Medriva

MEDRIVA COVID-19 RAPID ANTIGEN TEST

PACKAGE INSERT

Version 4 Effective date: 11/2021

INTENDED USE

The COVID-19 Antigen Test is a rapid test for the qualitative detection of SARS-CoV-2 nucleocapsid antigen in anterior nasal swabs. It is used to aid in the diagnosis of SARS-CoV-2 infection that may lead to COVID-19 disease. The test is suitable for people with symptoms. Children aged 2-15 years should be supported by an adult; not suitable for use in children under 2 years. The test is single use only and intended for self-testing, it is recommended to use this test within 7 days of symptom onset.

PRINCIPLE

The COVID-19 Antigen Test is a qualitative immuno-assay based on a membrane for the detection of SARS-CoV-2 Nucleocapsid (N) antigen in nasal swabs. In this assay, an anti-SARS-CoV-2-N antibody is immobilised in the test zone of the membrane. After a sample is placed in the sample well, it reacts with anti-SARS-CoV-2-N antibody coated particles that are on the sample pad. This mixture migrates chromatographically along the length of the test membrane and interacts with the immobilised anti-SARS-CoV-2-N antibody.

If the sample contains SARS-CoV-2 antigen, a coloured line appears in the test line region, indicating a positive result. If the sample does not contain SARS-CoV-2 antigen, no coloured line appears in this area, indicating a negative result. As a procedural control, a coloured line always appears in the control line region, indicating that the correct sample volume has been added and the membrane has been wetted through.

REACTION SYSTEM

The test contains an anti-SARS-CoV-2-N antibody as capture reagent and another anti-SARS-CoV-2-N antibody as detection reagent. A goat anti- mouse antibody is used in the control line system.

QUALITY CONTROL

Internal quality controls are included in the test. The colour line appearing in the control area (C) is an internal positive procedure control which confirms adequate specimen volume and correct procedure technique.

VARIANTS DETECTABLE BY THIS TEST

The test has been tested and proven to detect multiple Variants of COVID-19, including Alpha, Beta, Gamma, Kappa, Mu, and most importantly, the Delta Variant. It should be noted that the manufacturer's R&D team is constantly working to ensure that these tests can detect any new variants that become known.

LIMIT OF DETECTION

The limit of detection for COVID-19 Antigen Test was determined to be 50 TCID50/mL using inactivated SARS-CoV-2 Virus.

REAGENTS AND MATERIALS PROVIDED

Pack size	Contents
1 Test / Box	1 Test device, 1 Extraction Tube with Extraction Buffer, 1 Nasal swab, 1 Package insert
5 Tests / Box	5 Test device, 5 Extraction Tube with Extraction Buffer, 5 Nasal swab, 1 Package insert
20 Tests / Box	20 Test device, 20 Extraction Tube with Extraction Buffer, 20 Nasal swab, 4 Package insert

PRECAUTIONS

1. Do not use after the expiry date.
2. Read the Package insert carefully before use and use only the components included in this test .
3. Make sure that the foil pouch containing the test is not damaged before opening it for use. The test should be used within 30 minutes after opening the foil pouch.
4. Do not eat, drink or smoke in the area where the samples and kits are handled.
5. Carry out the test at a room temperature of 15 - 30 °C.
6. Humidity and temperature can influence the results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (4-30 °C). The test is stable to 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.

INTERFERING SUBSTANCES

The following compounds have been tested using the COVID-19 Antigen Test and no interference was observed with Whole Blood, Mucin, Mupirocin, Oxymetazoline, Dexamethasone, Flunisolide, Budesonide Nasal Spray, Phenylephrine, Rebetol, Relenza, Tamiflu, Tobryaycin, HAMA (human anti-mouse) antibodies and Biotin.

