COVID-19/Influenza A+B Antigen Combo Rapid Test Cassette

HEO TECHNOLOGY

English

REF	
010027 010028	1 5

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For additional language instructions please visit www.covidflu.com.au

An Antigen Rapid Test for the detection of SARS-Cov-2 and Influenza A/B in nasal swab. For Self-Testing use.

In-vitro diagnostic test for self-testing

[Intended use]

The COVID-19/ Influenza A+B Antigen Combo Rapid Test Cassette is a lateral flow immunoassay for the qualitative detection of nucleocapsid antigens in nasal swab specimens collected from patients against the respiratory infection for SARS-CoV-2 (within the first 7 days of the onset of symptoms) and influenza A/B (within the first 4 days of the onset of symptoms). This test is intended for use as an aid in the differential diagnosis of SARS-CoV-2 and influenza A/ B viral infections in humans in conjunction with clinical and epidemiological risk factors.

The test does not require any special training for sample collection, processing, or test operation. This kit is intended for layperson's home use in a non-laboratory environment. Test results of this kit are for clinical reference only. It is recommended that a comprehensive analysis of the disease be conducted based on clinical manifestations of patients and other laboratory tests.

[Principle of test]

The COVID-19/ Influenza A+B Antigen Combo Rapid Test Cassette is a lateral flow immunoassay and contains two independent tests, the SARS-CoV-2 antigen test, and the Influenza A/B antigen test. In the test procedure, a specimen is collected by nasal swab and placed onto sample well of test cassette as 3 drops for Influenza A/B test zone and 3 drops for SARS-CoV-2 test zone. Then allow the solution in the sample well to migrate through the pads containing highly sensitive detector antibodies conjugated to gold dye for detection of nucleocapsid antigens.

[Warnings and precautions]

1. For *in vitro* diagnostic use only; Only use the test once and only with the provided parts.
2. Do not use this test as the only guide to manage your illness. Please contact your State or Territory Coronavirus testing services to get a laboratory test if your symptoms are persisting or worsening, or if you are concerned at any time.
3. Test can only be performed by person over 15 years age. Any persons or children under 15 years will require adult supervision or assistance. Not to be performed on children under 2 years of age.
4. Keep out of reach of children to reduce the risk of accidentally drinking the extraction reagent or swallowing small parts.
5. Do not use this product after the expiration date.
6. Avoid contact with Extraction Reagent. If the extraction reagent is accidentally exposed to a person's skin or eye, rinse with plenty of running water immediately. If irritation persists, seek medical assistance.
7. This test involves taking a sample from deep inside your nose. When doing the test, pay particular attention to the instructions on how to swab your nose. Incorrect swabbing may lead to an inaccurate test result.
8. The test cassette should remain in the sealed pouch until use.
9. To reduce the risk of infection spreading, discard the used test in the Biosafe Bag provided and dispose according to local regulations.
10. False negative results may occur if testing is not performed within the first 7 days of symptom onset.
11. The tests are less reliable in the later phase of infection and in asymptomatic individuals.

[What is included in the test kit]

Components	010027	010028
1. Test Cassette	1Test cassette (1Test/pouch x1 pouch)	5Test cassette (1Test/pouch x 5 pouches)
2. Extraction Reagent Tube	1 single-use bottle,each with 400 μL extraction buffer	5 single-use bottle,each with 400 μL extraction buffer
3. Swab	1 sterile, single use pecimen sampling swab	5 sterile, single use pecimen sampling swab
4. Waste Bag	1x	5x
5. Instructions for Use	1x	1x

[Storage and stability]

1. Stored at 4℃-30℃, the validity period is 24 months (see the label for the specific batch number and expiration date). Not to use the kit beyond the expiry date.
2. After the pouch is unsealed, the device should be used as soon as possible within 1 hour.

