English

Rapid SARS-CoV-2 and Flu A+B Antigen Test Card (Nasal Swab)

SELF-TEST Instructions For Use

REF 8AL90-001S, 8AL90-005S, 8AL90-020S

REVISION DATE: 2023-05
MSAC30044-ENG-0

INTENDED USE

Rapid SARS-CoV-2 and Flu A+B Antigen Test Card (Nasal Swab) is a single-use test kit intended for qualitative detection of SARS-CoV-2 and Influenza A + B antigens present in nasal swab specimen from symptomatic individuals suspected of infected with COVID-19 within the first 7 days of symptom onset and/or Influenza A+B within the first 4 days of symptom onset. The Rapid SARS-CoV-2 and Flu A+B Antigen Test Card (Nasal Swab) is intended to be used manually by untrained layusers (self-testing) in a private setting to aid in the diagnosis of SARS-CoV-2 and/or Influenza A/B infection. Children under 16 years old should be assisted by an adult.

SUMMARY

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. 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 diarrhea are found in a few cases.

Influenza (commonly known as 'flu') is a highly contagious, acute viral infection of the respiratory tract. It is a communicable disease easily transmitted through the coughing and sneezing of aerosolized droplets containing live virus. Influenza outbreaks occur each year during the fall and winter months. Type A viruses are typically more prevalent than type B viruses and are associated with most serious influenza epidemics, while type B infections are usually milder.

PRINCIPLES

The Rapid SARS-CoV-2 and Flu A+B Antigen Test Card (Nasal Swab) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 Nucleocapsid protein and Influenza A/B HA protein in human nasal swab specimen. SARS-CoV-2 and Influenza A/B specific antibodies are coated on test lines region. During testing, the specimen reacts with SARS-CoV-2 and Influenza A/B antibodies-coated particles on the test device. The mixture then migrates upward on the membrane by capillary action and reacts with the SARS-CoV-2 and Influenza A/B antibodies on test lines region. If the specimen contains SARS-CoV-2 Nucleocapsid protein or Influenza A/B HA protein, a colored band will appear in the respective test line region. If the specimen does not contain the antigen to SARS-CoV-2 or Influenza A/B, no colored line will appear in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that a proper volume of specimen has been added and membrane wicking has occurred.

LIMITATION

1. Device performance was evaluated with nasal swab specimen only. To obtain an optimal result, adhere strictly to the procedures provided in this instructions for use.
2. The Rapid SARS-CoV-2 and Flu A+B Antigen Test Card (Nasal Swab) will only indicate the presence of SARS-CoV-2 and/or Influenza A/Influenza B antigens in the specimen.
3. A negative result does not mean a person is not infectious or does not have SARS-CoV-2/influenza, particularly in those who have been in contact with the virus. If symptoms persist the person should seek medical attention and further testing is required.
4. A negative result does not rule out infection with another type of respiratory virus.
5. Positive results of COVID-19 - may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors. A positive result for influenza A and/or B does not preclude an underlying co-infection with another pathogen, therefore the possibility of an underlying bacterial infection should be considered.
6. Failure to follow these procedures may alter test performance.
7. False negative results may occur if a specimen is improperly collected, handled or when inadequate amount of viruses are present in the specimen.
8. Specimens collected more than 7 days after symptom onset may produce a false negative result because the viral load is lower.
9. Tests result is less reliable in later phase of infection or asymptomatic individuals because the viral load is lower.

CLINICAL PERFORMANCE

The clinical precision of the Rapid SARS-CoV-2 and Flu A+B Antigen Test Card (Nasal Swab) was established with 1453 nasal swab specimens collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19 or Influenza. The following table summarizes the clinical precision of the Rapid SARS-CoV-2 and Flu A+B Antigen Test Card (Nasal Swab) as compared to RT-PCR (Ct value is within the range of 14.28 to 37).

