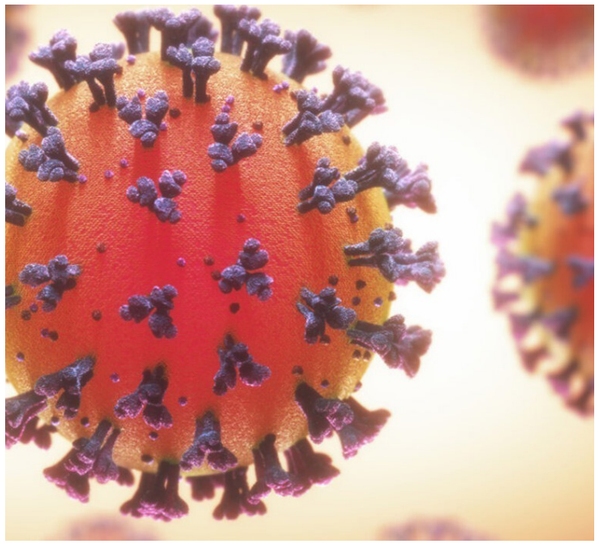


COVIFIND™

By Meril

INSTRUCTIONS FOR USE

SUMMARY

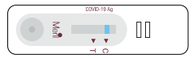
Corona viruses belong to the Nidovirales Coronaviridae and Coronavirus a large class of viruses found widely in nature. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhoea are found in a few cases.

INTENDED PURPOSE & PRINCIPLE

CoviFind COVID-19 Antigen Self-Test (home use) is an In-Vitro diagnostics immunochromatographic rapid assay kit, which is used as an aid in diagnosis and for the qualitative detection of SARS-CoV-2 specific antigen in nasal swab specimens from symptomatic individuals. This test is authorised and intended for collection of nasal specimens from individuals aged 18 years or older who have experienced COVID like symptoms within the last seven days and for use in the home, workplace or elsewhere. Anyone under 18 years will require adult supervision or assistance.

CoviFind COVID-19 Antigen Self-Test (home use) is an immunoassay kit for rapid and qualitative determination of SARS-CoV-2 infection from swab specimens. Monoclonal anti-SARS-CoV-2 nucleocapsid antibody is coated on the test line region. Antigens of SARS-CoV-2 in the specimens react with the anti-SARS-CoV-2 monoclonal nucleocapsid antibody coupled with gold conjugate and form an antigen-antibody complex followed by reaction with anti-SARS-CoV-2 monoclonal nucleocapsid antibodies immobilized in the test line. This complex migrates on the membrane, where it will be captured by the monoclonal anti-SARS-CoV-2 antibody. A coloured test line would be visible in the result window if SARSCoV-2 antigens are present in the specimen. The intensity of coloured test line will vary depending upon the amount of SARS-CoV-2 antigen present in the specimen. If SARS-CoV-2 antigens are not present in the specimen, then no line appears in the test line. The control band is used for procedural control and should always appear if the test procedure is performed correctly.

KIT CONTENTS



Test Device

Test Swab

Disposal Bag

Extraction Tub & dropper cap

Instructions for Use

TEST PREPARATION

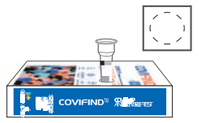
Wash your hands
Mark sure they are dry before starting the best

Remove the test components from the box and place the... on a flat surface.

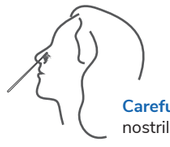
Remove the test device from the pouch.

Peel the Aluminium foil from the pre-filled buffer tube.

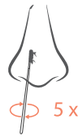
Push the buffer tube in to the **perforated circle**.



SAMPLE COLLECTION: STEP 1



Carefully insert the swab into one nostril 2–4cm or until resistance is met



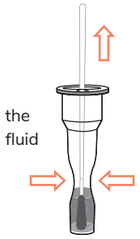
Slowly rotate the swab, gently rubbing it along the insides of your nasal passage at least five (5) times.

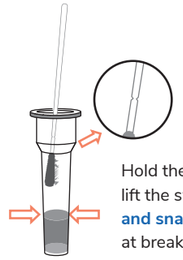
Using the same swab, repeat in the other nostril.

SAMPLE COLLECTION: STEP 2

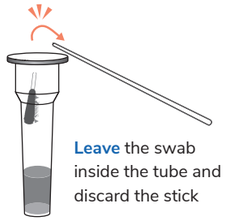
Insert the swab in the buffer tube and **swirl it 8-10 times** in the fluid.