[Limitations]

1. The test should be used for the qualitative detection of SARS-CoV-2 antigens and Influenza A/B antigen in nasal swab specimens only. The intensity of the T-line does not necessarily correlate to SARS-CoV-2 and Influenza A/B viral titer in the specimen.
2. Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result.
3. The test is a presumptive test only. If you get a positive result, follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

4. Negative results may occur if the level of antigen in the specimen is below the detection limit of the test. Repeat testing after 1-3 days is recommended, if there is an ongoing suspicion of infection, being in a high risk setting or where there is an occupational risk or have a known exposure to COVID-19 and Influenza A/B.
5. Negative results do not rule out SARS-CoV-2 and Influenza A/B infection.
6. A Negative result does not rule out infection with another type of respiratory virus.
7. A positive result cannot necessarily determine whether a person is infectious. Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
8. Positive results do not rule out co-infections with other pathogens.
9. The kit is a presumptive test. Positive results may occur, Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary and if unwell seek medical assistance.
10. It will be recommended to repeat testing (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.
11. It is for use as an aid for diagnosis only and individuals with a positive result or who are unwell, you need to consult a medical practitioner for follow-up clinical care.
12. If there is an ongoing suspicion of infection, being in a high risk setting or where there is an occupational risk or other requirement, repeat testing (e.g. within 1-3 days) is recommended
13. Negative results may not mean that a person is not infectious and if symptoms are present the person must seek immediate further testing by PCR.

[Frequently asked questions (FAQ)]

How does the HEO COVID-19/Influenza A+B Antigen Combo Rapid Test Cassette work?

The HEO COVID-19/Influenza A+B Antigen Combo Rapid Test Cassette is a type of test called an antigen test. When you have COVID-19/Influenza A/Influenza B, the SARS-CoV-2 virus (the virus that causes COVID-19)/Influenza A virus/Influenza B virus can be present in your nasal secretions. The HEO COVID-19/Influenza A+B Antigen Combo Rapid Test Cassette can detect small parts of SARS-CoV-2 virus/Influenza A virus/Influenza B virus in your nasal secretions. These small parts of the SARS -CoV-2 virus/Influenza A virus/Influenza B virus are known as proteins or antigens.

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 doctor.

What are the potential benefits and risks of this test?

Potential risks include:

- Possible discomfort during sample collection.
- Possible incorrect test results (see Limitations section).

Potential benefits include:

- The results, along with other information, can help your doctor make informed recommendations about your treatment/ care.
- The results of this test may help limit the spread of COVID-19/Influenza A/Influenza B to your family and others in your community.

[Performance characteristics]

Clinical Performance

A clinical evaluation was conducted comparing the results obtained using the COVID-19/Influenza A+B Antigen Combo Rapid Test Cassette with RT-PCR test result. The clinical trial included 841 nasal swab specimens. The COVID-19 Antigen Rapid Test showed a sensitivity of 96.17% (95% confidence interval: 94.04% - 98.29%, N=313) and a specificity of 100% (95% confidence interval: 99.43%-100%, N=528) compared to RT-PCR;The clinical trial included 833 nasal swab specimens,The Influenza A Antigen Rapid Test showed a sensitivity of 99.06% (95% confidence interval: 94.90% - 99.97%, N=107) and a specificity of 100% (95% confidence interval: 99.9%-100%, N=726) compared to RT-PCR;The Influenza B Antigen Rapid Test showed a sensitivity of 97.34% (95% confidence interval: 92.43% - 99.44%, N=113) and a specificity of 100% (95% confidence interval: 99.9%-100%, N=720) compared to RT-PCR.

Usability Study

472 people self-sampled and self-tested using the HEO 2019-nCoV/Influenza A+B Antigen anterior nasal Self Test. 472 people were also tested with a PCR.The COVID-19 Antigen Rapid Test showed 100% (149 out of 149 people) of positive samples and 100% (323 out of 323 people) of negative samples; The Influenza A Antigen Rapid Test showed 100% (60 out of 60 people) of positive samples and 100% (412 out of 412 people) of negative samples; The Influenza B Antigen Rapid Test showed 100% (72 out of 72 people) of positive samples and 100% (400 out of 400 people) of negative samples

Limit of Detection (Analytical Sensitivity)

The COVID-19 Antigen Rapid Test can detect SARS-CoV-2 virus as low as 100 $TCID_{50}$/mL.

The Influenza A Antigen Rapid Test can detect N1H1/N3H2 virus as low as 1.0×10^3 $TCID_{50}$/mL.

The Influenza B Antigen Rapid Test can detect Victoria virus as low as 1.0×10^3 $TCID_{50}$/mL.

