Fanttest

REF : ICF - 535

English

COVID-19 / Influenza A&B Antigen Test Kit

INTENDED USE

The COVID-19/Influenza A&B Antigen Test Kit is a lateral flow immunoassay for the qualitative detection of SARS-COV-2, influenza A and influenza B viral nucleoprotein antigens in nasal swabs from subjects. The symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. The test is intended as an aid in diagnosis of symptomatic individual meeting the case definition for COVID-19 within the first 7 days of symptom onset and meeting the case definition for Influenza A&B within the first 4 days of symptoms onset.

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

The rapid COVID-19 antigen test is a lateral flow immunoassay based on the principle of the double antibody sandwich technique. A monoclonal SARS-CoV-2 nucleocapsid protein antibody conjugated with colored microparticles and sprayed onto the conjugation pad is used as a detector. During the test, the SARS-CoV-2 antigen in the sample interacts with the SARS-CoV-2 antibody conjugated with colored microparticles, creating an antigen-antibody labeled complex. This complex migrates on the membrane by capillary action up to the Test line where it is captured by the pre-coated monoclonal SARS-CoV-2 nucleocapsid protein antibodies. A colored test line (T) would be visible in the result window if SARS-CoV-2 antigens are present in the sample. The absence of the T line indicates a negative result. The control line (C) is for procedural control and should appear whenever the test procedure is being performed properly. The influenza A&B rapid test is a lateral flow immunoassay based on the principle of the double antibody sandwich technique. The monoclonal antibodies against influenza A and Influenza B are used as detectors and sprayed onto the conjugation pad. During the test, antigen and labeled-antibody complexes are formed which migrate to the membrane via capillary action. If the sample contains influenza A antigen, the complex will be captured by the precoated monoclonal influenza A antibody, resulting in a visible colored line forming at the A region in the result window, If the sample contains influenza B antigen, the complex is captured by the precoated influenza B monoclonal antibody to form a visible colored line at the B region in the result window. The control line (C) is for procedural control and should appear whenever the test procedure is being performed properly.

PRECAUTIONS

1.For in vitro diagnostic use only.

2.Do not use after the expiration date.

3.Perform the test at room temperature 15 to 30°C.

4.The test cassette should remain in the sealed pouch until use.

5.Please read all information in this leaflet before performing the test.

6.Components from difference lots must not be mixed or used together.

7.Positive result cannot necessarily determine whether a person is infectious.

STORAGE AND STABILITY

Pack in sealed bag and lay at temperature (2-30°C). Do not freeze.

After opening the pouch, the test should be used within one hour. Prolonged contact with hot and humid environment will cause the product to deteriorate.

The Test Kit is stable within the expiration date printed on the label.

LIMITATION

1. False negative results may occur if the level of antigen in the sample is below the detection limit of the test. Testing for COVID-19 should be within the first 7 days of symptoms onset and testing for Influenza A&B should be within the first 4 days of symptoms onset when viral shedding is highest.

2. The tests are less reliable in the later phase of infection and in asymptomatic individuals.

3. 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 risk.

4. Negative results may not mean that a person is not infectious and if symptoms persist please seek medical assistance.

5.Self-testing is for presumptive screening only and follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

6. A negative result does not rule out infection with another type of respiratory virus.

7. 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.

8. Individuals who have tested positive should follow guidance of local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.Individuals with a positive result or who are unwell are advised to consult a medical practitioner for follow-up clinical care for Influenza.

9. False positive results may occur from improper sample collection, not following this instruction guide.

10. The performance of COVID-19/Influenza A&B Antigen Test Kit 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.

SAFETY INFORMATION

Dispose of the kit components in the bio-safety bag and into your household waste.

Wearing a mask can help protect you and those around you if you are in an area with community transmission and physical distancing is not possible.

Follow the directions of your local state or territory government health department to protect yourself.

Test kit solutions should only be used as directed; do not ingest; do not dip the swab into provided solution or other liquid before inserting the swab into the nose; avoid contact with skin and eyes; keep out of the reach of children and pets before and after use. If the extraction buffer comes in contact with the skin or eyes, flush with plenty of water. If irritation persists, seek medical advice from a doctor or your local medical centre.

