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English

RAPID SARS-COV-2 ANTIGEN TEST CARD
SELF-TEST Instructions for use

SELF TEST FOR NASAL SWAB SPECIMENS

Catalog Number REF : 8AL10-001S (1 Test/Box), 8AL10-005S (5 Tests/Box), 8AL10-020S (20 Tests/Box)

- **For private use/home use/self-testing.**
- **Please follow the instructions for use carefully.**
- **The repacking of 5 and 20 packs into smaller units is not permitted (separating is prohibited).**

INTENDED USE

Rapid SARS-CoV-2 Antigen Test Card is a one step lateral flow test for the detection of SARS-CoV-2 virus antigen in nasal swabs from individuals suspected of having COVID-19 within the first seven days of symptom onset. The Rapid SARS-CoV-2 Antigen Test Card is intended to be used manually by untrained lay users (self-testing) in a private setting to aid in the diagnosis of SARS-CoV-2 infection. Children under 14 years of age should be assisted by an adult.

SUMMARY

COVID-19 is an acute respiratory infectious disease caused by the SARS-CoV-2 virus. Infected people either with or without symptoms can be a source of infection. The incubation period can be from 1 to 14 days, but usually 3 to 7 days. Common symptoms include fever, fatigue, loss of smell and / or taste, and a dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

LIMITATIONS

- The test is to be used only for the detection of SARS-CoV-2 viral antigen in nasal swab specimens. The amount of SARS-CoV-2 viral antigen cannot be determined using this test.
- Proper specimen collection is critical. Failure to follow the procedure may result in inaccurate test results.
- Improper collection, storage, or even freezing and thawing of the specimen can lead to inaccurate test results.
- Specimens collected more than 7 days after symptom onset may produce a false negative result because the viral load is lower.
- Tests are less reliable in asymptomatic individuals because the viral load is lower.
- As with all diagnostic tests, a diagnosis should not be based on the result of a single test. Contact your State or Territory Coronavirus testing services to get a laboratory PCR test.
- A negative result does not exclude viral infection with SARS-CoV-2 or another type of respiratory virus and should be confirmed by a laboratory RT- PCR if COVID-19 symptoms are present.
- A positive result does not rule out an additional infection with other disease-causing agents.
- The SARS-CoV-2 rapid antigen test can detect both viable and non-viable SARS-CoV-2 material. A positive result cannot say if a person is infectious.
- The performance of the SARS-CoV-2 rapid test is dependent on the amount of virus present and may not correlate with other diagnostic methods performed on the same specimen.
- Users should test specimens as soon as possible after specimen collection and within two hours of specimen collection.
- Sensitivity for nasal or oropharyngeal swabs may be lower than nasopharyngeal swabs. The method of nasopharyngeal swab sampling should only be performed by healthcare professionals.
- Rapid SARS-CoV-2 Antigen Test Card detects all circulating variants of concern as at 1 February 2022
- It could be possible that future virus mutations might be detected with lower sensitivity or not at all.
- The kit was validated with the swabs provided. Use of alternative swabs may result in false negative results.
- Cross-reactivity of the test was evaluated by testing viruses and other microorganisms. The listed viruses and other microorganisms have no effect on the test results, except the Human SARS-coronavirus. Positive test results do not rule out co-infections with other disease-causing agents. Positive results may occur in cases of infection with SARS-CoV.

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FREQUENTLY ASKED QUESTIONS (FAQ)

1. How does the detection work?

The N protein of the SARS-CoV-2 virus reacts with reagents at the test line and, if present, results in a colour change, i.e. a red line appears. Therefore, if the sample does not contain any viral proteins or antigens, there will be no red test line (T).

2. When should I test myself?

You can test yourself whether you have symptoms or not. Studies show that earlier testing within the first 7 days of illness is most reliable due to more virus present which is easier to detect. Since the test result is a snapshot valid for that point in time, testing should be repeated as recommended by local authorities.

3. What can affect my test result? What should I pay attention to?

Be sure to blow your nose several times before collecting the specimen.
Be sure to collect visible sample material (nasal secretions).
Perform the test immediately after taking the sample. Follow the instructions for use carefully.
Apply the drops of extraction solution only to the sample well (S).
Too many or too few drops of extraction solution can lead to an invalid or incorrect test result.
Apply only 3 drops.

4. The test card is clearly discoloured or smudged? What is the reason for this?

Please note that the test card should not be used with more than 3 drops of sample, as the liquid absorption of the test card is naturally limited.
If the control line does not appear or the test card is badly smudged or discoloured, making it unreadable, please repeat the test with a new test card according to the instructions.