The Influenza B Antigen Rapid Test can detect Yamagata virus as low as 3.7×10^4 $TCID_{50}$/mL.

Variants

The performance of COVID-19 Antigen Rapid Test is not affected by Alpha, Beta, Gamma, Delta ,Omicron variants.

The performance of Influenza A Antigen Rapid Test is not affected by A/Guangdong-Maonan/SWL1536/2019, A/Victoria/2570/2019, A/Wisconsin/588/2019, A/Cambodia/e0826360/2020,A/Hong Kong/2671/2019, A/Darwin/9/2021, A/Darwin/6/2021, A/SouthAustralia/34/2019,A/Singapore/INFMH-16-0019/2016, A/ Anhui/1/2013 variants.

The performance of Influenza B Antigen Rapid Test is not affected by B/Phuket/3073/2013, B/Colorado/06/2017, B/Brisbane/60/2008, B/Washington/02/2019 ,B/Austria/1359417/2021 variants.

Cross Reactivity (Analytical Specificity)

No cross-reactivity was observed with the following viruses when tested at the concentration of 1.0×10^5 PFU/mL: Adenovirus (type 1, 2, 3, 5, 7, 55), Human metapneumovirus, Parainfluenza virus (type 1, 2, 3, 4), Respiratory syncytial virus, Enterovirus, Rhinovirus, Human coronavirus 229E,SARS-coronavirus,MERS-coronavirus, Human coronavirus OC43, Human coronavirus NL63, Human coronavirus HKU1,Pneumocystis jirovecii (PJP) .

No cross-reactivity was observed with the following bacteria when tested at the concentration of 1.0×10^6 CFU/mL: Mycoplasma pneumoniae, Chlamydia pneumoniae, Legionella pneumophila, Haemophilus influenzae, Streptococcus pyogenes (group A), Streptococcus pneumoniae, Candida albicans, Staphylococcus aureus,Staphylococcus epidermidis.

Interference

The following potential interference substances were evaluated with the COVID-19/Influenza A+B Antigen Combo Rapid Test Cassette at the concentrations listed below and were found not to affect test performance.

Substance (Concentration), Whole Blood (4%), Mucin (2mg/ml),Zanamivir (5mg/ml), Ribavirin (5mg/ml), Arbidol (5mg/ml), Oseltamivir phosphate (10mg/ml), Saline nasal spray (15%), Oxymetazoline (15%), Phenylephrine (15mg/ml), Fluticasone propionate (5mg/ml), Dexamethasone (5mg/ml), Tobramycin (5μg/ml), Mupirocin (10mg/ml), Triamcinolone (10mg/ml), Histamine dihydrochloride (10mg/ml), Benzocaine (5mg/ml), Menthol (10mg/ml), Zanamivir (5mg/ml),

[Assistance and Contact information]

In the event you are experiencing problems with the test, please contact our authorized representative in Australia as above.

Additionally, you may wish to report poor performance or usability issues to the Therapeutic Goods Administration (TGA) via the Users Medical Device Incident Report, 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

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

Australian Capital Territory Department of Health	Business hours: 02 5124 9213 Coronavirus helpline (8am to 8pm daily): 02 6207 7244 https://health.act.gov.au
New South Wales Department of Health	General enquiries: 1300 066 055 Coronavirus hotline (Service NSW, 24/7): 137 788 https://www.health.nsw.gov.au
Northern Territory Department of Health	General enquiries: 08 8922 8044 Coronavirus hotline (National helpline): 1800 020 080 https://health.nt.gov.au
Queensland Department of Health	13HEALTH: 13 432 584 Coronavirus hotline: 134COVID, 134 268 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 https://www.sahealth.sa.gov.au/
Tasmanian Department of Health	General enquiries: 1300 135 513 Public Health Hotline (coronavirus): 1800 671 738 https://www.health.tas.gov.au
Victorian Department of Health	Department of Health and Human Services: 1300 650 172 Victorian coronavirus hotline (24/7): 1800 675 398 https://www.dhhs.vic.gov.au
Western Australian Department of Health	General enquiries: 08 9222 4222 Coronavirus hotline: 13COVID (8am to 6pm, Mon– Fri), 1800 595 206 https://www.healthywa.wa.gov.au

