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Combined rapid test for SARS-CoV-2 and influenza A/B (Kewei)

FAST

EASY

ACCURATE

ADVENT life
Health in Your Hands

KEWEI

THE COMPANY

Our ambition is to make healthcare widely accessible by empowering self-care globally.

Driven by our spirit of innovation, **Advent Life** specialises in self-tests for a wide range of medical conditions, while also offering other products that allow everyone to take health into their own hands. We enable people to take the first step themselves and at their own convenience.

Advent Life focuses on bringing the best from the world while prioritising safety and easy-to-use products. We design premium brands that are delivered to pharmacies, hospitals, laboratories, public organisations and government institutions.

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WHAT IS COVID?

Covid-19 is an acute respiratory infectious disease caused by SARS-CoV-2. The most common symptoms are coughing and fever, but sore throat, headache and muscle aches, as well as general weakness and shortness of breath, may also occur. Nausea, conjunctivitis, swollen lymph nodes and drowsiness, change or loss of taste and smell are some of the less common symptoms of the disease.

The flu is characterised by a sudden onset of high fever, cough and sore throat, accompanied by headache and/or muscle and joint pain. The patient may also feel general weakness, chills, sweating, loss of appetite, runny nose and nausea. The most common complication of the flu is pneumonia. Flu symptoms usually last more than a week.

PURPOSE

Combined rapid test for SARS-CoV-2 and influenza A/B (swab) is an in-vitro diagnostic test for the qualitative detection of coronavirus antigens and influenza A and B antigens in a nasopharyngeal swab using the rapid immunochromatographic method.

HOW IT WORKS?

The Coronavirus (SARS-Cov-2) Antigen Rapid Test is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies. The test device is composed of three parts, namely sample pad, reagent pad and reaction membrane. The whole strip is fixed inside a plastic device. The reagent membrane contains the colloidal gold conjugated with the monoclonal antibodies against the coronavirus; the reaction membrane contains the secondary antibodies for the coronavirus, and the polyclonal antibodies against the mouse globulin, which are pre-immobilised on the membrane. When the sample is added into the sample window, conjugates dried in the reagent pad are dissolved and migrate along with the sample.

The Influenza A&B Rapid test is a qualitative, lateral flow immunoassay for the detection of Influenza A and Influenza B nucleoproteins in nasal swab, throat swab or nasal aspirate samples. In this test, antibody specific to the Influenza A and Influenza B nucleoproteins is separately coated on the test line regions of the test device.

During testing, the extracted sample reacts with the antibody to Influenza A and/or Influenza B that are coated onto particles. The mixture migrates up the membrane to react with the antibody to Influenza A and/or Influenza B on the membrane and generate one or two coloured lines in the test regions.

CLINICAL EVALUATION RESULTS

Influenza A rapid test

Sensitivity: 94.20%
Specificity: 99.23%
Accuracy: 98.18%

Influenza B rapid test

Sensitivity: 93.15%
Specificity: 99.62%
Accuracy: 98.20%

Coronavirus (SARS-CoV-2) rapid test

Sensitivity:95.52%
Specificity:100.00%
Accuracy: 97.64%

FAST AND RELIABLE RESULTS

Time: 10 minutes.
Store between +2°C and +30°C. Do not freeze!
1 test per box.

The test device should be used within 1 hour after taking out from the aluminum foil bag. Keep away from sunlight, moisture, and heat.
Easy to read.

CONTENT

PROVIDED MATERIALS:

1 sealed aluminium pouch containing:

1 Test cassette
1 Sterilised swab
1 Tube with extraction buffer
1 Instruction for use

Only open the protective pouch when you are ready to use the test. The desiccant bag should not be used.

INSTRUCTIONS

Testing procedure always starts with a good preparation. Place the content of the box on a clean, dry and flat surface (e.g. table).
Then the testing follows:

SAMPLING AND PREPARATION

1. Read the instructions for use.

2. Insert the sterile swab about 2 cm into one nostril and gently rotate the swab at least five times, rubbing it against the walls of the nostril, then repeat the procedure with the other nostril.