SARS-CoV-2 Test:

Rapid SARS-CoV-2 and Flu A+B Antigen Test Card (Nasal Swab)		RT-PCR		Total
		Positive	Negative	
SARS-CoV-2 Antigen	Positive	393	3	396
	Negative	13	486	499
Total		406	489	895
Relative Sensitivity		96.80% (95%CI: 94.59%~98.28%)		
Relative Specificity		99.39% (95%CI: 98.22%~99.87%)		
Accuracy		98.21% (95%CI: 97.11%~99.15%)		

Detection Rate of Positive Samples with Different Ct Values:

Ct Value	RT-PCR Positive	SARS-CoV-2 Antigen Test Positive	PPA
≤27	271	271	100%
27 - 30	51	50	98.0%
>30	84	72	85.7%

Influenza A Test :

Rapid SARS-CoV-2 and Flu A+B Antigen Test Card (Nasal Swab)		RT-PCR		Total
		Positive	Negative	
Influenza A Antigen	Positive	68	2	70
	Negative	3	485	488
Total		71	487	558
Relative Sensitivity		95.77% (95%CI: 88.14%~99.12%)		
Relative Specificity		99.59% (95%CI: 98.52%~99.95%)		
Accuracy		99.10% (95%CI: 97.92%~99.71%)		

Detection Rate of Positive Samples with Different Ct Values:

Ct Value	RT-PCR Positive	Influenza A Antigen Test Positive	PPA
≤27	14	12	85.7%
27 - 30	31	30	96.8%
>30	26	26	100%

Influenza B Test :

Rapid SARS-CoV-2 and Flu A+B Antigen Test Card (Nasal Swab)		RT-PCR		Total
		Positive	Negative	
Influenza B Antigen	Positive	48	3	51
	Negative	3	504	507
Total		51	507	558
Relative Sensitivity		94.12% (95%CI: 83.76%~98.77%)		
Relative Specificity		99.41% (95%CI: 98.28%~99.88%)		
Accuracy		98.92% (95%CI: 97.67%~99.60%)		

Detection Rate of Positive Samples with Different Ct Values:

Ct Value	RT-PCR Positive	Influenza B Antigen Test Positive	PPA
≤27	12	10	83.3%
27 - 30	14	13	92.9%
>30	25	25	100%

LAYMEN STUDY

Studies were conducted to evaluate:

- the capability of a non-professional to perform the self-test without additional assistance. 100% (150 /150) of participants were capable of independent home testing. For SARS-CoV-2, the tests correctly identified 96% (48 / 50) of positive samples and 100% (100/100) of negative samples. For Influenza A, the tests correctly identified 100% (7/7) of positive samples and 100% (143/143) of negative samples. For Influenza B, the tests correctly identified 100% (13/13) of positive samples and 100% (137/137) of negative samples.
- the capability of a non-professional to interpret the results of the self-test. 99.7% (335 out of 336) of participants were capable of interpreting all the different possibilities of results.

Limit of Detection

The limit of detection of the test device is in the following table:

Virus Strains	Detection Level
BetaCoV/Wuhan/IPBCAMS-WH-01/2019	78 $TCID_{50}$/mL
A/Beijing/262/95(H1N1)	10 $TCID_{50}$/mL
A/Shangdong/9/93(H3N2)	50 $TCID_{50}$/mL
A/Victoria/2454/2019	5 μg/mL
A/Darwin/9/2021(H3N2)	5 μg/mL
B/Shangdong/7/97(Victoria)	50 $TCID_{50}$/mL
B/Jiangsu/10/03(Yamagata)	100 $TCID_{50}$/mL
B/Darwin/7/2019	2 μg/mL
B/Austria/1359417/2021	2 μg/mL

Variants

The SARS-CoV-2 variant Alpha (UK B.1.1.7), Delta (Indian B.1.617.2), Gamma (B.1.1.28), VUI-21ARP-03 (Indian B.1.617.3), Beta (South Africa B.1.351) and Omicron (B.1.1.529, BA.2, BA.4, BA.5) could be detected by the Rapid SARS-CoV-2 and Flu A+B Antigen Test Card (Nasal Swab) at specific concentrations.

