COVID-19 / Influenza A&B Antigen Test Kit

**INTENDED USE**

The COVID-19/Influenza A&B Antigen Test Kit is a lateral flow immunoaassay 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 COVID-19 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 on 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.

**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 SPECIFICATIONS**

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 mucosa. Swab contact with skin and mucosa is necessary. 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.

**MEDICAL DEVICE INCIDENT REPORT**

You can contact the Therapeutic Goods Administration (TGA) to report poor performance or usability issues via the Users Medical Device Incident Report, emailing iris@tga.gov.au or calling 1800 809 361 (8:30am to 5:00pm Monday to Friday).

**SPEEDY COVID-19 RESULTS**

**Symptoms or Exposure?**

1. If you are showing symptoms of a respiratory illness and have been in contact with, or you believe you have been in contact with, anyone with COVID-19/Influenza A&B, the test should be repeated in 48 hours.

2. If you are unwell and have been in contact with someone who has had COVID-19/Influenza A&B, the test should be repeated in 48 hours.

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

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

Caution:
Positive result: Please follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance for SARS-CoV-2 and individuals with a positive result or who are unwell are advised to consult a medical practitioner for follow-up clinical care for influenza.
Negative result: Please monitor for symptoms for several days (e.g. within 1-3 days) if symptoms persist or if unwell please consult a medical practitioner for follow-up clinical care.
Invalid result: Please retest with a new device.

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