3. Take one tube and tear off the foil wrapping from the tip.

4. Place the sample swab in the buffer. Twist the soft end of the swab and mix it with the buffer for at least 30 seconds, pressing the swab against the bottom and sides of the tube to ensure that the sample is fully extracted into the buffer.

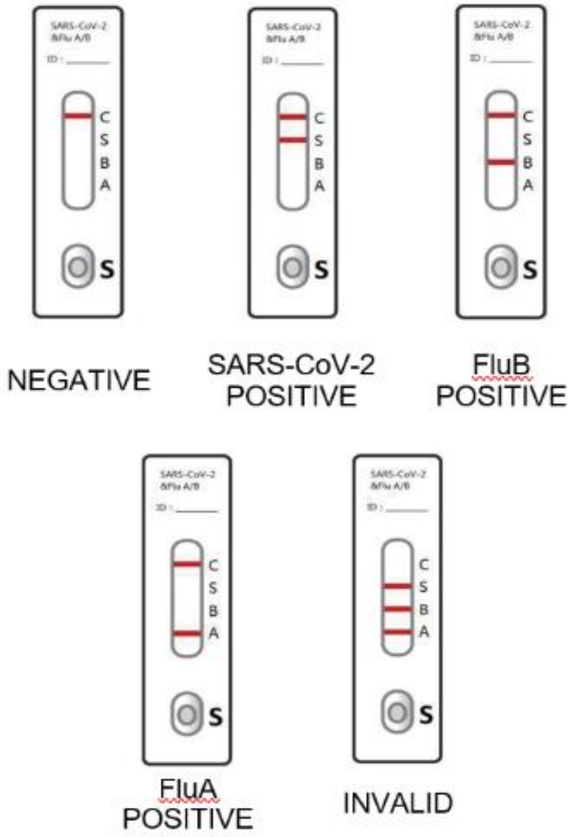
5. Screw the dropper cap onto the tube and shake vigorously to mix the sample with the buffer.

6. Remove the test cartridge from the protective packaging and place the device on a clean and flat surface.

7. Add 2 drops of the collected sample to each of the specially adapted holes of the test cartridge.

8. Read the result after 10 to 20 minutes. Do not interpret the result after more than 20 minutes.

RESULTS



POSITIVE SARS-Cov-2: Two red lines appear. One red line appears in the control region (C), and one red line in the test region (T).

POSITIVE Influenza A: Two distinct coloured lines appear. One coloured line should be in the control region (C) and another coloured line should be in the Influenza A region (A). A positive result in the Influenza A region indicates that Influenza A antigen was detected in the sample.

POSITIVE Influenza B: Two distinct coloured lines appear. One coloured line should be in the control region (C) and another coloured line should be in the Influenza B region (B). A positive result in the Influenza B region indicates that Influenza B antigen was detected in the sample.

POSITIVE Influenza A and Influenza B: Three distinct coloured lines appear. One coloured line should be in the control region (C) and two coloured lines should be in the Influenza A region (A) and Influenza B region (B). A positive result in the Influenza A region and Influenza B region indicates that Influenza A antigen and Influenza B antigen were detected in the sample.

NEGATIVE: Only one red line appears in the control region (C), and no line in the test region (T/A/B).

INVALID: No red line appears in the control region (C). The test is invalid even if there is a line on test region (T/A/B). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and repeat the test using a new test device.

***NOTE:**

The shade of colour may vary, but it should be considered positive whenever there is even a faint line.

IMPORTANT INFORMATION

The test is for professional in vitro diagnostic use only. The test should be used for the detection of Influenz A and/or B virus and/or coronavirus antigens in a nasopharyngeal swab.

Do not use after the expiration date.

Before opening, make sure that the foil package containing the test device is not damaged. Perform the test at room temperature from 15°C to 30°C.

Wear gloves when handling samples and avoid touching the reagent membrane and sample window. All samples and used accessories must be treated as infectious and disposed of in accordance with local regulations.

Avoid using bloody samples.

Store the rapid test device at room temperature or refrigerated (2-30°C).

Do not freeze.

All reagents are stable until the expiration date marked on their outer packaging and buffer vial.

Keep away from sunlight, moisture, and heat.