Cross-reactivity

The following viral strains (at tested concentration) had no impact on the performance of SARS-CoV-2 test line: Adenovirus type 3, Adenovirus type 7, Human coronavirus OC43, Human coronavirus 229E, Human coronavirus NL63, Human coronavirus HKU1, MERS COV Florida, Influenza A H1N1, Influenza A H3N2, Influenza B, Human Rhinovirus 2, Human Rhinovirus 14, Human Rhinovirus 16, Measles, Mumps, Parainfluenza virus 2, Parainfluenza virus 3, Respiratory syncytial virus, Human metapneumovirus, Parainfluenza virus 1, Parainfluenza virus 4, Enterovirus type 71, Chlamydophila pneumoniae. There is cross reactivity between SARS-CoV-1 and SARS-CoV-2 at concentration of 1ng/mL and above in detection of SARS-CoV-1 recombinant nucleocapsid protein.

The following viral strains (at tested concentration) had no impact on the performance of Influenza A+B test lines: Adenovirus type 3, Adenovirus type 7, Human coronavirus OC43, Human coronavirus 229E, Human coronavirus NL63, Human coronavirus HKU1, MERS COV Florida, Human Rhinovirus 2, Human Rhinovirus 14, Human Rhinovirus 16, Measles, Mumps, Parainfluenza virus 2, Parainfluenza virus 3, Respiratory syncytial virus, SARS-CoV-1, Human Metapneumovirus, Parainfluenza virus 1, Parainfluenza virus 4, Enterovirus type 71, Chlamydophila pneumoniae.

The following organisms produced negative results when tested with the Rapid SARS-CoV-2 and Flu A+B Antigen Test Card (Nasal Swab): Arcanobacterium, Candida albicans, Corynebacterium, Escherichia coli, Moraxella catarrhalis, Neisseria lactamica, Neisseria subflava, Pseudomonas aeruginosa, Staphylococcus aureus subspaureus, Staphylococcus epidermidis, Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus salivarius, Streptococcus sp group F, Haemophilus influenzae, Legionella pneumophila, Mycobacterium tuberculosis, Bordetella pertussis, Mycoplasma pneumoniae, Pneumocystis carinii, Nasal cavity wash pooled human donors.

INTERFERENCE

Test result is not interfered by following substances at certain concentrations: Whole Blood, Mucin, Budesonide Nasal Spray, Dexamethasone, Flunisolide, Mupirocin, Oxymetazoline, Phenylephrine, Rebetol, Relenza, Tamiflu, Tobramycin, HAMA, Biotin.

FREQUENTLY ASKED QUESTIONS (FAQ)

1. How does the Rapid SARS-CoV-2 and Flu A+B Antigen Test Card (Nasal Swab) work?

The viral proteins of SARS-CoV-2 and/or influenza A/B react with reagents at the test lines and, if present, results in a colour change i.e a red line appears. Therefore if the sample does not contain any viral antigens, there will be no red test lines.

2. When should the test be used?

SARS-CoV-2 and/or Influenza A/Influenza B antigen can be detected in acute respiratory tract infection, it is recommended to run the test when you are suspected of having COVID-19 and/or Influenza A/Influenza B.

3. How to interpret the test result if color and intensity of the lines are different?

The test lines should be homogeneous and clearly visible. The test should be considered as positive no matter how faint the coloured band is in the Test Zone (T, A, B).

4. What do I have to do if the result is negative?

A negative result indicates you are negative or the viral load is too low to be detected. However, it is possible to get a false negative result in minority of COVID-19 and/or Influenza A/Influenza B infected patients. This means you could possibly be infected with COVID-19 and/or Influenza A/Influenza B despite you have a negative test reult.

If you experience symptoms (headache, fever, migraine, loss of sense of smell or taste, etc.), If symptoms persist, advice to conduct repeat testing and consult a medical practitioner for follow-up clinical care.

The test can be repeated (e.g. within 1-2 days) if 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.

5. What do I have to do if the result is positive?

A positive result indicates the presence of SARS-CoV-2 /Influenza A/Influenza B antigens in collected specimens. 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.

