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Covid antigen test (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.

In some people, the infection may be asymptomatic, but it can also affect the respiratory system and other systems in the human body. In severe cases, symptoms may include shortness of breath and chest pains, and the disease may require specialist medical care or hospitalisation.

PURPOSE

The rapid antigen test for the detection of Covid-19 is an immunochromatographic test for the qualitative in vitro detection of the nucleocapsid protein antigen of Coronavirus 2019 in nasal secretions.

The product is certified by the testing and certification center in the EU and is approved by the Bulgarian Drug Agency to be used at home by persons without medical training.

The swab for collecting a sample is gentle, with extremely low invasiveness: less than two centimtres. The test is published in the general list of the European Commission for rapid antigen tests - category A.

CLINICAL EVALUATION RESULTS

Sensitivity: 99.21%
Specificity: 98.51%
Accuracy: 100%

FAST AND RELIABLE RESULTS

Time: 15-20 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.

PROVIDED MATERIALS:

1 sealed aluminium pouch containing:

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

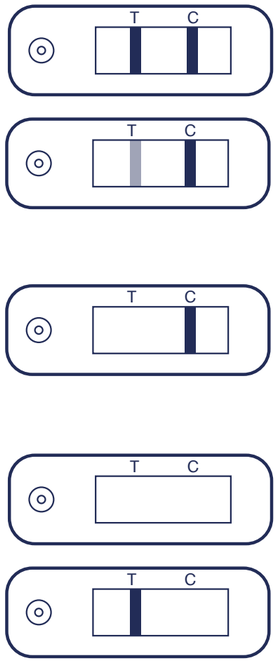
Only open the protective pouch when you are ready to use the test. The desiccant bag should not be used.

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:

1. Bring the product, reagents and samples to room temperature (15~30°C) before use.
2. Insert the sterilised swab in 2,5 cm into the nostril. Rotate 5 times in order to collect enough mucus. Repeat with the other nostril.
3. Take out the extraction tube with buffer and open it.
4. Place the sample in the extraction buffer. Rotate the swab for approximately 20 seconds while pressing the head against the inside of the tube.
5. Remove the swab while squeezing its head against the walls of the tube.
6. Add 3 drops of the sample to the sample well and start the timer.
7. Read the result in 15-20 minutes.
8. Don't read the result after 20 minutes.

RESULTS



POSITIVE: Two coloured lines appear. A coloured line should be in the control line region (C), a coloured line appears in the test line (T) region. Positive results indicate the presence of viral antigens, but the clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out a bacterial infection or co-infection with other viruses. The agent detected may not be the deffinite cause of disease.

NEGATIVE: Only one coloured control line appears. Negative results are presumptive. Negative test results do not exclude infection and should not be used as the sole basis for treatment or other patient management decisions, including infection control decisions, particularly in the presence of clinical signs and symptoms consistent with COVID-19, or in those who have been in contact with the virus. It is recommended that these results be confirmed by a molecular testing method, if necessary, for patient management.

INVALID: Control line fails to appear. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

NOTE:
The intensity and the colour of the lines do not have any importance for the interpretation of the test results.

IMPORTANT INFORMATION

The test is intended for single use and for in vitro diagnostics only.

The test results cannot be used as a basis for diagnosing and ruling out pneumonia, caused by SARS-CoV-2. The procedure must be carried out in strict compliance with the instructions.

Do not use damaged or expired products.

The test should be performed as soon as possible after opening it.

Do not use samples that have been stored too long or are contaminated.

Please follow the procedures for laboratory testing of infectious diseases.

Waste should be treated as infectious and disposed of in designated areas.

Improper use may affect the accuracy of the results, such as insufficient mixing of the sample, an insufficient amount of the sample, incorrect time for reading the result, etc.

IMPORTANT INFORMATION

The test should be stored at a temperature of 2°C to 30°C in a cool, dark and dry place.

The test card must be stored in the aluminum package and used within 1 hour after opening under the specified conditions (temperature between 2°C-30°C, humidity 40%-60%).

The buffer should be used immediately after opening.

Use gloves when handling the samples and test kit.

Do not put the samples in your mouth.

Given that the test taker's hands may be contaminated with a virus DURING the test, do not touch vulnerable areas such as the mouth, nasal cavity or eyeballs with your hands. Therefore, one should not smoke, eat, drink, apply make-up or handle contact lenses while handling the samples and test components.

Each test component remains stable until the expiration date under the appropriate handling and storage conditions. Do not use an expired test