Medriva

REF COVG-602ST

IVD Specimens: Nasal Swab

For self-testing

MEDRIVA COVID-19 RAPID ANTIGEN SELF-TEST

Version/Rev Rev 001 Effective Date 1st of January 2023

INTENDED USE

The Medriva COVID-19 Rapid Antigen Self-test is a single-use test kit intended to be used as an aid in the diagnosis for SARS- Cov-2 that causes COVID-19. The kit uses a self-collected nasal swab specimen and is intended to detect SARS-CoV-2 that causes COVID-19. SARS-CoV-2 antigen testing is typically used in the acute phase of infection, with samples tested within the first 7 days of symptom onset when the antigen is generally detectable in the upper respiratory tract.

The Medriva Self-test is intended to be used by lay users as a self-test in the home and workplace (in offices, airports, schools, for sporting events, etc.). Positive results are indicative of the presence of SARS-CoV-2, but do not rule out bacterial infection or co-infection with other viruses. Individuals who test positive should seek guidance from their local State or Territory Health Department on the need for confirmation testing, and if unwell should seek medical assistance.

Negative results do not rule out SARS-CoV-2 infection. Individuals who test negative and continue to experience COVID-like symptoms should seek guidance from their local State or Territory Health Department on the need for confirmation testing, and if unwell should seek medical assistance.

SUMMARY

The novel coronaviruses belong to the beta genus. COVID-19 is an acute infectious disease of the respiratory tract. Currently, patients infected with the novel coronavirus are the main source of infection. Infected people without symptoms can also infect others. According to the current state of knowledge, the incubation period is 1 to 14 days, usually 3 to 7 days.

TEST PRINCIPLE

The Medriva COVID-19 Rapid Antigen Self-test is a qualitative, lateral flow immunoassay for the detection of the SARS-CoV-2 N protein in human nasal swabs. In this test, antibody specific to the SARS-CoV-2 N protein is coated on the test line regions of the test cassette. During testing, the extracted specimen migrates up the membrane to react with the SARS-CoV-2 N protein antibody on the membrane and generates one coloured line in the test (T) region. The presence of this coloured line indicates a positive result.
To serve as a procedural control, a coloured line will always appear in the control (C) region if the test has performed properly.

PRECAUTIONS

Please read these instructions for use completely before performing the test.

- For self-testing in vitro diagnostic use only.
- Single use only; do not re-use.
- Keep out of the reach of children.
- Wash hands thoroughly before and after performing the test.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- **Do not drink the buffer in the kit.** Handle the buffer carefully;
- avoid contact with skin or eyes. Rinse any area of contact immediately with running water. Contact you doctor if any irritation occurs.
- Store in a dry place at 2-30°C. **Do not freeze.** The test must remain in the sealed pouch until ready to use. Do not expose to moisture.
- Follow the test timing instructions **strictly**. Ensure that an appropriate volume of sample is used for testing. Failure to follow the timing instructions, or using too much or too little sample may affect the accuracy of the results.
- Do not use the test in children under 2 years old.
- Testing of children over 2 years old and adolescents less than 18 years should be supervised or performed by an adult. Small children should be swabbed with the help of a second adult.
- Do not use if the foil packaging is damaged or has been opened. Do not use after the expiry date. Do not dismantle and touch the test window of the test cassette.
- This test kit is intended to be used as a preliminary test only. Please follow the guidance from your local State or Territory Health Department on the need for confirmation testing, and if unwell seek medical assistance.
- After completing the test, place all components in the sealable waste bag provided and dispose of them in household or residual waste bin.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). Do not use beyond the expiry date printed on the sealed pouch.
The test must remain in the sealed pouch until use. Do not freeze.
Do not expose to moisture or sunlight.

COMPONENTS

CONTENTS	PACK SIZE		
	1 TEST / KIT	5 TESTS / KIT	20 TESTS / KIT
Cassette & Desiccant	1	5	20
Extraction Tube & Reagent	1	5	20
Disposable Sterile Swab	1	5	20
Biohazard Bag	1	5	20
Instructions For Use (IFU)	1	1	4

MATERIALS REQUIRED BUT NOT PROVIDED

Timer and disinfection products, e.g. soap, hand sanitiser, rubbing alcohol, etc.

