The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) is a single-use test kit intended to detect the SARS-CoV-2 virus that causes COVID-19 with self-collected nasal swab specimens. It is designed to test for the presence of the SARS-CoV-2 virus in nasal swab specimens.

**INTENDED USE**
- For self-testing
- For self-diagnostic use only
- Do not use after the expiration date printed on the package
- Do not use if the package is damaged or has been opened
- For use in a few cases1.

**SUMMARY**
- The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) is intended to be used by laypersons as a self-test for home and workplace (in offices, for sporting events, airports, schools, etc.).

**PRECAUTIONS**
- 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.
- Please read all the information in this package insert before performing the test.
- It is not advised for in vitro diagnostic use only. Do use after the expiration date printed on the package.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not drink the buffer in the use. Carefully handle the extract avoiding skin contact. If the kit is damaged or has been opened, do not use it.
- Do not store the kit under 2°C - 8°C (41°F - 46°F), avoiding areas of extreme temperature. If the kit is damaged or has been opened, do not use it.
- Do not use the test once the color and the intensity of the lines are different.
- The test is intended to be used as a preliminary test and repeatedly abnormal results should be discussed with doctor or medical professional.

**STORAGE AND STABILITY**
- Store as packed 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.

**MATERIALS PROVIDED**
- Tests cassette
- Package insert
- Sterile swab
- Biodegradable bag

**LIMITATIONS**
- 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, it is because the very early infection may not be detected; it is recommended to test again with a new test or with a molecular diagnostic device to rule out infection in these individuals.
- 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.

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This is a qualitative test for the detection of SARS-CoV-2 Nucleocapsid Protein antigen present in nasal swab specimen. For self-testing or in vitro diagnostic use.

**REVIEW REFERENCE**
This chapter is based on research and articles from the following sources:

**INDEX OF SYMBOLS**

**VARIABLES**
- SARS-CoV-2-variant Alpha (UK: B.1.1.7) (Detected concentration 10⁶ viral RNA copies/L) Small children should be vaccinated with the help of a second adult.
- SARS-CoV-2-variant Beta (South Africa: B.1.351) (Detected concentration 10⁵ viral RNA copies/L) The SARS-CoV-2 Antigen Rapid Test is intended to be used as a preliminary test and repeatedly abnormal results should be discussed with doctor or medical professional.
- SARS-CoV-2-variant Delta (Brazil: P.1) (Detected concentration 10⁵ viral RNA copies/L) The SARS-CoV-2 Antigen Rapid Test is intended to be used as a preliminary test and repeatedly abnormal results should be discussed with doctor or medical professional.
- SARS-CoV-2-variant Gamma (Brazil: P.1) (Detected concentration 10⁵ viral RNA copies/L) The SARS-CoV-2 Antigen Rapid Test is intended to be used as a preliminary test and repeatedly abnormal results should be discussed with doctor or medical professional.
- SARS-CoV-2-variant Delta + (Brazil: P.1) (Detected concentration 10⁵ viral RNA copies/L) The SARS-CoV-2 Antigen Rapid Test is intended to be used as a preliminary test and repeatedly abnormal results should be discussed with doctor or medical professional.
- SARS-CoV-2-variant Lambda (Peru: B.1.617.2) (Detected concentration 10⁵ viral RNA copies/L) The SARS-CoV-2 Antigen Rapid Test is intended to be used as a preliminary test and repeatedly abnormal results should be discussed with doctor or medical professional.
- SARS-CoV-2-variant Mu (Colombia: B.1.621) (Detected concentration 10⁵ viral RNA copies/L) The SARS-CoV-2 Antigen Rapid Test is intended to be used as a preliminary test and repeatedly abnormal results should be discussed with doctor or medical professional.
- SARS-CoV-2-variant Omicron (South Africa: B.1.1.529) (Detected concentration 10⁵ viral RNA copies/L) The SARS-CoV-2 Antigen Rapid Test is intended to be used as a preliminary test and repeatedly abnormal results should be discussed with doctor or medical professional.

**Limitation of detection**
- The SARS-CoV-2 Antigen Rapid Test can detect SARS-CoV-2 -2 heat-inactivated virus strain as low as 10⁴ TCID₅₀.

**Interfering substances**
- The interfering substances below were applied with negative, SARS-CoV-2 Antigen rapid test positive. No substances showed any interference with the COVID-19 Antigen Rapid Test (Nasal Swab).

**Manufacturers**

**For Support Customer Call :** 1800 472 743

**For information on the correct use of this test and for interpretation of the test results.**

**Customer Service Hours:** 24 Hours, 7 Days

**State and territory contact numbers**

**Confidential testing of positive results by a laboratory PCR test is required.**

For your local Covid testing center and Laboratory please contact

Australia Capital Territory Coronavirus Helpline (Bam-8pm daily) 1800 472 743
South Australia Coronavirus Helpline (Service NSW 24/7) 1800 620 980
Northern Territory Coronavirus Hotline (National Health Line) 1800 020 080
Queensland Coronavirus Helpline (134 COVID) 1800 061 962
Victoria Coronavirus Hotline (24/7) 1800 595 206
Western Australia Coronavirus Hotline 13COVID (Bam-8pm Mon-Fri) 1800 595 206

Contact the TGA to report poor performance or usability issues in the self-test environment report an issue via the Users Medical Devices Incident Report, email: info@ga.gov.au or call 1800 839 381

**BIBLIOGRAPHY**

**Number:** 146573800
**Effective Date:** 2021-10-08
**© All Diagnostics Ltd 2021**
Before testing, scan the QR code to watch the how to use video, or visit www.mycovidtest.com.au/how-it-works/

For additional language instructions please visit www.mycovidtest.com.au/product-resources

**1. PREPARE FOR THE TEST**

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

1B. Ensure 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 (1D). 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 with Extraction buffer.

1D. Remove the sterile swab from the pouch and rotate the swab for 10 -15 seconds.

1E. Hold the Tube firmly with one hand. Place the swab head against the inside of the Extraction tube. Press the swab head against the tube and rotate the swab for 10 - 15 seconds. Gently remove Swab from nostril.

2. COLLECT THE NASAL SAMPLE

2A. 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.

2B. 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.

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

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. Remove the swab while squeezing the swab head against the inside of the Extraction tube. Place the swab in the biosafety bag.

2F. Close the cap of the extraction tube.

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 flat and level surface.

3B. Open the small cap of the specimen extraction tube.

3C. 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 white cap back on extraction tube and wait 15 minutes.

4. READ TEST RESULT

4A. Do not move the test cassette during test developing.

4B. Invert the specimen extraction tube and add 3 drops of extracted specimen to the sample well (S) of the test cassette.

5. DISPOSE THE TEST KIT

5A. After the test is completed, place all the components into the plastic Bio-safety bag (supplied).

5B. Dispose according to local regulation.

For Customer Support Call 1800 472 743 for information on the correct use of this test and for interpretation of the test results. Customer Service Hours are M24 Hours, 7 Days.