Pinch the Swab tube through the tube to remove any remaining fluid

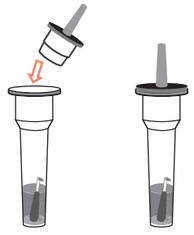




Hold the buffer tube firmly, lift the swab till **breakpoint and snap** the swab handle at breakpoint

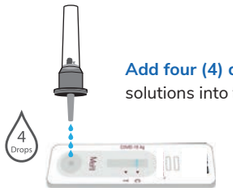


Leave the swab inside the tube and discard the stick



Place the cap on top of the buffer tube

RUN TEST

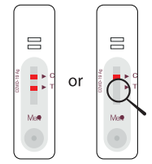


Add four (4) drops (~100µl) of the solutions into the sample well

Wait 15-20 minutes

READ RESULTS

POSITIVE

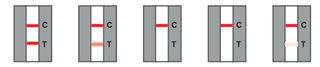


WHAT SHOULD I DO IF THE RESULT SHOWS POSITIVE?
Refer to your relevant health authority for advice on whether a PCR test is required to confirm your result. You should also inform the immediate contacts you have had in past 24 hours so they can take any appropriate precautions.

If **Control (C)** and **Test (T)** bands both appear, the test indicates for the presence of antigens to SARS-CoV-2 in the sample.

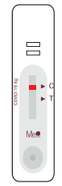
Look very closely! Even a faint line at the bottom indicates a positive result.

Different possibilities of positive result

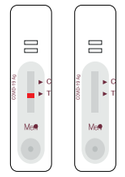


NEGATIVE

WHAT SHOULD I DO IF THE RESULT SHOWS NEGATIVE?
Negative results may require additional testing to confirm your results if you are symptomatic. If symptomatic, continue antigen testing every 24 hours for three (3) days or take a laboratory PCR test. If asymptomatic, it is likely that you were not infectious at the time the test was taken. A negative test result, however, is not a guarantee that you do not have coronavirus, take any appropriate If only the Control (C) band appears, the test indicates that the result is Negative.



INVALID



If no Control (C) band appears, then the assay is invalid regardless of colour development on Test (T) band as indicated below. Repeat the assay with a new device.

DISPOSAL OF TEST KIT

Place the swab, tube and test device into the disposal bag

Seal the disposal bag and dispose the bag in a non-recycle waste bin

Scan the QR code for more information about Covifind.

Safe Interact Pty Ltd
26/155 Cooper Road, Yagoona 2199 NSW Australia
PRODUCT INFORMATION: https://covifind.care
For assistance regarding the use of the product and interpretation of test results call 1800 954 338. This service is available between 9 am and 7 pm (AEST), or 9 am and 8 pm (AEDT), 7 days per week.

TEST PROCEDURE

- Wash and dry your hands before commencing test.
- Remove the components from the box and place on a flat surface.
- Remove the Test device from the Pouch.
- Remove the Aluminium Foil from the pre-filled buffer tube
- Push the buffer tube in to the perforated circle on the front of the box.
- Remove the sterile swab from the tail end. DO NOT touch the swab head.
- Carefully insert the swab into one nostril 2–4 cm or until resistance is met.
- Slowly rotate the swab while rubbing against the sides of the nasal passage at least five (5) times.
- Using the same swab repeat in the other nostril.
- Insert the swab into the buffer tube and swirl it around 8–10 times.
- Pinch the Swab tip through the Tube to remove any remaining fluid.
- Hold the buffer tube firmly and lift the swab till the break point and snap the swab handle.
- Discard the handle for disposal.
- Secure the cap on top of the buffer tube.
- Squeeze four (4) drops from the tube into the sample well of the test device.
- Read the results between 15 and 19 minutes. Beyond 20 minutes and the test is invalid.
- Place the swab, tube and test device into the disposal bag, seal and dispose in a non-recycle waste bin.
- Wash and dry your hands upon completion.

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- Read instructions prior to performing this test. Follow all instructions to achieve valid results.
- Do not use the kit contents beyond the expiry date.
- Do not store the test kit in direct sunlight.
- Do not freeze the kit or expose the kit over 30°C.
- Do not eat or smoke while handling specimens.
- Wash your hands thoroughly before and after the test is completed.
- Clean up spills thoroughly using an appropriate disinfectant.
- Place all of the items in the bag provided and dispose in a non-recyclable rubbish bin.
- Use only the ingredients provided in the kit.
- Keep the test kit out of reach of children.
- Do not touch the swab head as touching will cause the test to be incorrect.
- The provided Swab should be used only for nasal specimen collection.
- Avoid contact of any liquids with eyes and skin.
- If the swab stick breaks during specimen collection, dispose the kit and recommence with a new Test Kit.
- Each single Test Device, Swab, Tube, Cap, Bottle and Bag are single use. Do not reuse individual components.
- Do not use the test kit if the pouch is damaged or the seal is broken.
- The swab specimen should be tested immediately after collection.
- Do not re-use any of the items in the Test kit for any other purpose.