LIMITATIONS

- The Medriva COVID-19 Rapid Antigen Self-test is only intended for personal use. The test should only be used once for the detection of SARS-CoV-2 nucleocapsid antigens in anterior nasal swab specimens. The intensity of the test line does not necessarily relate to the SARS-CoV-2 viral load in the sample.
- Tests are presumptive only. Results from antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- A positive result should not be viewed as a definitive diagnosis, but should be assessed in the context of clinical symptoms and other diagnostic methods.
- A positive result cannot necessarily determine whether a person is infectious, nor does it exclude an underlying co-infection with another pathogen and, therefore, the possibility of an underlying bacterial or other viral infection.
- A positive test result does not differentiate between SARS-CoV and SARS-CoV-2.
- There exists a very small probability of a false positive result due to presence of non-SARS-COV-2 coronavirus strains such as coronavirus HKU1, NL63, OC43 or 229E.
- A false negative test can result if the amount of antigen in a sample is below the detection limit of the test, or if the sample was taken incorrectly or not properly stored.
- A false negative test can result if testing is not is performed within the first 7 days of symptom onset. Tests are less reliable in the later phase of infection and in asymptomatic individuals. A negative result does not rule out the possibility of infection with SARS-CoV-2 or the possibility another type of respiratory virus or bacterial infection.
- Repeat antigen rapid testing is recommended every 24 hours for 3 days if there is a suspicion of infection, exposure to high-risk settings or other occupational risks.
- Excess blood or mucus on the specimen may interfere with test performance and may yield a false positive result.
- Please follow the guidance from your local State or Territory Health Department on whether confirmatory testing is necessary, and if unwell seek medical assistance.
- All materials including the extraction buffer used in the testing should be considered potentially infectious and should be disposed of in the waste bag provided with the test in the household or residual waste bin.
- Test can only be performed by adults over 18 years of age. Any persons or children under 18 years will require adult supervision or assistance.
- The performance of Medriva COVID-19 Rapid Antigen Self-test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

FREQUENTLY ASKED QUESTIONS

WHAT IF THE TEST IS POSITIVE?

A positive test result means it is very likely you currently have COVID-19. Follow the guidance from your local State or Territory Health Department for guidance on whether confirmatory testing is necessary, and if unwell seek medical assistance.

WHAT IF THE TEST IS NEGATIVE?

A negative test result indicates that you are unlikely to currently have COVID-19. Please continue to follow social distancing, washing hands regularly and wearing masks when contacting others. Infection is not guaranteed to be excluded since a low viral load or a possible sampling error can result in a false result. If this is suspected, repeat the test every 24 hrs for 3 days, since the coronavirus cannot be precisely detected in all phases of an infection.

HOW DO I KNOW THAT THE TEST WAS RUN PROPERLY?

A procedural control is included in the test. When a coloured line appears in the control line region (C) of the cassette, it confirms that the test has run correctly. If no line appears on the control line region (C) indicating insufficient sample volume, incorrect test procedure or an expired test, then reread the instructions and repeat the test with a new cassette. If the new test again shows no line in the C region, please contact the TGA for local support services, or to report poor performance and usability issues in the self-test environment via the Users Medical Device Incident Report: email iris@tga.gov.au or call 1800-809-361.

WILL THIS TEST HURT?

No, the nasal swab is not sharp, and it should not hurt. Sometimes the swab can feel slightly uncomfortable or tickly. If you feel pain, please stop the test and seek advice from a healthcare provider.

I HAVE A NOSEBLEED AFTER SWABBING MY NOSE. WHAT SHOULD I DO?

In the unlikely event your nose starts bleeding, apply pressure to your nose until the bleeding stops and consult a healthcare professional.
Do not insert the swab again.

CAN I USE MY OWN SWAB?

No, you must only use the components included in the test kit.

CAN I REUSE ANY OF THE COMPONENTS OF THE TEST KIT?

No, no component can be reused and do not mix the components of one kit with another.

COULD I SWAB JUST ONE NOSTRIL?