LIMITATIONS

1. Each test can only be used once.
2. Interpretation of any result after 20 minutes may result in wrong test results.
3. Children aged 2 to 15 years old should have their samples collected and tested by an adult. Do not use the test for anyone under 2 years of age.
4. Positive results do not rule out bacterial infection or co-infection with other viruses.
5. A positive result cannot determine whether you are infectious
6. Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance
7. False negative results are more likely to occur if the test is performed after 5 days of symptom onset.
8. False negative results are more likely to occur in the later phase of infection and in asymptomatic individuals.
9. A negative result does not rule out infection with another type of respiratory virus.
10. Negative results does not preclude SARS-CoV-2 infection and the person not being infectious.
11. Even if the result is negative, you still need to observe all protective and hygienic measures.
12. The test cannot differentiate between SARS-CoV-1 and SARS-CoV-2 Virus.
13. Repeat testing is recommend (between 24-48 hours after your first test) if there is an ongoing suspicion of infection, being in a high risk setting or where there is an occupational risk or other requirement.

CROSS-REACTIVITY

The COVID-19 Antigen Test has been tested for other Strain and virus (Table below). The results showed no cross-reactivity.

Candida albicans	Influenza A H3N2
Staphylococcus epidermidis	Influenza B
Corynebacterium	Human Rhinovirus 12
Streptococcus pneumoniae	Human Rhinovirus 14
Escherichia coli	Human Rhinovirus 16
Streptococcus pygenes	Measles
Moraxella catarrhalis	Mumps
Streptococcus salivarius	Parainfluenza virus 2
Neisseria lactamica	Parainfluenza virus 3
Streptococcus sp group F	Respiratory syncytial virus
Nesseria subflava	Human coronavirus 229E
Pseudomonas aeruginosa	MERS
Arcanobacterium	Human coronavirus OC 43
Influenza A H1N1	Human Coronvirus NL63

Please note that the concentration levels are not listed above, however, if one would like obtain this information, please contact ProcureNet APAC Pty Ltd email or phone (contact details can be found at the bottom of the document).

PERFORMANCE CHARACTERISTICS

The clinical performance of the COVID-19 Antigen Test for patient self-testing was evaluated using nasal swab samples collected from 100 study participants in multiple prospective studies.

The clinical evaluations were performed by the manufacturers and Independent laboratory. A PCR Test was collected from all 100 participants by a professional using a nasopharyngeal swab after completing their self-test, the participants include children (age 10-17), adults (18-84) and elders (age over 85).

The Clinical performance was evaluated using samples that were professionally tested, This included 375 participants in one study whereby all samples were taken using a nasal swab and second nasopharyngeal swab for PCR testing.

CLINICAL PERFORMANCE WITH NASAL SWABS

Self-test clinical result				
	Antigen	PCR	Sensitivity	Specificity
Positive	34	35	97%	/
Negative	64	65	/	98%
95% confidence interval			84.1-99.9%	91-99.9%
Professional clinical result				
	Antigen	PCR	Sensitivity	Specificity
Positive	118	125	94.4%	/
Negative	249	250	/	99.6%
95% confidence interval			88.7-99.5%	97.5-99.9%

If there are poor performance or usability issues, please contact the TGA to report an issue via the Users Medical Device Incident Report, email iris@tga.gov.au or call 1800 809 361.

SUPPORT SERVICES

Information regarding available support services can also be obtained by contacting your local state and territory health department at:

Symbol	Meaning	Symbol	Meaning
IVD	Medical in vitro diagnosis		Storage temperature Limits (4-30°C)
	Manufacturer		Tests per set
LOT	Batch code		Do not reuse
	Follow the Package insert	EC REP	Authorised Representative in the European Community
	Expiry date	REF	Catalogue number
	Date of manufacture		Indicates that you should keep the product dry

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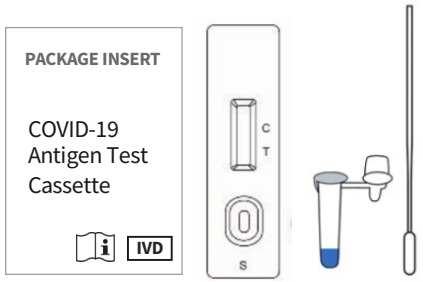
NASAL SWAB SPECIMEN COLLECTION

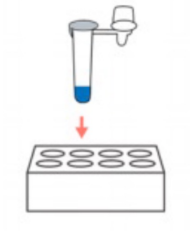
1

2



Check the kit contents before testing. Kit includes: Package insert, Test Cassette, Extraction Tube with Extraction Buffer and Sterile Swab.