DESCRIPTION OF SYMBOLS USED

IVD	In vitro diagnostic medical device		Manufacturer
REF	Catalogue number	LOT	Batch code
	Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Consult instructions for use or consult electronic instructions for use
	Temperature limit	Σ	Contains sufficient for <n> tests
	Keep dry		

MEDICAL DEVICE INCIDENT REPORT

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

LOCAL STATE AND TERRITORY HEALTH DEPARTMENTS CONTACT

Australian Capital Territory Coronavirus hotline (02)62077244 (8:00am-8:00pm daily)	http://health.act.gov.au/
New South Wales Department of health 137788	http://health.nsw.gov.au/
Northern Territory Department of health (National helpline):1800020080	http://health.nt.gov.au/
Queensland Department of Health 13COVID or 134268	http://health.qld.gov.au/
South Australian Department of Health 1800253787 (9am to 5pm daily)	http://www.sahealth.sa.gov.au/
Tasmanian Department of Health 1800671738 (coronavirus)	http://health.tas.gov.au/
Victorian Department of Health 1800675398 (24/7)	http://www.dhhs.vic.gov.au/
Western Australian Department of Health 13COVID (8:00am to 6:00pm, Mon-Fri) or 1800595206	http://healthywa.wa.gov.au/

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

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

Australia sponsor (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

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

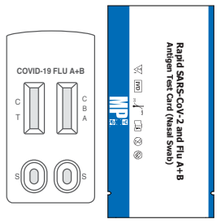
Scan this QR code for video instruction, product information and electronic Instructions for use

Rapid SARS-CoV-2 and Flu A+B Antigen Test Card (Nasal Swab)

MATERIALS PROVIDED

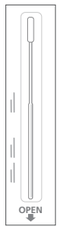
Components	1 Test/box	5 Tests/box	20 Tests/box
Test cassette	1	5	20
Sterile swab	1	5	20
Extraction buffer	1	5	20
Instructions for use	1	1	4
Tube holder	Back of box	Back of box	1
Biosafety bag (Optional)	1	5	20

Test Cassette

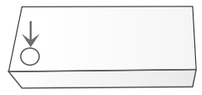


Extraction Buffer

Sterile Swab

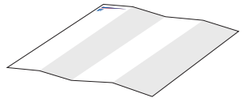


Tube Holder



Biosafety Bag (Optional)

Instructions For Use (This Leaflet)



MATERIAL REQUIRED BUT NOT PROVIDED

Timer

PRECAUTIONS

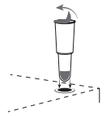
Read this instructions for use before using the test.

- For self-testing in vitro diagnostic use only. Do not use beyond the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- **Do not drink the buffer in the kit.** Carefully handle the buffer and avoid its contact with skin or eyes, rinse with plenty of running water immediately if contacting.
- Store in a dry place at 2-30 °C (36-86 °F), avoiding areas of excess moisture. Do not use the product if the pouch is damaged or the seal is broken. DO NOT FREEZE.
- The test cassette must remain in the sealed pouch until use.
- This test kit is intended to be used as a preliminary test only. Any repeatedly abnormal results should be discussed with your doctor or medical professional.
- Follow the recommended time strictly.
- The test can only be used once. Do not dismantle and touch the test window of the test cassette.
- Children under 16 years of age should be assisted by an adult.
- Test for children under 2 years of age must not be performed.
- Wash hands thoroughly before and after handling.
- Please ensure that an adequate amount of samples are used for testing. Too much or too little sample volume may lead to deviation of results.

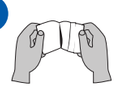
PROCEDURE

1 

Wash your hands with soap and water for at least 20 seconds before and after test. If soap and water are not available, use hand sanitizer with at least 60% alcohol.

2 

Remove the cover of extraction buffer tube and place the tube in the tube holder on the box.

3 

Remove the sterile swab from the pouch.

NOTE: Do not touch the soft tip of the swab.

4 

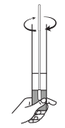
Insert the soft tip of the swab into your nostril until you feel slight resistance (Approx. 2cm up your nose). Slowly twist the swab, rubbing it along the inside of your nostril for 5-10 times against the nasal wall. Gently remove swab from nasal cavity.

NOTE:

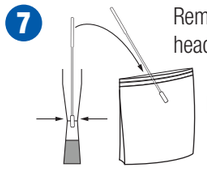
- This may feel uncomfortable. Do not insert the swab any deeper if you feel strong resistance or pain.
- When the nasal mucosa is damaged or bleeding occurs, nasal swab collection is not recommended.
- If you are swabbing others, please wear a face mask. For children, you may not need to insert the swab too far into the nostril. For very young children, you may need another person to hold the child's head while swabbing.