No. Please use the swab to collect specimen from both of your nostrils to ensure sufficient sample collection to generate an accurate result.

PERFORMANCE OF THE TEST

1. LIMIT OF DETECTION

The detection limit for the Medriva COVID-19 Rapid Antigen Self-test is 400 $TCID_{50}$/mL.

2. VARIANTS

Yes, Medriva COVID-19 Rapid Antigen Self-test can detect Alpha, Beta, Gamma, Delta and Omicron COVID-19 mutants based on the studies conducted so far.

3. CLINICAL PERFORMANCE

A clinical evaluation was conducted comparing the results obtained using the Medriva COVID-19 Rapid Antigen Self-test (nasal swab) to an RT-PCR.
A total of 409 swab samples including 103 positive samples and 306 negative samples from the anterior nose were tested. All the swab specimens were confirmed as positive or negative and validated with Ct value by the RT-PCR as a comparator method.

Medriva COVID-19 Rapid Antigen Self-test	RT-PCR		Total
	Positive	Negative	
Positive	103	0	103
Negative	6	300	306
Total	109	300	409

Explanation

94.5% Sensitivity: In total 109 PCR-confirmed positive samples, 103 PCR confirmed positive samples were correctly detected by the Medriva Rapid Antigen Self-test. There were 6 false negative cases.
100% Specificity: In total 300 PCR confirmed negative samples were, all correctly detected by the Medriva Test.
98.50% Reliability: In total 409 PCR-confirmed samples, 403 PCR-confirmed samples were correctly detected by the Medriva Test.

4. USABILITY STUDY

A usability study was performed by 111 lay persons in the self-testing environment using the package insert with quick reference guide only. Relative sensitivity was 97.43% (38/39); relative specificity was 100% (72/72). The results showed that the labelling provided with the test kit was comprehensive and the ease of use was suitable for its intended population.

5. ANALYTICAL SPECIFICITY

A. INTERFERING SUBSTANCES

The Medriva COVID-19 Rapid Antigen Self-test showed no interference by the following substances:

Whole blood, ibuprofen , tetracycline, mucin, erythromycin, tobramycin, menthol, afrin, compound benzoin gel, cromolyn glycate, chloramphenicol, mupirocin, oseltamivir, naphazoline hydrochloride nasal drops, fluticasone propionate spray, deoxyepinephrine hydrochloride.

B. CROSS REACTIVITY

No cross reactivity has been observed on testing by following commonly found respiratory/ oropharyngeal pathogens; however, a false result due to presence of these organisms at a level higher than tested cannot be ruled out:

Staphylococcus aureus, Group A streptococci, Measles virus, Mumps virus , Adenovirus type 3, Mycoplasma pneumonia, Human Parainfluenza virus type 2, Human Metapneumovirus, Bordetella parapertussis, Influenza B Victoria strain, Influenza B strain, Influenza A H1N1 2009, Influenza A H3N2, H7N9, H5N1, Epstein-Barr virus, Enterovirus CA16, Rhinovirus, Respiratory syncytial virus, Streptococcus pneumoniae, Candida albicans, Chlamydophila pneumoniae, Bordetella pertussis, Pneumocystis jirovecii, Mycobacterium tuberculosis, Legionella pneumophilia, MERS Coronavirus. SARS Coronavirus, Haemophilus influenzae, Streptococcus pyogenes, Pooled human nasal wash (bacterial complex cannot be tested)

SUPPORT SERVICES AND CUSTOMER SUPPORT

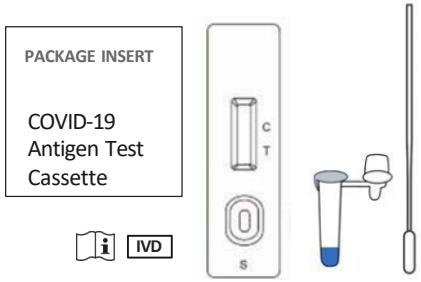
Australian Capital Territory Coronavirus Helpline	(8am-8pm Daily) 02 6207 7244
New South Wales Coronavirus Helpline	(Service NSW 24/7) 137 788
Northern Territory Coronavirus National Hotline	(National Helpline) 1800 020 080
Queensland Coronavirus Helpline	(134COVID) 134 268
South Australia Coronavirus Helpline	(9am -5 pm Daily) 1800 253 787
Tasmanian Public Health Hotline	(Coronavirus) 1800 671 738
Victoria Coronavirus Hotline	(24/7) 1800 675 398
Western Australia Coronavirus Hotline 13COVID	(8am- 6pm Mon Fri) 1800 595 206

