SARS-CoV-2 Antigen Rapid Test (Self-Testing)  
Package Insert

**REF** L031-118M5  REF L031-118PS  REF L031-11825  English

A rapid test for the detection of SARS-CoV-2 nucleocapsid antigens in anterior nasal swab specimens. For in vitro diagnostic use only. For self-testing.

Carefully read the instructions before performing the test.

**PREPARATION**

1. Wash or sanitize your hands. Make sure they are dry before starting the test.
2. Read the instructions before using SARS-CoV-2 Antigen Rapid Test kit.
3. Check the expiration date printed on the cassette foil pouch.
4. Open the pouch. Place the test cassette on a flat and clean surface. Check for the Result window and Specimen well on the cassette.

**TEST PROCEDURE**

1. Carefully remove the aluminum foil from the top of extraction buffer tube, avoid spilling.
2. Insert the tube into the hole on the kit box. (Or place the tube in the tube holder.)
3. Open the swab packaging at stick end. *Caution: Do not touch the absorbent tip of the swab with your hands.*
4. Insert the entire absorbent tip of the swab into one nostril. Using gentle rotation, push the swab less than 2.5 cm from the edge of the nostril.
5. Rotate the swab 5 times brushing against the inside of the nostril. Remove the swab and insert it into the other nostril. Repeat step 4.
6. Remove swab from the nostril.
7. Insert the swab into the tube and swirl for 30 seconds.
8. Rotate the swab 5 times while squeezing the side of the tube.
9. Remove the swab while squeezing the tube.
10. Gently squeeze the tube and dispense 4 drops of solution into the Specimen well.
11. 4x
12. 15-30 min.
13. Read the result when the timer reaches 15-30 minutes. Do not read after 30 minutes.

**SPECIMEN COLLECTION**

A nasal swab sample can be self-collected by an individual aged 18+ years. Children under 18 years of age should be performed by a parent or legal guardian. Not to be used on children under 2 years of age.

**RESULT INTERPRETATION**

Only the control line (C) and no test line (T) appears. This means that no SARS-CoV-2 antigen was detected.

A negative test result indicates that you are unlikely to currently have COVID-19 disease. Continue to follow all applicable rules and protective measures when contacting with others. There may be an infection even if the test is negative. If it is suspected, repeat the test after 1 - 2 days, as the coronavirus cannot be precisely detected in all phases of an infection.

Both the control line (C) and test line (T) appears. This means that SARS-CoV-2 antigen was detected. **NOTE:** Any faint line in the test line region (T) should be considered positive.

A positive test result means it is very likely you currently have COVID-19 disease. Contact your State or Territory Coronavirus testing services to get a laboratory PCR test immediately. Follow the local guidelines for self-isolation.

Control line (C) fails to appear. Not enough specimen volume or incorrect operation are the likely reasons for an invalid result. Review the instructions again and repeat the test with a new cassette. If the test results remain invalid, contact your State or Territory Coronavirus testing services.

**SAFELY DISPOSE OF YOUR TEST KIT**

Once your test is complete, put all of the used test kit contents in the waste bag provided. Put in your general household waste.

Orvato Healthcare Helpline: +61 02 9641 2829 (9am – 7pm | 7 Days per week)
The SARS-CoV-2 Antigen Rapid Test is a lateral flow test for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal swab specimens directly from individuals suspected of COVID-19 within the first seven days of the onset of symptoms. It does not differentiate between SARS-CoV-1 and SARS-CoV-2. Results are for the identification of SARS-CoV-2 RNA. This antigen is generally found in upper respiratory samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but individual history and other diagnostic information is necessary to determine infection status. Negative results do not rule out bacterial infection or co-infection with other viruses.

The agent detected may not be the exact cause of disease. Negative results from individuals with symptoms beyond seven days should be treated as likely negative. Confirm with a PCR test if a negative result is suspected. Negative results do not rule out other viral or bacterial pathogens. A positive result does not rule out other viral or bacterial infections. A negative result, from an individual having symptoms beyond seven days, should be treated as likely negative and confirmed with a PCR test. The test is less reliable in the later phase of infection and in asymptomatic individuals. The test should not be used on children under 2 years of age.

The SARS-CoV-2 Antigen Rapid Test is used for self-testing use only. The test should only be used by an adult under 18 years of age should be tested by an adult. The test cassette contains anti-SARS-CoV-2 antibodies and goat anti mouse IgG. The intensity of test lines is proportional to the concentration of SARS-CoV-2 antigens. The test line for a low viral load sample may become visible within 30 minutes. The test line for a high viral load sample may become visible within 15 minutes, or as soon as the test cassette is removed from the test area.

Performance of the SARS-CoV-2 Antigen Rapid Test was established with 605 nasal swabs collected from individuals who were suspected of COVID-19. The sensitivity is confirmed as 97.1% (160/167), Specificity is 99.5% (433/435) and an Overall Accuracy is 98.8% (598/605).

Sensitivity
The sensitivity is confirmed as 93.9% and specificity is confirmed as 100% in the hands of the lay person questionnaire together with the observation recorded by a HCP showed that the test is slightly less sensitive in the asymptomatic individuals.

Specificity
Specificity is confirmed as 99.8% (280/281) with different virus variants including: Alpha, Beta, Gamma, Delta, Kappa, Eta, Mu, Nu, and Omicron. Cross-reactivity was evaluated. No cross-reactivity or interference was observed with the test. The test is not reliable in the later phase of infection and in asymptomatic individuals. The test should not be used on children under 2 years of age.

Accuracy
The test is valid for up to 2 days after the extraction buffer tube was used. The test result is valid for up to 6 days after the test was performed. The test is less reliable in the later phase of infection and in asymptomatic individuals.

Limit of Detection (LOD)
The LOD of SARS-CoV-2 Antigen Rapid Test is 100 TU/mL.

Interfering Substances
The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated. Each substance was tested in the absence or presence of SARS-CoV-2 virus at low positive level. The substances tested are listed below and were found not to affect test performance.

1. Aloe vera
2. Almond
3. Apple
4. Avocado
5. Banana
6. Broccoli
7. Carrot
8. Coffee
9. Corn
10. Date
11. Fennel
12. Ginger
13. Grapes
14. Honeydew
15. Mango
16. Oranges
17. Papaya
18. Peaches
19. Persimmon
20. Pineapple
21. Plums
22. Raspberry
23. Rosemary
24. Strawberries
25. Tomatoes
26. Tangerine
27. Thyme
28. Watermelon

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Performance Characteristics
Critical Evaluation: Sensitivity, Specificity and Accuracy

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