (all the way across the window)
3. A reddish background of NC film shows on the result window.

**What you need to do:**

- Possibly caused by incorrect test execution.
- Repeat the test with a new kit.
- If the test results remain invalid, contact the sponsor hotline for further guidance.

**Warning!** Please DO NOT take any decision of medical relevance without consulting your doctor/general practitioner.

**Customer Support**

For assistance regarding to the use of the test kit and interpretation of test results, call What you need to do: 1300 417 415. The service is available between 9am to 7pm (AEST), 7 days per week.