For support and user assistance, contact us on 1800 950 861. This service is available between 9 am and 8pm (AEST), 7 days a week. Please scan the QR code to access instruction guide and additional information or visit https://youtu.be/OzG9KcWgn78

Medriva

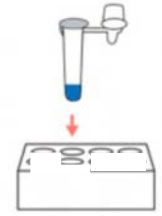
1 NASAL SWAB SPECIMEN COLLECTION

2 CHECK KIT CONTENTS



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

3 PLACE EXTRACTION TUBE IN THE REST

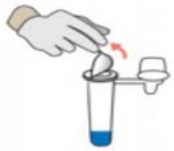


Place the Extraction Tube in the scored area in the carton.

INDEX OF SYMBOLS

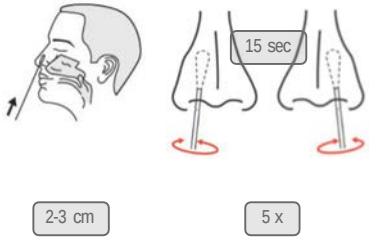
Symbol	Meaning	Symbol	Meaning
IVD	in vitro diagnostic medical device		Do not use if package is damaged
	Do not reuse		Keep dry
LOT	LOT Number		Keep away from sunlight
	Consult Instructions for use		Store between 2- 30°C
	Use by date	REF	Catalogue number
	Tests per kit		Manufacturer

4 REPLACE CAP



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

5 SPECIMEN COLLECTION

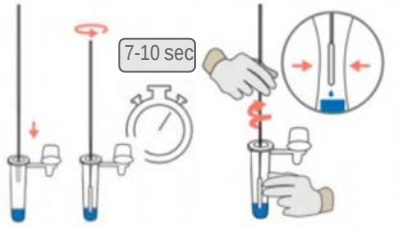


Carefully remove the swab without touching the tip. Insert the entire tip of the swab 2 to 3 cm into the right nostril. Note the breaking point of the nasal swab. You can feel this with your fingers when inserting the nasal swab or check it in the mirror.

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.

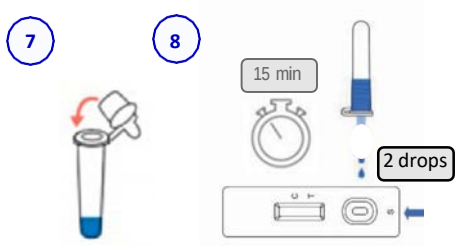
Swab the inside of the nostril in a circular motion 5times for at least 15 seconds. Please perform the test immediately with the swab.

6 PROCESS SPECIMEN



Place the swab in the extraction tube. Rotate the swab for 7 to 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.

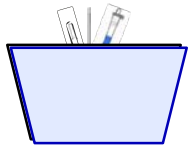
7 & 8 PROCESS SPECIMEN CONTINUED



Mix thoroughly by flicking the bottom of the tube. Place 2 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.

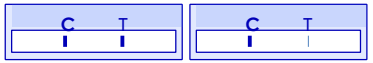
9 DISPOSAL



Discard test in waste bin; do not recycle.

INTERPRETATION OF TEST RESULTS

Positive:

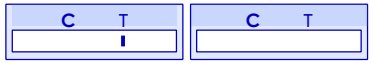


Two colored lines appear. One colored line appears in the control region (C) and one colored line appears in the test region (T). NOTE: The test is considered positive as soon as even a **faint** line appears. A positive result means that SARS-CoV-2 antigens were detected in your sample. A positive test 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 every 24 hrs for 3 days since the coronavirus cannot be precisely detected in all phases of infection.

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

AUSTRALIAN AUTHORISED REPRESENTATIVE:

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