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 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.

**PERFORMANCE CHARACTERISTICS**

**For COVID-19**

1. Limit of detection
   The limit of detection of the test is 1.0x10^9 TCID50/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 90.60%(120/132) known confirmed Positives) and a Specificity of 89.80%(540/595 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 92.30%(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 2.08x10^9 TCID50/mL
   Flu A H3N2/South Africa/34/2019 is 7.76x10^9 TCID50/mL
   Flu B Australia/13594/2017 (Victoriae lineage) is 2.84x10^9 TCID50/mL
   Flu B Phuket/3073/2013 (Yamagata lineage) is 1.08x10^9 TCID50/mL
   Flu A H1N1/Beijing/262/95 is 1.05x10^9 TCID50/mL
   Flu A H3N2/Shangdong/9/93 is 2.26x10^9 TCID50/mL
   Flu B Victoria lineage/Shandong/7/97 is 1.825x10^9 TCID50/mL
   Flu B Yamagata lineage/Jiangsu/10/03 is 2.44x10^9 TCID50/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 90.92%(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 89.66%(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. The tests correctly identified 87.50%(35/40) of positive samples and 97.14%(68/70) 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 B52, Adenovirus 1, Adenovirus 2, Adenovirus 3, Adenovirus 4, Adenovirus 5, Adenovirus 7, Adenovirus 15, Human coronavirus 229E, Human coronavirus OC43, Staphylococcus aureus, Human norovirus NL24, 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 A16e, Coxsackie virus B5, Coxsackie virus A24, Enterovirus E70, 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, Oseillavirin phosphate, Peramivir, Lopinavir, Ritonavir, Arbidol, Levofloxacin, Azithromycin, Moxifloxacin, Metronidazole, Tobramycin, Histamine hydrochloride, Phenylephrine Hydrochloride, Oxymetazoline hydrochloride spray, Physiological seawater nasal spray, Budesonide formate nasal spray, Fluticasone propionate nasal spray.

**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.

**REFERENCES**

Hangzhou Fanttest Biotech Co., Ltd. Room 307, 17 Chisholm St, Wolli Creek NSW 2205 E-mail: info@fanttest.com +86 571 86335573

**SYMBOLS**

Do not use - recall
Use by date
In vitro diagnostic medical device
Keep away from sunlight
Store between 2-30°C
Keep dry
Consult instructions for use
Do not use if package is damaged and consult instructions for use
Contains sufficient for n tests
Catalogue number

**E-MARKET PLACE**

http://www.137788.cn/promotion/13929655.html
http://www.137075.cn/promotion/13929660.html
http://www.139916.cn/promotion/13929665.html
http://www.136972.cn/promotion/13929670.html
http://www.135798.cn/promotion/13929675.html

**ROAD SHOW**

2020 COVID-19 Testing Solutions National Roadshow
COVID-19 / Influenza A&B Antigen Test Kit

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

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. 5 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.

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 apparent colored line appears in the test region (T).

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 apparent red line appears in the influenza A and B test region (T).
INVALID: Control line fails to appear.

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.

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

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

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

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