Index of Symbol

Do not reuse	For *in vitro* diagnostic use only	Lot number	Use by
Store between 4-30 ℃	Consult instructions for use	Keep away from sunlight	Caution
Catalogue number	Contains sufficient for <n> tests	Keep dry	Manufacturer
Do not use if package is damaged			

Hangzhou HEO Technology Co.,Ltd.
Address: Room 201, Building 3, No. 2073 Jinchang Road, Liangzhu Street, Yuhang District, Hangzhou, Zhejiang, 310000, China

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AusPharma Medical Devices
203 Darling St, Balmain, NSW, 2041, Australia
Web: www.covidflu.com.au
Email: supports@covidflu.com.au
Tech support: +61 2 8206 9037
hours: 9 am- 7 pm (AEST) , 7 days per week

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Effective Date: March 6,2023

[Preparing to do the test]

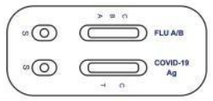
1. Keep a clock, timer or stopwatch at hand.
2. **Ensure that all test components are kept at room temperature (15-30 ℃).**
3. Ensure that the packaging is intact; Do not use the test if there is visible damage of the foil packaging.
4. Open the box and you will get the components shown below:

Instructions for Use

Swab

Extraction Reagent Tube

Waste bag



Test Cassette

Note: *Only open the foil packaging of the test cassette when you are ready to carry out the test. Use the test cassette within one hour after opening.*

[Before starting]

Wash your hands in soapy water and dry thoroughly.

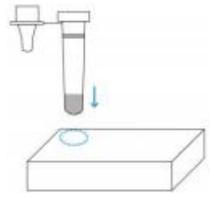
[Step-By-Step Instructions]

1. Open Extraction Reagent Tube

Carefully tear off the sealed foil film on the extraction reagent tube.

2. Insert Tube into Box

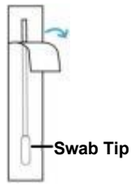
Gently press the tube through the perforated hole in the box.



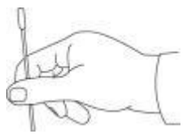
3. Remove the Swab

a. Open the swab package at the stick end.

Note: *Keep fingers away from swab tip.*



b. Take out the swab.



4. Swab the Left Nostril

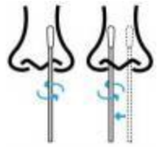
a. Gently insert the entire tip of the swab, app. **2.5 cm** into the left nostril.

b. Firmly brush the swab against the inside of the nostril in a circular motion **5 times** or more.

*(Approximately **1.5 times** the length of the swab tip)*

5. Swab the Right Nostril

a. Remove the swab from the left nostril and insert it into right nostril about **2.5 cm**.



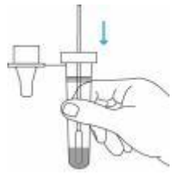
b. Firmly brush the swab against the inside of the nostril in a circular motion **5 times** or more.

CHECK!
You should swab both nostrils.

Note: *A false negative result may occur if sample collection is not thoroughly undertaken.*

6. Insert the Swab into the Tube

Insert the nasal swab into the tube which contains the extraction reagent.



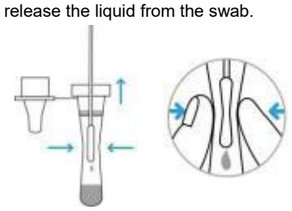
7. Rotate the Swab 5 Times

a. Rotate the swab at least **5 times** while pressing the swab tip against the bottom and the sides of the tube.

b. Let the tip of the swab soak in the tube for **1 minute**.

8. Remove the Swab

a. Remove the swab while squeezing the sides of the tube against the swab, to release the liquid from the swab.



b. Cover the tube with the provided cap tightly and insert the tube back into the box.

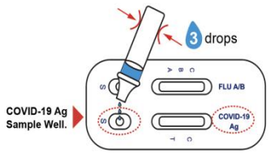
9. Take out the Test Cassette from the pouch

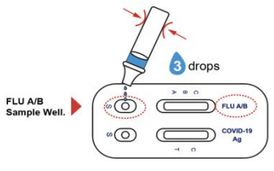
Open the sealed pouch and take out the test cassette.

***Note**: Test cassette must lay **FLAT** on the table during the entire testing.*

10. Add Sample to the Sample Well

3 drops must be added to each of the two sample wells.





