

ARTG ID: XXXXX 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. 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 self-testing by laypersons in the home or other non-laboratory environment.

# PRINCIPLE

The COVID-19/Influenza A&B Antigen Test Kit is qualitative detection of SARS-CoV-2, Influenza A and B antigens based on principal of immunochromatography. During testing, antigen in the specimen reacts with anti-SARS-CoV-2 antibody-coated particles and with anti-Influenza A antibody-coated particles as well as with anti-Influenza B antibody-coated particles in the conjugation pad to produce the immune complex. The complex migrates along the membrane by capillary action to the test region. The complex then respectively reacts with antibodies. If the specimen does contain antigen of SARS-CoV-2, Influenza A/B, colored line will appear in the test region. Indicating a positive result.

# **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
- To avoid inaccurate results, use only the components in this test kit. Do not substitute test kit components from a different batch.
- 7. Positive result cannot necessarily determine whether a person is infectious.

# STORAGE AND STABILITY

Store the test kit in the original packaging at  $2^{\circ}\text{C}$  -  $30^{\circ}\text{C}$ . Do not freeze. Test kit contents remain stable until the expiration date printed on the outer packaging.

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.

### LIMITATION

- In particular, false negative results may occur if the testing is not performed within the first 7 days
  of the onset of COVID-19 or within the first 4 days of influenza A&B symptoms or if the antigen
  level in the sample is below the detection limit.
- 2. The tests are less reliable in the later phase of infection and in asymptomatic individuals.
- 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. A negative result does not rule out infection with another type of respiratory virus. And a positive result cannot necessarily determine whether a person is infectious.
- 5. The test can only be used once.
- 6. 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.

# SAFETY INFORMATION

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.

# **CLINICAL PERFORMANCE**

# For COVID-19

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.

#### For influenza A tes

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.

## **Usability Study**

110 lay users in different age distribution, different education level and different gender participated in usability study conducted in the self-testing environment. Compared to RT-PCR, the clinical performance of COVID-19/Influenza A+B Antigen Test kit in hands of lay persons showed a sensitivity of 92.3% (95% confidence interval: 79.68%-97.35%, N=39) and a specificity of 97.18% (95% confidence interval: 90.30%-99.22%, N=71) for COVID-19 antigen, a sensitivity of 87.5% (95% confidence interval: 73.68%-94.54%, N=40) and a specificity of 97.14% (95% confidence interval: 90.17%-99.21%, N=70) for influenza A antigen and a sensitivity of 90.0% (95% confidence interval: 76.95%-96.04%, N=40) and a specificity of 95.71% (95% confidence interval: 88.14%-98.53%, N=70) for influenza B antigen.

#### LIMIT OF DETECTION (ANALYTICAL SENSITIVITY) LoD Titer (TCIDsa/mL) SARS-CoV-2 wild type 1.0×10 Flu A H1N1/Wisconsin/588/2019 2 08×103 Flu A H3N2/SouthAustralia/34/2019 7 76×10<sup>2</sup> Flu B Austria/1359417/2021(Victoria lineage) 2.84×10<sup>3</sup> 1.08×10<sup>4</sup> Flu B Phuket/3073/2013 (Yamagata lineage) Flu A H1N1/Bejing/262/95 3.105×10<sup>2</sup> 2.26×10<sup>2</sup> Flu A H3N2/Shangdong/9/93 Flu B Victoria lineage/Shandong/7/97 1 825×103 Flu B Yamagata lineage/Jiangsu/10/03 2.44×103

# FREQUENTLY ASKED QUESTIONS

#### 1. Will other diseases affect the result?

The potential cross-reactivity of the following pathogens was evaluated with SARS-CoV-2, Influenza A and B negative and positive samples using the COVID-19/Influenza A&B Antigen Test Kit. No cross-reactivity results was observed.

Virus or organisms			
Human coronavirus NL63	Influenza A H5N1 virus	Coxsackie virus CA16e	
Human coronavirus HKU1	Influenza B Yamagata	Coxsackie virus B5	
Human coronavirus Oc43	Influenza B Victoria	Coxsackie virus A24	
Human coronavirus 229E	Haemophilus influenzae	Candida albicans	
MERS-CoV	Adenovirus 1	Human Metapneumovirus A2	
Respiratory syncytial virus Type A	Adenovirus 2	Legionella pneumophila	
Respiratory syncytial virus Type B	Adenovirus 3	Mycobacterium tuberculosis	
Parainfluenza virus 1	Adenovirus 4	Mycoplasma pneumoniae	
Parainfluenza virus 2	Adenovirus 5	Pneumocystis jiroveci	
Parainfluenza virus 3	Adenovirus 7	Streptococcus pneumoniae	
Parainfluenza virus 4	Adenovirus 55	Staphylococcusaureus	
Seasonal influenza A H1N1 virus	Enterovirus EV70	Rhinovirus A2	
Influenza A H3N2 virus	Bordetella pertussis	Rhinovirus B52	
SARS-CoV-1	Chlamydia pneumoniae	Streptococcus pyogenes	

#### 2. Does these substances interfere with the test?

The following substances were spiked into samples and tested with the COVID-19/Influenza A&E Antigen Test Kit. No interference results was observed.

