The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) is a lateral flow chromatographic immunoassay single-use test kit intended to qualitatively determine the presence of SARS-CoV-2 that causes COVID-19 in self-collected nasal swab specimens. The test is intended for use in symptomatic individuals meeting the case definition for COVID-19 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.

The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 nucleocapsid protein antigens in human swab specimen.

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 use if the test cassette or the test window of the test cassette is damaged or has been opened, please do not use.

This kit is intended to be used as a preliminary test only and repeatedly abnormal results should be discussed with doctor or medical professional.

Follow the indicated time strictly.

- The test must be used 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.
- Keep out of the reach of children.
- Test for children and other people who should be used with an adult.
- Store in a dry place at 2-30 °C (36-86 °F), avoiding exposure of moisture. If the foil packaging has damaged or has been opened, please do not use.

STORAGE AND STABILITY
Store 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 package.

Do not use beyond the expiration date.

Performance was evaluated with nasal swab specimens only, using the procedures provided in this package insert. The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) will only indicate the presence of SARS-CoV-2 antigens in the specimen.

If the test result is negative or non-reactive and clinical symptoms persist or in a high risk setting or there is sufficient reason to do so, it is 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 health authority.

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 test should be considered to rule out infection.

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3. 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 test should be considered to rule out infection.

4. Positive results of COVID-19 may be due to infection with non-SARS-CoV-2 coronavirus strains or other respiratory viruses.

5. Failure to follow these procedures may alter test performance.

6. False negative results may occur if a specimen is improperly collected or handled.

7. False positive results may occur if inadequate levels of viruses are present in the specimen.

8. The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) is less reliable in the later stages of infection, it is recommended to test again with a new test 1-2 days later or contact the nearest health authority.

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10. 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 test should be considered to rule out infection.

11. Tests are less reliable in asymptomatic individuals.

12. It is possible to have a negative result that is incorrect (false negative).

13. False negative results may occur if a specimen is improperly collected or handled. It is advisable for this test to give a negative result that is incorrect (false negative).

14. The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) is a diagnostic test only and the only confirmatory testing of positive results by a laboratory PCR test and follow-up clinical care.

15. False negative results are not rare that the viral load is too low to be recognized by the test. It is recommended to test again with a new test 1-2 days later or contact the nearest health authority.

16. If you experience COVID-like symptoms, follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

17. False negative results may occur if a specimen is improperly collected or handled. It is advisable to follow the test with a new test 1-2 days later or contact the nearest health authority.

18. A consultation with the doctor is always recommended for such tests based on immunological principles.

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20. If you experience COVID-like symptoms, follow-up testing with a laboratory PCR test and you'll have had the test as needed.

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22. A consultation with the doctor is always recommended for such tests based on immunological principles.
1. **SPECIMEN COLLECTION**

Remove the cover of the tube with Extraction buffer and place the tube in the tube holder.

Nasal swab specimen Collection

1. Remove the sterile swab from the pouch.
2. Insert the swab into your nostril until you feel slight resistance (Approx. 2cm up your nose). Slowly twist the swab, rubbing it along the insides of your nostril for 5-10 times against the nasal wall.

**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.

3. Gently remove the swab.
4. Using the same swab, repeat step 2 in your other nostril.
5. Withdraw the swab.

6. **SPECIMEN PREPARATION**

1. Place the swab into the Extraction tube, ensure it is touching the bottom and stir the swab to mix well. Press the swab head against to the tube and rotate the swab for 10-15 seconds.

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

3. Close the cap or fit the tube tip onto the tube.

7. **TESTING**

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

2. Invert the specimen extraction tube and add 3 drops of extracted specimen to the sample well(S) of the test cassette and start the timer.

3. **READING THE RESULTS**

- **POSITIVE:** Two distinct colored lines appear.

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

*NOTE:* The intensity of the color in the test line region (T) will vary based on the amount of SARS-CoV-2 antigen present in the sample. So any faint colored lines in the test region (T) should be considered positive.

A positive result means it is very likely you have COVID-19, but the positive samples should be confirmed to reflect this. Immediately go into self-isolation in accordance with the local guidelines and immediately contact your State or Territory Coronavirus testing services to get a laboratory PCR test and you will be explained the next steps.

- **NEGATIVE:** One colored line appears in the control region (C). No colored line appears in the test line region (T).

You are unlikely to have COVID-19. However, it is possible for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19. This means you could possibly still have COVID-19 even though the test is negative.

If you experience symptoms such as headaches, migraines, fever, loss of sense of smell or taste, contact the nearest Covid test centre according to the rules of your local authority. 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 cannot be precisely detected in all phases of an infection.

Even with a negative test result, distance and hygiene rules must be observed, migration/traveling, attending events and etc. should follow your local COVID guidelines/requirements.

- **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 with your doctor or a COVID-19 test center.

8. **DISPOSE THE TEST KIT**

After the test is complete, place all the components in a biosafety bag and tightly sealed, then dispose in household waste or rubbish bin. Dispose according to local regulations.

For Customer Support Helpline: Call (03) 5986 5465 9am-7pm (AEST), 7 days per week for information on the correct use of this test and for interpretation of the test results.