5. I have taken the test, but I don't see a control line (C). What should I do?

Your test result is invalid. Observe the answer to question 4 and repeat the test with a new test card according to the instructions for use.

6. I am unsure about reading the result. What should I do?

For the result to be positive, 2 straight horizontal lines must be clearly visible with the full width of the cassette. If you are still unsure about the results, photograph the result within 15-20 minutes and contact your State or Territory Coronavirus testing services to get a laboratory PCR test.

7. My result is positive. What should I do?

For further information on how a positive RAT will be recorded and guidance on confirmation testing if necessary, contact your State or Territory health authority. Anyone who tests positive and feels unwell should seek medical assistance.

8. My result is negative. What should I do?

If the test kit only clearly shows the control line, this may mean that you are negative or that the viral load is too low to be detected. If you experience symptoms (headache, fever, migraine, loss of sense of smell or taste, etc.), please contact your State or Territory Coronavirus testing services to get a laboratory PCR test. The test can be repeated (e.g. within 1-3 days) if there is an ongoing suspicion of infection, being in a high risk setting or where there is an occupational risk or other requirement. Even with a negative result, continue to adhere to social distancing rules, contact restrictions, and hygiene measures.

LAYMEN STUDY

Physician run studies were conducted to evaluate:

- the capability of a non-professional to perform the self-test without additional assistance
- the capability of a non-professional to interpret the results of the self-test 99% (99 out of 100) of participants were capable of independent home testing. 91% (91 out of 100) of participants were capable of interpreting all the different possibilities of results.

ACCURACY

The accuracy of the rapid SARS-CoV-2 antigen test card was determined using 833 nasal swabs, performed by self-testing, correctly identified 100% (503 out of 503) of SARS-CoV-2 negative nasal samples with a confidence interval of 99.90% to 100.00% (known as test specificity). Among 330 positive patients confirmed with RT-PCR, which included 42 patients who presented without clinical symptoms (such as fever, cough, sore throat) prior to and during sample collection, 324 were self-test positive which showed a detection rate of 98.18% with a confidence interval of 96.74% to 99.62% (known as test sensitivity).

LIMIT OF DETECTION

The limit of detection of this test is 130 $TCID_{50}$/mL of virus.

CROSS-REACTIVITY

The following 27 microorganisms had no impact on the performance of the Rapid SARS-CoV-2 Antigen Test Card: Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Enterovirus EV71, Respiratory syncytial virus, Rhinovirus, Influenza A virus (H1N1), Influenza A virus (H3N2), Influenza B virus (Yamagata), Influenza B virus (Victoria), Adeno virus, MERS-coronavirus, Chlamydia pneumoniae, Streptococcus pneumoniae, Streptococcus pyogenes, Bordetella pertussis, Mycobacterium tuberculosis, Legionella pneumophila, Mycoplasma pneumoniae, Haemophilus influenzae, Candida albicans, Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli.

INTERFERENCE

None of the following substances at the tested concentration showed any interference with the test: Whole Blood 1%, Phenylephrin 15%, Menthol 0.15%, Fluticasone Propionate 5%, Oseltamivir Phosphate 0.5%, Biotin 1200 ng/mL, Alkalol 10%, Tobramycin 0.0004%, Cromolyn 15%, Mupirocin 0.25%, sodium chloride 5%,Mucin 2% , Oxymetazoline 15%, Benzocaine 0.15% , Zicam Nasal Spray 5%, Human Anti-mouse Antibody (HAMA) 60 ng/mL.

EXPLANATION OF SYMBOLS

SYMBOL	DEFINITION
IVD	In vitro diagnostic medical device
Σ	Contains sufficient for <x> tests
	Do not re-use
STERILE EO	Sterilized using ethylene oxide
	Avoid direct sunlight
EC REP	Authorized Representative
LOT	Lot number
	Caution

SYMBOL	DEFINITION
	Consult instructions for use
	Keep dry
	Do not use if package is damaged
REF	Catalogue Number
	Manufacturer
	Use-by date
30°C 2°C	Store within 2 – 30°C
CE	European Conformity

Private Label Manufacturer:

MP Biomedicals Asia Pacific Pte Ltd
2 Pioneer Place, Singapore 627885
Tel: +65 6775 0008
Email: enquiry_ap@mpbio.com

Original Equipment Manufacturer:

Xiamen Boson Biotech Co., Ltd
90-94 Tianfeng Road, Jimei
North Industrial Park, Xiamen,
Fujian, 361021, P.R. China.