KIT COMPONENTS

- Prefilled buffer tube with cap
- Sterile Nasal Swab
- Test Device
- Disposal Bag
- Instructions for Use This document.

STORAGE AND STABILITY

The kit should be stored between 2° to 30°C.

Do not store in the direct sunlight.

In the event that the desiccant pouch has changed colour from blue to light pink or colourless, the device should not be used.

CAN THE COVIFIND COVID-19 ANTIGEN TEST DETECT VARIOUS VARIANTS OF COVID-19?

Yes, the CoviFind COVID-19 Antigen Self-Test (home use) can detect Alpha, Beta, Gamma, Delta and Omicron COVID-19 mutants based on the studies conducted so far.

Date of Issue

LIMITATIONS

- The CoviFind COVID-19 Antigen Self-Test (home use) is designed for the primary test of SARS-CoV-2.
- The results obtained with this test should be interpreted as a presumptive test only and requires confirmation by a PCR test as required in your geographic location.
- A negative or non-reactive test result does not preclude the possibility of exposure to or infection with SARS-CoV-2 virus at any time.
- Failure to follow the test procedure and interpretation of test results may adversely affect the test performance and/or produce invalid results.
- Positive test results do not exclude co-infections with other pathogens.
- The accuracy of the test depends on the sample collection process. Improper sample collection, improper sample storage may affect the test result.
- If the test is not performed within seven (7) days of symptom onset, false negatives may occur.
- A positive result does not guarantee infection.
- The test is less reliable in the later phase of infection and in asymptomatic individuals.
- Repeat testing within 1–3 days is recommended in occupational risk, high risk settings or if there is an ongoing suspicion of infection.
- Reading the results later than 20 minutes will give incorrect results.
- Negative test results are not intended to rule in other non-SARS viral or bacterial infections.

TEST LIMITATIONS

- The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 antigen from nasal swab.
- Failure to follow these instructions and interpretation of test results may adversely affect test performance and/or produce invalid results.
- A negative test result may occur if the specimen was collected, extracted or transported improperly.
- If symptoms continue, you should repeat the test after 1–2 days, as the coronavirus may not be detectable in the very early phases of infection. You are also advised to continue following local guidelines for self-isolation and consult your doctor.
- Positive test results do not rule out co-infections with other pathogens.
- Reading the test results earlier than 15 minutes or later than 19 minutes may give incorrect results.
- The CoviFind COVID-19 Antigen Self-Test (home use) is not intended to detect from defective (non-infectious) virus during the later stages of viral shedding that might be detected by PCR molecular tests. Therefore, a positive result cannot necessarily determine whether a person is infectious.
- Due to cross-reactivity with high concentrations of SARS-CoV, a false positive result may occur in the case of infection with SARS-CoV.
- Wait four (4) hours before repeating the test following an invalid result.
- The test is less reliable in the later phase of infection and asymptomatic individuals.
- Failure to follow the test procedure and interpretation of test results may adversely affect the test performance and/or produce invalid results.

USABILITY REPORT

A usability study was conducted with a pool of 106 lay persons in the self-testing environment. The sensitivity was found to be >90% and the specificity was confirmed to be 100% in the hand of the lay person, comparing with a professional PCR test. Therefore the Summative Evaluation has proven that the usability of the COVIFIND COVID-19 Antigen Self Test ensures a safe and proper use of the device.

PERFORMANCE EVALUATION OF COVIFIND COVID-19 ANTIGEN SELF TEST:

A. Diagnostic Sensitivity:

Overall Diagnostic Sensitivity of COVIFIND COVID-19 Antigen Self Test:
Total 120 SARS-CoV-2 positive nasal swab specimens were tested with COVIFIND COVID-19 Antigen Self Test and 114 out of 120 specimens were detected as positive. So, diagnostic sensitivity of COVIFIND COVID-19 Antigen Self Test is calculated as 95.00% (95% CI : 89.43 % to 98.14%).

B. Diagnostic Specificity:

Overall Diagnostic Specificity of COVIFIND COVID-19 Antigen Self Test:
Total 405 SARS-CoV-2 negative specimens were tested with COVIFIND COVID-19 Antigen Self Test. All specimens were identified as negative when tested with COVIFIND COVID-19 Antigen Self Test. So, overall Diagnostic specificity of COVIFIND COVID-19 Antigen Self Test is calculated as 100.00% (95% CI: 99.09% to 100%).