PERFORMANCE CHARACTERISTICS

For COVID-19

1. Limit of detection

The limit of detection of the test is $1.0x10^2 TCID_{50}$/mL

2. Clinical sensitivity/Clinical specificity

Using COVID-19/Influenza A&B Antigen Test Kit by professional was compared to the RT-PCR kit. A sensitivity of 92.5% (148/160 known confirmed Positives) and a specificity of 98.33% (295/300 known confirmed Negatives) were determined for the COVID-19 (SARS-CoV-2) Antigen Test Kit.

3. Usability study

210 people self-sampled and self-tested using the COVID-19/Influenza A&B Antigen Test Kit. 110 people were also tested with a PCR. The tests correctly identified 92.3% (36/39) of positive samples and 97.18% (69/71) of negative samples.

For Influenza A&B

1. Limit of detection

Flu A H1N1/Wisconsin/588/2019 is $2.08 \times 10^3 TCID_{50}$/mL.

Flu A H3N2/SouthAustralia/34/2019 is $7.76 \times 10^2 TCID_{50}$/mL.

Flu B Austria/1359417/2021(Victoria lineage) is $2.84 \times 10^3 TCID_{50}$/mL.

Flu B Phuket/3073/2013 (Yamagata lineage) is $1.08x\ 10^4 TCID_{50}$/mL.

Flu A H1N1/Bejing/262/95 is $3.105 \times 10^2 TCID_{50}$/mL.

Flu A H3N2/Shangdong/9/93 is $2.26 \times 10^2 TCID_{50}$/mL.

Flu B Victoria lineage/Shandong/7/97 is $1.825 \times 10^3 TCID_{50}$/mL.

Flu B Yamagata lineage/Jiangsu/10/03 is $2.44 \times 10^3 TCID_{50}$/mL.

2. Clinical sensitivity/Clinical specificity

For influenza A test

Using COVID-19/Influenza A&B Antigen Test Kit by professional was compared to the RT-PCR kit. A sensitivity of 89.12%(131/147 known confirmed Positives)and a Specificity of 98.33%(472/480 known confirmed Negatives)were determined for the COVID-19/Influenza A&B Antigen Test Kit.

For influenza B test

Using COVID-19/Influenza A&B Antigen Test Kit by professional was compared to the RT-PCR kit. A sensitivity of 89.86%(124/138 known confirmed Positives)and a Specificity of 98.18%(540/550 known confirmed Negatives)were determined for the COVID-19/Influenza A&B Antigen Test Kit.

3. Usability study

210 people self-sampled and self-tested using the COVID-19/Influenza A&B Antigen Test Kit. 110 people were also tested with a PCR.

For influenza A test

The tests correctly identified 87.5% (35/40) of positive samples and 97.14% (68/70) of Negative samples.

For influenza B test

The tests correctly identified 90% (36/40) of positive samples and 95.71% (67/70) of Negative samples.

FREQUENTLY ASKED QUESTIONS

1.Will other diseases affect the result ?

No cross reactivity has been observed on testing by following commonly found Respiratory syncytial virus Type A, Respiratory syncytial virus Type B, Seasonal influenza A H1N1 virus, Influenza A H3N2 virus, Influenza A H5N1 virus, Influenza B Yamagata, Influenza B Victoria, Rhinovirus A2, Rhinovirus B52, Adenovirus 1, Adenovirus 2, Adenovirus 3, Adenovirus 4, Adenovirus 5, Adenovirus 7, Adenovirus 55, Human coronavirus 229E, Human coronavirus Oc43, Staphylococcus aureus, Human coronavirus NL63, Human coronavirus HKU1, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Haemophilus influenzae, Streptococcus pneumoniae, Mycoplasma pneumoniae, Chlamydia pneumoniae, MERS, Human Metapneumovirus A2, Coxsackie virus CA16e, Coxsackie virus B5, Coxsackie virus A24, Enterovirus EV70, Candida albicans. However, a false result due to presence of these organisms at a level higher than tested cannot be ruled out.

2.Does these substances interfere with the test ?