Swabs:

Goodwood Medical Care Ltd.
1-2 Floor, 3-919 Yongzheng Street, Jinzhou District,
Dalian, 116100 Liaoning, China

EC REP
CE 0197 CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo No18, CP 29006, Màlaga, Spain

Jiangsu Hanheng Medical Technology Co., Ltd.
16- B4, #1 North Qingyang Road, Tianning District,
213017, Changzhou, Jiangsu, China

EC REP
CE 0197 Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany

Distribution in Australia by:
MP Biomedicals Australasia Pty Ltd, Unit 2/29 Bearing Road, Seven Hills NSW 2147
Tel.: +61 2 8824 2100 Email: custserv.au@mpbio.com

Online Support: Call +61 1800 490 603 from 9am to 8pm, 7 days or scan this QR code for live chat

In the event you are experiencing problems with the test, please contact MP Biomedicals Australasia Pty Ltd.

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.

To contact your local state/territory health department click on the following link:
https://www.health.gov.au/about-us/contact-us/local-state-and-territory-health-departments

Local state and territory health departments

Contact details and websites of the local state and territory health departments.

Australian Capital Territory Department	Coronavirus helpline (8am to 8pm daily) 02 6207 7244 https://www.health.gov.au/contacts/australian-capital-territory-department-of-health	ACT Health
New South Wales Department of Health	Coronavirus hotline (Service NSW, 24/7) 137 788 https://www.health.gov.au/contacts/new-south-wales-department-of-health	NSW Health
Northern Territory Department of Health	Coronavirus hotline (National helpline) 1800 020 080 https://www.health.gov.au/contacts/northern-territory-department-of-health	Department of Health Northern Territory
Queensland Department of Health	Coronavirus hotline: 134COVID 134 268 https://www.health.gov.au/contacts/queensland-department-of-health	Queensland Health
South Australian Department of Health	Coronavirus hotline (9am to 5pm daily) 1800 253 787 https://www.health.gov.au/contacts/south-australian-department-of-health	SA Health
Tasmanian Department of Health	Public Health Hotline (coronavirus) 1800 671 738 https://www.health.gov.au/contacts/tasmanian-department-of-health	Department of Health Tasmania
Victorian Department of Health	Victorian coronavirus hotline (24/7) 1800 675 398 https://www.health.gov.au/contacts/victorian-department-of-health	Department of Health and Human Services Victoria
Western Australian Department of Health	Coronavirus hotline: 13COVID (8am to 6pm, Mon–Fri) 1800 595 206 https://www.health.gov.au/contacts/western-australian-department-of-health	WA Health

REVISION DATE: 2022-07
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RAPID SARS-COV-2 ANTIGEN TEST CARD

Quick Reference Guide for Patients

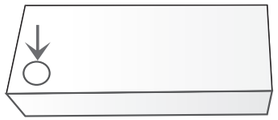
SELF TEST FOR NASAL SWAB SPECIMENS

This guide is a reference for using the Rapid SARS-CoV-2 Antigen Test Card. It is essential that you read the Instructions for Use for patients before using this test.

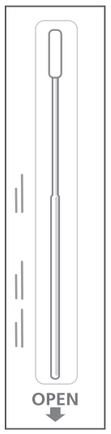
Refer to this QR code for video instruction

MATERIALS PROVIDED

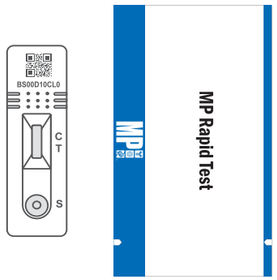
Components	For 1 Test/Box	For 5 Tests/Box	For 20 Tests/Box
Rapid SARS-CoV-2 Antigen Test Card (sealed foil pouch)	1	5	20
Sterile swab	1	5	20
Extraction buffer tube	1	5	20
Instructions for use (this leaflet)	1	1	4
Tube stand	Back of box	1	1



Tube stand



Sterile Swab in Sealed Wrapper



Test Card (sealed foil pouch)

Extraction buffer tube

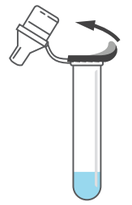
PREPARATION

- Wash your hands.
- Clear clean and dry a flat surface.
- Check the kit contents.
- Make sure that nothing is damaged or broken.
- Have a timer ready.
- Blow your nose several times before taking the sample.
- Wash your hands again.