Note 1: *A false negative result may occur if less than 3 drops of sample is used.*

Note 2: *The result will not be affected if 1-2 more drops of sample are accidently added – as long as you can read a C-line (see Read result below).*

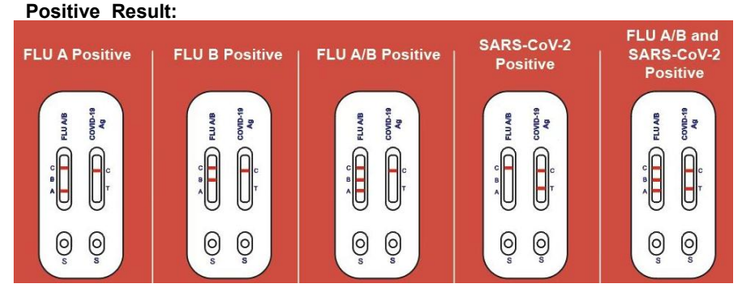
11. Wait 15 Minutes

Read the test result at **15-20** minutes, **DO NOT** read the result after 20 minutes.

Note: *False results can occur if the test results are read before 15 minutes or after 20 minutes.*

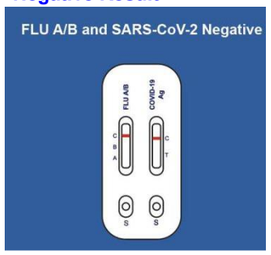
[Read result]

Positive Result:



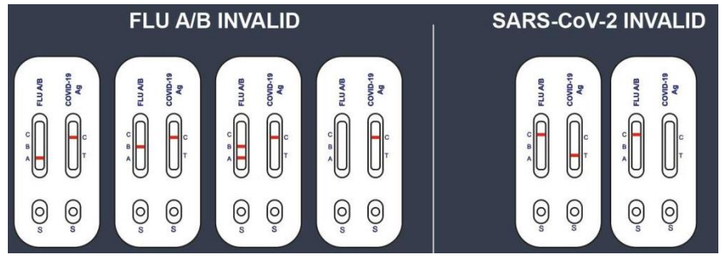
THE SHADE OF LINES MAY VARY, BUT EVEN IF A FAINT/WEAK LINE APPEARS, IT SHOULD BE CONSIDERED POSITIVE.
If you have a POSITIVE result, follow the guidance from your local State or Territory Health Department for guidance if necessary. If you are unwell seek medical assistance for SARS-CoV-2 and individuals with a positive result or who are unwell must consult a medical practitioner for follow-up clinical care for Influenza.

Negative Result



ONLY RED LINES APPEAR IN THE CONTROL REGIONS (C), AND NO LINE IN THE REGION (A), (B), AND (T).
The negative result indicates that there are no Flu A/B and SARS-CoV-2 particles in the sample or the number of viral particles is below the detectable range. Even if you get a negative result, you still need to follow all public health advice on limiting the spread Covid-19 and Flu A/B.If symptoms persist, repeat testing and consult a medical practitioner for follow-up clinical care.

Invalid Result



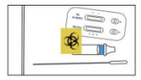
NO RED LINE APPEARS IN THE CONTROL REGION (C) FOR FLU A/B.The test is invalid even if there is a line on the region (A), (B) or (A) and (B).

NO RED LINE APPEARS IN THE CONTROL REGION (C) FOR SARS-COV-2.The test is invalid even if there is a line on the region (T).

WHEN NO RED LINE APPEARS IN THE CONTROL REGION (C) FOR BOTH TESTS, THE TEST IS INVALID FOR BOTH FLU A/B AND SARS-COV-2.

Insufficient sample volume or incorrect procedural techniques are the most likely reasons for the control line (C) failure.Review the test procedure and repeat the test using a new test device. If invalid result continues after repeating, please contact AusPharma Medical Devices on the provided contact number or email for assistance.

[Dispose of the used test kit]



Collect all parts of the test kit and place in the waste bag that can be placed in the general waste.

Wash your hands thoroughly after handling.

Scan the QR code to watch how to use the device and access other resources .
For additional language instructions please visit www.covidflu.com.au
For further support call： 02 8206 9037,
Hours: 9 am-7 pm (AEST), 7 days per week