Substances			
Mucin	Phenylephrine Hydrochloride	Histamine hydrochloride	
Human blood (EDTA anticoagulated)	Arbidol	Alpha interferon	
Bedomethasone dipropionate nasal aerosol	Zanamivir	Azithromycin	
physiological seawater nasal spray	Ribavirin	Oseltamivir phosphate	
Triamcinolone acetonide nasal spray	Peramivir	Meropenem	
Mometasone furoate nasal spray	Lopinavir	Tobramycin	
Fluticasone propionate nasal spray	Ritonavir	Hexadecadrol	
Budesonide nasal spray	Levofloxacin	Flunisolide	
Oxymetazoline hydrochloride spray	Ceftriaxone		

#### 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 ?

Influenza A			
A/Vietnam/HN31242/2007	A/Victoria/2570/2019	A/Brisbane/02/2018	
A/Shanghai/2/2013	A/Switzerland/8060/2017	A/Michigan/45/2015	
A/RR/8/34	A/Hong Kong/45/2019	A/Hong Kong/2671/2019	
A/California/04/2009	A/Wisconsin/588/2019		
A/Darwin/9/2021	A/Darwin/6/2021		
A/SouthAustralia/34/2019	A/Bean Goose/Hubei/chenhuXVI35-1/2016		
A/Guizhou/54/89	A/Singapore/INFMH-16-0019/2016		
	Influenza B		
B/SichuanGaoxin/531/2018	B/Austria/1359417/2021	B/Brisbane/60/200	
B/Hong Kong/3417/2014	B/Washington/02/2019		
B/Phuket/3073/2013	B/Colorado/06/2017		

# 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: 00m Monday to Friday).

# LOCAL STATE AND TERRITORY HEALTH DEPARTMENTS CONTACT

Australian Capital Territory Coronavirus hotline

New South Wales Department of health

137788 
 ♠ http://health.nsw.gov.au/

Queensland Department of Health

13COVID or 134268 ♠ http://health.qld.gov.au/

South Australian Department of Health

**Tasmanian Department of Health** 

(coronavirus): 1800671738 (http://health.tas.gov.au/

Victorian Department of Health

Western Australian Department of Health

SYM	

2	Do not re-use	Ω	Use-by date
IVD	In vitro diagnostic medical device	类	Keep away from sunlight
2°C - 30°C	Store between 2-30°C	Ť	Keep dry
Ţį	Consult instructions for use	<b>®</b>	Do not use if package is damaged and consult instructions for use
LoT	Batch code	ш	Manufacturer
$\Box$	Contains sufficient for <n> tests</n>	REF	Catalogue number



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> Code:XXXXX Version No.: XXX Effective Date:XXXXX

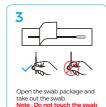


# COVID-19 / Influenza A&B Antigen Test Kit

Note: Use test only one time.







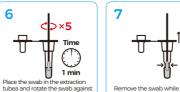
tip with finger



Gently insert the swab 1.5-2.5cm into the LEFT nostril or until resistance is felt. Slowly rotate the swab at least 5 times.



Remove the swab from the LEFT nostril and insert into the RIGHT nostril. Again, rotate 5 times.





squeezing the sides of the tube to extract the liquid from the

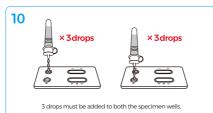


Scan the QR code or visit our website for instructional video. product information and IFU:

diagfest covid-19influenza-abantigen-test-kit-product/











the walls of the tube 5 times. Allow

the swab to stand in the extraction

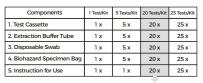
buffer tube for 1 minute

6





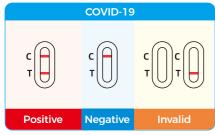
Wash your hands thoroughly

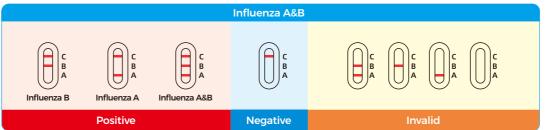


Materials required but not provided : Timer 20 independent 1 test/kit

#### For the sterilized swab

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





COVID-19 POSITIVE: Two colored lines appear on the membrane. One line appears in the control region (C) and the other line appears in the test region (T). COVID-19 NEGATIVE: Only one colored line appears in the control region (C). No colored line appears in the test region (T). COVID-19 INVALID: Control line fails to appear.

Influenza A POSITIVE: It is positive for Influenza A antigen if two Red lines appear. One red line should be in the control line region (C), and the other one appears in the A test line region. Influenza B POSITIVE: It is positive for Influenza B antigen if two Red lines appear. One red line should be in the control line region (C), and the other one appears in the B test line region. Influenza A and B POSITIVE: It is positive for both the antigens of Influenza A and Influenza B if three red lines appear. One Red line should be in the control line region (C), and another two should appear in A test line region and B test line region.

NEGATIVE: One Red line appears in the control region (C). No red line appears in the influenza A and B test region (T). INVALID: Control line fails to appear.

# **Caution:**

- For COVID-19 positive results: Follow the guidance from your local State or Territory Health Department for reporting of positive results and confirmation testing if required. If unwell, seek medical assistance,
- For Influenza positive results: If you have a positive result or are unwell, contact a medical practitioner for follow up clinical care.
- For negative results: A negative result does not mean you do not have COVID-19, Influenza A, and/or Influenza B. If symptoms persist or you feel unwell, please contact a medical practitioner for follow up clinical care.

• For Invalid result: Please retest with a new test cassette and a freshly collected specimen. Report repeated invalid results to the sponsor. Customer Support help line: 02 7908 9566 Customer Service hours: 12 AM ~ 17 PM, 5 Days. ~ UTC+10