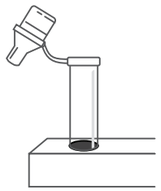
IMPORTANT INFORMATION BEFORE THE EXECUTION

- Read this instruction guide carefully.
- Do not use the product beyond the expiration date.
- The test can only be used once.
- Do not use the product if the pouch is damaged or the seal is broken.
- Store the test device at 2 to 30°C in the original sealed pouch. Do Not Freeze.
- The product should be used at room temperature (15°C to 30°C). If the product has been stored in a cool area (less than 15°C), leave it at normal room temperature for 30 minutes before using.
- Handle all specimens as potentially infectious.
- Follow the specimen collection steps carefully. Inadequate or incorrect specimen collection, storage, and transport may yield inaccurate test results.
- Use the swabs included in the test kit to ensure optimal performance of the test.
- Correct specimen collection is the most important step in the procedure. Make sure to collect enough specimen material (nasal secretion) with the swab.
- The specimens should be tested as soon as possible after collection.
- Children under 14 years of age should be assisted by an adult.

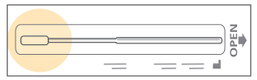
PROCEDURE



1 Remove the seal from the extraction buffer tube.
CAUTION: Open it away from your face and be careful not to spill any of the liquid.

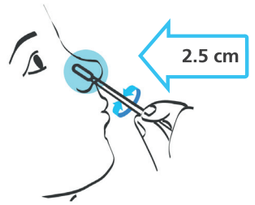


2 Place the extraction buffer tube in the tube stand to avoid spilling the liquid.



3 Find the swab in the sealed wrapper. Identify the soft, fabric tip on the swab.

4 Peel open the wrapper of the swab and carefully pull out the swab.
CAUTION: Do not touch the soft, fabric tip of the swab with your hands.

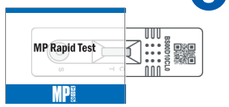


5 Carefully insert the swab into one nostril. The swab tip should be inserted at least 2.5 cm from the edge of the nostril. Roll the swab 3-4 times along the mucosa inside the nostril to ensure that both mucus and cells are collected. Leave swab in the nostril for several seconds. Using the same swab, repeat this process for the other nostril.
CAUTION: This may feel uncomfortable. Do not insert the swab any deeper if you feel strong resistance or pain.

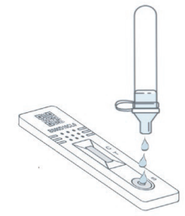
6 Place the swab with the sample into the extraction buffer tube. Rotate the swab 3-5 times. **Leave the swab in the extraction solution for 1 minute.**

7 Pinch the extraction buffer tube together with fingers while removing the swab to leave as much solution in the tube as possible. Place the swab back into the swab wrapper.

8 Install the nozzle cap onto the extraction buffer tube tightly.
Replace the tube in the tube holder.



9 Open the foil pouch and remove the test card. Place the test card on a flat and level surface. CAUTION: Once opened, the test card must be used immediately.



10 Invert the extraction buffer tube and add 3 drops only of test specimen into the specimen well (S), by gently squeezing the extracion buffer tube.
CAUTION:
Do not add drops to the larger well.
Do not add more than 3 drops
Do not agitate the tube. Avoid the formation of air bubbles.

11 Read the results at 15-20 minutes.
CAUTION: Results after 20 minutes may not be accurate.

DISPOSAL INSTRUCTIONS

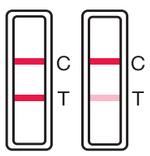
Place all the used test components into a tear-resistant waste bag and dispose of them in the trash according to local waste regulations.

Online Support: Call +61 1800 490 603 from 9am to 8pm, 7 days

INTERPRETATION OF RESULTS

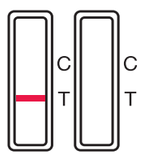
NEGATIVE

If one coloured band appears in the Control Zone (C) and no colored band appears in the Test Zone (T) within 15-20 minutes, the test result is negative and valid. **A negative result does not exclude a viral infection with SARS-CoV-2 and should be confirmed by laboratory RT-PCR if COVID-19 is suspected.**



POSITIVE

If two coloured bands appear, with one coloured band in the Control Zone (C) and another in the Test Zone (T) within 15-20 minutes, the test result is positive and valid. **The result should be considered as positive no matter how faint the coloured band is in the Test Zone (T).**
Contact your State or Territory health authority for guidance on confirmation testing



INVALID

If no coloured band appears in the control area (C) within 15-20 minutes, the test is invalid even if there is a coloured band in the Test Zone (T). Repeat the test with a new test card.

QUALITY CONTROL

The control line is used to control the procedure. The control line appears when the test has been performed correctly and the reagents are reactive.