Results showed that the COVID-19/Influenza A&B Antigen Test Kit was not interfered with by the following substances: Mucin, Human blood (EDTA anticoagulated), Alpha interferon, Zanamivir, Ribavirin, Oseltamivir phosphate, Peramivir, Lopinavir, Ritonavir, Arbidol, Levofloxacin, Azithromycin, Ceftriaxone, Meropenem, Tobramycin, Histamine hydrochloride, Phenylephrine Hydrochloride, Oxymetazoline hydrochloride spray, physiological seawater nasal spray, Beclomethasone dipropionate nasal aerosol, Hexadecadrol, Flunisolide, Triamcinolone acetonide nasal spray, Budesonide nasal spray, Mometasone furoate nasal spray, Fluticasone propionate nasal spray.

3.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.

4.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.

5.Can the test detect various variants of COVID-19 ?

Yes, the following SARS-CoV-2 variants can be detected with the COVID-19 (SARS-CoV-2) Antigen Test Kit : Alpha, Beta, Gamma, Delta and Omicron.

6.Which strains of influenza the test covers ?

A/Vietnam/HN31242/2007, A/Shanghai/2/2013, A/RR/8/34, A/California/04/2009, A/Bean Goose/Hubei/chenhu XVI35-1/2016, A/Guizhou/54/89, B/Sichuan-Gaoxin/531/2018, B/Hong Kong/3417/2014, A/Darwin/9/2021, A/Darwin/6/2021, A/HongKong/2671/2019, A/HongKong/45/2019, A/SouthAustralia/34/2019, A/Switzerland/8060/2017, A/Singapore/INFMH-16-0019/2016, A/Victoria/2570/2019, A/Wisconsin/588/2019, A/Brisbane/02/2018, A/Michigan/45/2015, B/Phuket/3073/2013, B/Austria/1359417/2021, B/Washington/02/2019, B/Colorado/06/2017, B/Brisbane/60/2008.

SYMBOLS

	Do not re-use		Use-by date
IVD	In vitro diagnostic medical device		Keep away from sunlight
2°C–30°C	Store between 2-30°C		Keep dry
	Consult instructions for use		Do not use if package is damaged and consult instructions for use
LOT	Batch code		Manufacturer
Σ	Contains sufficient for <n> tests	REF	Catalogue number

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Customer Support help line: **02 8328 1008**
Customer Service hours: **9 AM ~ 8 PM, 7 Days**

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Website: www.sonictec.com.au

Code:1054010300
Version No.: xxx
Effective Date:xxx

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Note: Use test only one time. Testing by adult only or under adult supervision.

MEDICAL DEVICE INCIDENT REPORT

You can contact the Therapeutic Goods Administration (TGA) to report poor performance or usability issues via the online Users Medical Device Incident Report, emailing iris@tga.gov.au or calling 1800 809 361(08:30am to 5:00pm Monday to Friday).

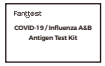
LOCAL STATE AND TERRITORY HEALTH DEPARTMENTS CONTACT

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	☎ (9am to 5pm daily)1800253787 🌐 http://www.sahealth.sa.gov.au/
Tasmanian Department of Health	☎ (coronavirus) 1800671738 🌐 http://health.tas.gov.au/
Victorian Department of Health	☎ (24/7) 1800675398 🌐 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/


Test Cassette


Disposable Swab


Extraction Buffer Tube



Instruction for Use


Biohazard Specimen Bag

Components	1 Test/Kit	5 Tests/Kit	25 Tests/Kit
1. Test Cassette	1 x	5 x	25 x
2. Extraction Buffer Tube	1 x	5 x	25 x
3. Disposable Swab	1 x	5 x	25 x
4. Biohazard Specimen Bag	1 x	5 x	25 x
5. Instruction for Use	1 x	1 x	25 x

Materials required but not provided : Timer

For the sterilized swab

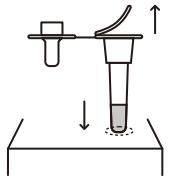
CE 0197 MDR 2017/745 EU Hangzhou Yiguoren Biotechnology Co., Ltd.
CE 0197 MDD 93/42/EEC Jiangsu HanHeng Medical Technology Co., Ltd.
CE 0197 MDD 93/42/EEC Jiangsu Changfeng Medical Industry Co.,Ltd.