5 

Using the same swab, repeat step 4 with the other nostril. Withdraw the swab from nasal cavity.

6 

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.

7 

Remove the swab while squeezing the swab head against the inside of the extraction tube.

Place the swab in a plastic bag.

8 

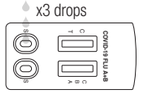
Fit the tube tip onto the tube.

9 Remove the test cassette from the sealed foil pouch and use it within one hour.

NOTE:

To obtain an optimal result, perform the test immediately after opening the foil pouch. Place the cassette on a flat and leveled surface.

10 Invert the specimen extraction tube and add 3 drops of extracted specimen to each sample well (S) of the test cassette and start the timer.



NOTE:

Do not move the test cassette when the test is running.

11 

Read the result at 10 minutes. Do not read the result after 20 minutes.

DISPOSAL INSTRUCTIONS

Place all the used test components into plastic bag and tightly sealed, then dispose according to local regulation

INTERPRETATION OF RESULTS

POSITIVE

SARS-CoV-2:

Two colored lines appear in the COVID-19 (left) window. One colored line should be in the control region (C) and another colored line should be in the Test region (T).

Influenza A:

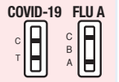
Two colored lines appear in the FLU A+B (right) window. One colored line should be in the control region (C) and another colored line should be in the Influenza A region (A).

Influenza B:

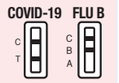
Two colored lines appear in the FLU A+B (right) window. One colored line should be in the control region (C) and another colored line should be in the Influenza B region (B).

POSITIVE Influenza A and Influenza B:* Three colored lines appear in the right window.
One colored line should be in the control region (C) and two colored line should be in the Influenza A region (A) and Influenza B region (B).

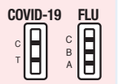
POSITIVE SARS-CoV-2 and Influenza A:* Two colored lines appear in the left window; and two colored lines appear in the right window.
Left window: One colored line should be in the control region (C) and another colored line should be in the Test region (T).
Right window: One colored line should be in the control region (C) and another colored line should be in the Influenza A region (A).



POSITIVE SARS-CoV-2 and Influenza B :* Two colored lines appear in the left window; and two colored lines appear in the right window.
Left window: One colored line should be in the control region (C) and another colored line should be in the Test region (T).
Right window: One colored line should be in the control region (C) and another colored line should be in the Influenza B region (B).



POSITIVE SARS-CoV-2 and Influenza A+B:* Two colored lines appear in the left window; Three colored lines appear in the right window.
Left window: One colored line should be in the control region (C) and another colored line should be in the Test region (T).
Right window: One colored line should be in the control region (C) and two colored line should be in the Influenza A region (A) and Influenza B region (B).

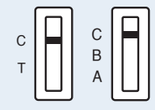


***NOTE:** The intensity of the color in the test line region (T/B/A) will vary based on the amount of SARS-CoV-2 and/or Influenza A+B antigen present in the sample. So any shade of color in the test region (T/B/A) should be considered positive.
A positive results means it is very likely you have COVID-19 and/or Influenza A/Influenza B, but the positive samples should be confirmed to reflect this.

POSITIVE SARS-CoV-2: Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
POSITIVE Influenza A and/or Influenza B: Individuals with a positive result or who are unwell are must consult a medical practitioner for follow-up clinical care.

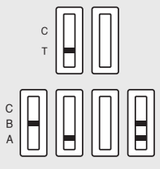
NEGATIVE

One colored line appears in the control region (C). No colored line appears in the test line region (T/B/A). A negative result does not exclude SARS-CoV-2 or Influenza A/B viral infection. If symptoms persist, advice to conduct repeat testing and consult a medical practitioner for follow-up clinical care.



INVALID

Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test card or contact the sponsor.



QUALITY CONTROL

The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are functioning well.

Customer Support Helpline: Call +61 1800 490 603 from 9a.m. to 8p.m., 7 days