C. Analytical Sensitivity (Limit of Detection):

Limit of detection for COVIFIND COVID-19 Antigen Self Test is 933TCID50/ml.

D. Analytical Specificity (Cross Reactivity)

The following Cross reactants and microorganisms had no impact on the performance of COVIFIND COVID-19 Antigen Self Test:

Microbial Organisms	
Adenovirus	Mycoplasma pneumoniae
Human Metapneumovirus (hMPV)	Moraxella Catarhallis
Parainfluenza virus -1	Chlamydia pneumoniae
Parainfluenza virus -4	Legionella pneumophila
Influenza A	Staphylococcus aureus
Influenza B	Staphylococcus epidermidis
Enterovirus	Mycobacterium tuberculosis
Respiratory syncytial virus	Human coronavirus 229E
Rhinovirus	Human coronavirus OC43
Haemophilus influenzae	Human coronavirus NI63
Streptococcus pneumoniae	MERS-coronavirus
Streptococcus pyogenes	Parainfluenza 2
Candida albicans	Parainfluuenza 3
Pooled human nasal wash	
Bordetella pertussis	

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,and Tobryaycin.

SYMBOLS USED ON LABELS:

REF	Catalogue No.	⚠	Caution
	Manufacturer		Consult instruction for use
	Manufacturing date		For single use only do not reuse
2°C 30°C	Storage temperature		Keep away from direct sunlight
IVD	In Vitro diagnostics		Do not use if box open or damaged
LOT	Batch No.	CE	European health and safety product label
	Expiry No.	EC REP	Authorized European Representative in European Community
	Keep dry	CE 0197	This CE mark concerns sterile nasal swab
	Suffcient for		

PRODUCT INFORMATION

- **Website** – covifind.care
- **IFU** – covifind.care/ifu
- **Video** – covifind.care/video

GENERAL INFORMATION

- **Manufacturer**
  Meril Diagnostics Pvt Ltd
  Second floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2,
  Muktanand Marg Chala, Vapi-396191 India
- **Authorised Distributor**
  Safe Interact Pty Ltd
  ACN 653 504 708
  26/155 Cooper Road, Yagoona 2199 NSW Australia
  PH: 1800 954 338 +61
  Email: covifind@safeinteract.com
  Web: https://safeinteract.com

IMPORTANT CONTACTS

- **Australian Capital Territory Department of Health**
  General enquiries: 02 5124 9213
  Coronavirus helpline (8am to 8pm daily): 02 6207 7244
  Website: https://health.act.gov.au/
- **New South Wales Department of Health**
  General enquiries: 1300 066 055
  Coronavirus hotline (Service NSW, 24/7): 137 788
  Website: https://www.health.nsw.gov.au/
- **Northern Territory Department of Health**
  General enquiries: 08 8922 8044
  Coronavirus hotline (National helpline): 1800 020 080
  Website: https://health.nt.gov.au/
- **Queensland Department of Health**
  General enquiries: 13HEALTH or 13 432 584
  Coronavirus hotline: 134COVID or 134 268
  Website: https://www.health.qld.gov.au/
- **South Australian Department of Health**
  General enquiries: 1300 232 272
  Coronavirus hotline (9am to 5pm daily): 1800 253 787
  Website: https://www.sahealth.sa.gov.au/
- **Tasmanian Department of Health**
  General enquiries: 1300 135 513
  Public Health Hotline (coronavirus): 1800 671 738
  Website: https://www.health.tas.gov.au/
- **Victorian Department of Health**
  Department of Health and Human Services
  Phone: 1300 650 172
  Victorian coronavirus hotline (24/7) : 1800 675 398
  Website: https://www.dhhs.vic.gov.au/
- **Western Australian Department of Health**
  General enquiries 08 9222 4222
  Coronavirus hotline: 13COVID (8am to 6pm, Mon–Fri)
  Website: https://www.healthywa.wa.gov.au/

For assistance regarding the use of the product and interpretation of test results call 1800 954 338 +61. This service is available between 9 am and 7 pm (AEST), or 9 am and 8 pm (AEDT), 7 days per week.

In the event you are experiencing problems with the test, please contact Safe Interact.

Additionally, you may wish to report poor performance or usability issues directly to the Therapeutic Goods Administration (TGA) via the Medical Device Incident Reporting scheme, email iris@tga.gov.au or call 1800 809 361.