Scan the QR code or visit our website for instructional video, product information and IFU: https://sonictec.com.au/shop

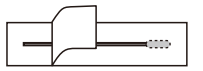
1


Wash your hands.

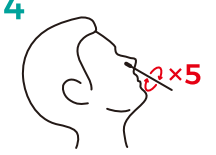
2


Tear the aluminum foil on the extraction buffer tube. Place extraction tube into box tube stand.

3

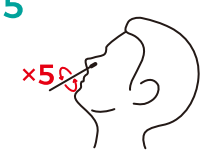

Open the swab package and take out the swab.
Note : Do not touch the swab tip with finger

4



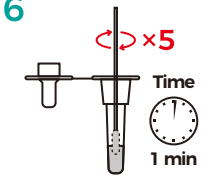
Tilt your head back slightly. Insert the swab about 1.5 to 2.5 cm into one nostril. Gently rotate the swab at least five times against the nasal wall.

5



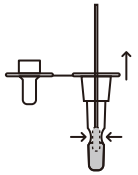
Insert the same swab about 1.5 to 2.5 cm into the second nostril. Again, gently rotate the swab at least five times against the nasal wall.

6

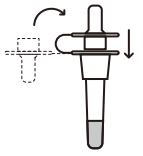


Insert the swab into the extraction buffer tube. Allow the swab to stand in the extraction buffer tube for 1 minute.

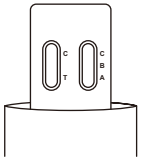
7


Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

8

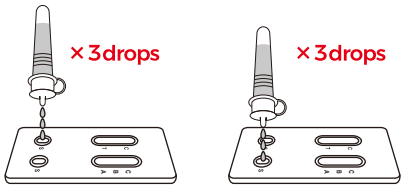

Press the nozzle cap tightly onto the tube.

9



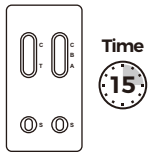
Open the foil pouch and take out the test device.

10



3 drops must be added to both the specimen wells.

11



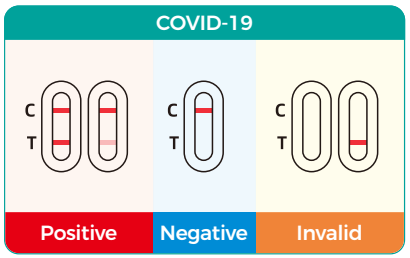
Read the result at 15 minutes. Do not interpret the result after 20 minutes.

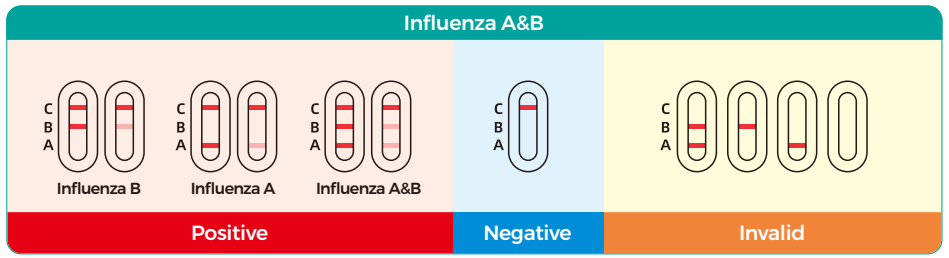
12


Please dispose of the test materials in a closed plastic bag with the household refuse. If there are local regulations, please follow them.

13


Wash your hands thoroughly after test completion.





Positive (COVID-19) 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) Individuals with a positive result or who are unwell are advised to consult a medical practitioner for follow-up clinical care.
Negative Advise to monitor for symptoms and if symptoms persist or if unwell please consult a medical practitioner for follow-up clinical care.
Invalid Retest with a new device.

Customer Support help line: 02 8328 1008 Customer Service hours: 9 AM ~ 8 PM, 7 Days.