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 these viruses 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 and B on the first 4 days of symptom 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 1.0x10^3 TCID/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% (148/161 known confirmed Positives) and a specificity of 98.8% (179/182 known confirmed Negatives) were determined for the COVID-19 (SARS-CoV-2) Antigen Test Kit.

For Influenza A&B

1. Limit of detection
   Flu A H1N1 Victoria/22/2009 is 2.8x 10^3 TCID/mL.
   Flu A H3N2/South Australia/34/2019 is 7.6x 10^3 TCID/mL.
   Flu B Australia/135/2015 (Victoria lineage) is 2.8x 10^3 TCID/mL.
   Flu B Phuket/3073/2013 (Yamagata lineage) is 1.0x 10^3 TCID/mL.
   Flu A H1N1 Beijing/262/2009 is 1.05x 10^3 TCID/mL.
   Flu A H3N2/Shangdong/9/93 is 2.26x 10^3 TCID/mL.
   Flu B Victoria lineage/Shandong/7/97 is 1.825x 10^3 TCID/mL.
   Flu B Yamagata lineage/Jiangsu/10/03 is 2.44x 10^3 TCID/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 98.8% (540/550 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. The tests correctly identified 92.3% (36/39) of positive samples and 97.18% (69/71) of negative samples.

4. Repetition of testing
   Repeat antigen rapid testing is recommended every 24 hours for 3 days if there is evidence of symptoms and contact with COVID-19 positive individuals.

LIMITATION

1. False negative results may occur if the level of antigen in the sample is below the detection limit of the test.

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 evidence of symptoms and contact with COVID-19 positive individuals.

4. Negative results may not mean that a person is not infectious or infection with another type of respiratory virus and if symptoms persist or unwell 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. Individuals with a positive result or who are unwell are advised to consult a medical practitioner for follow-up clinical care for SARS-CoV-2 or Influenza.

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 under 15 years will require adult supervision or assistance. Not to be performed.

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

8. The performance of COVID-19/Influenza A&B Antigen Test Kit was established based on the evaluation of a limited number of clinical specimens. Performance at the time of testing may vary depending on the variants circulating, including newly emerging variants and their prevalence, which change over time.

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.

Code: 1054610300
Version No.: 3.0
Effective Date: Nov 9, 2022
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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. 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.

**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).
- **Negative**: Only one colored line appears in the control region (C). No apparent colored line appears in the test region (T).
- **Invalid**: Control line fails to appear.

**Influenza A&B**

- **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 A**: 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**: 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.
- **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.

**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

**Components**
- 1 x Test Cassette
- 1 x Extraction Buffer Tube
- 1 x Disposable Swab
- 1 x Biohazard Specimen Bag
- 1 x Instruction for Use
- 20 x Components

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

**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.

**ARTG ID**: 395590
**REF**: ICF - 535

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