3



Place the Extraction Tube in the Workstation.

MORE INFORMATION:

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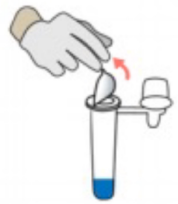
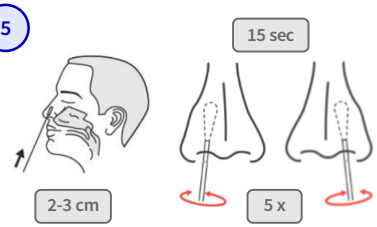


Peel off aluminium foil seal from the top of the extraction tube containing containing the extraction buffer.

5



Carefully remove the swab without touching the tip. Insert the entire tip of the swab 2 to 3 cm into the right nostril. Note the breaking point of the nasal swab. You can feel this with your fingers when inserting the nasal swab or check it in the mirror. Rub the inside of the nostril in circular movements 5 times for at least 15 seconds, now take the same nasal swab and insert it into the other nostril. Swab the inside of the nostril in a circular motion 5 times for at least 15 seconds. Please perform the test immediately with the swab.

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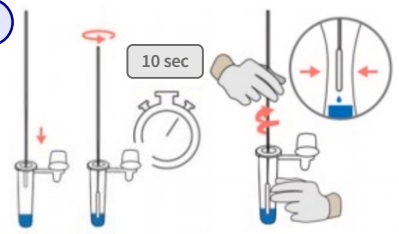

Place the swab in the extraction tube. Rotate the swab for about 10 seconds, Rotate the swab against the extraction tube, pressing the head of the swab against the inside of the tube while squeezing the sides of the tube to release as much liquid as possible from the swab.

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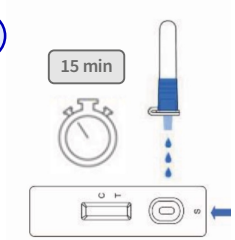

Mix thoroughly by flicking the bottom of the tube. Place 3 drops of the sample vertically into the sample window of the test . Read the result after 15 minutes.

Note: Read the result within 20 minutes. Otherwise, a repetition of the test is recommended.

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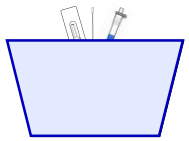
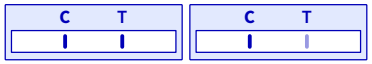


Discard test in waste bin; do not recycle.

INTERPRETATION OF TEST RESULTS

Positive:

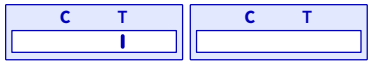


Two colored lines appear. One colored line appears in the control region (C) and one colored line appears in the test region (T). NOTE: The test is considered positive as soon as even a **faint** line appears. A positive result means that SARS-CoV-2 antigens were detected in your sample. A positive test result indicates that antigens from SARS-CoV-2 were detected, and you are likely to be infected and presumed to be contagious. **Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary and if unwell seek medical assistance".**

Negative:

One colored line appears in the control region (C). No apparent colored line appear in the test region (T). Negative results should be treated as presumptive only and may not mean you are not infectious. Repeat testing (e.g. within 1-3 days) is recommended if ongoing suspicion of infection, high risk setting or occupational or other requirement.

Invalid:



No colored line appears in the control region (C). The test is invalid even if there is one line in the test region (T). Invalid result indicates that your test has experienced an error and is unable to interpret the result of test. Insufficient sample volume or incorrect handling are the most likely reasons for this. It is recommended that you repeat the test with a new test kit. If you are experiencing COVID symptoms, the test kit may not be able to detect coronavirus if you are in the very early phases of infection. You are advised to continue following local guidelines for self-isolation, retesting and consult your doctor

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