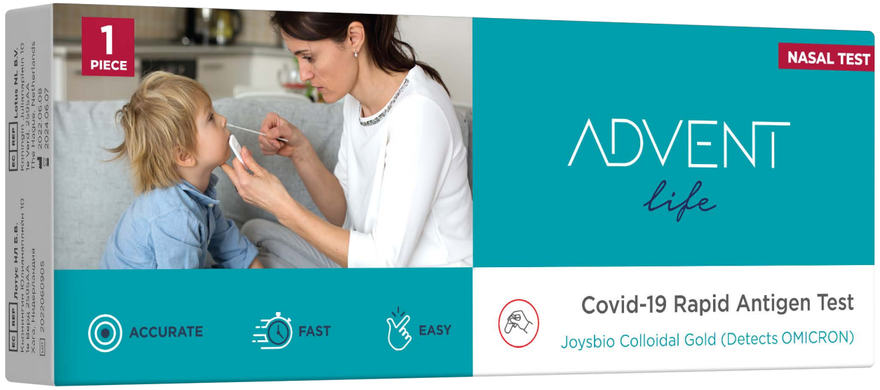
www.adventlife.net

Covid antigen test
(Joysbio Colloidal Gold, detects B.1.1.529-OMICRON)

FAST

EASY

ACCURATE



ADVENT life
Health in Your Hands

JOYSBIO

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.

For more information, visit **www.adventlife.net.**

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

For in vitro qualitative detection of SARS-CoV-2 nucleocapsid antigen in nasopharyngeal, nasal and oropharyngeal swab samples directly from individuals who are suspected of COVID-19 by their healthcare provider within the first 5 days after onset of symptoms.

CLINICAL EVALUATION RESULTS

Sensitivity: 98.13%

Specificity: 99.20%

Accuracy: 98.98%

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.

CONTENT

PROVIDED MATERIALS:

1 sealed aluminium pouch containing:

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

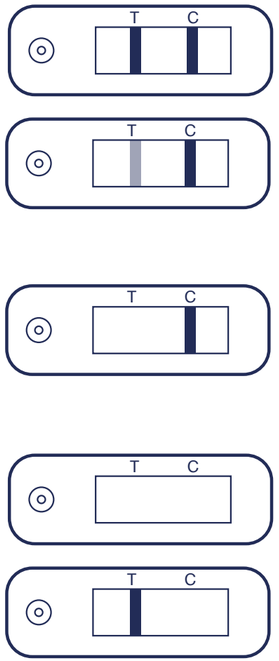
Only open the protective pouch when you are ready to use the test. The desiccant bag should not be used.

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:

1. Place the test cassette on a clean and leveled surface.
2. Peel off the sealing film of the extraction tube.
3. Using the swab, take a sample from both nostrils.
4. Insert the swab into the bottom of the extraction tube and roll it for five turns. Move the swab up and down in the buffer for a minimum of 20 seconds. Remove the swab while pushing against the walls of the extraction tube.
5. Close the cap on the extraction tube and mix thoroughly.
6. Gently squeeze the tube, dispensing three (3) drops of the sample into the sample well.
7. Read the test results between 15 and 20 minutes. Do not read the results after 20 minutes.

RESULTS



POSITIVE: Two 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

This product is only suitable for a qualitative test and auxiliary diagnosis.

The test results are only for clinical reference and should not be the only basis for clinical diagnosis and treatment. The clinical management of patients should be considered in combination with their symptoms, physical signs, medical history, other laboratory tests, therapeutic reaction, and epidemiological information. Users should test samples as quickly as possible after sample collection.

Positive test results do not rule out co-infections with other pathogens.

Results from the test should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.

A false-negative test result may occur if the level of viral antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly; therefore, a negative test result does not eliminate the possibility of SARS-CoV-2 infection.

The amount of antigen in a sample may decrease as the duration of illness increases. Samples collected after day 5 of the illness are more likely to be negative compared to an RTPCR assay.

Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.

The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 antigens from nasal swab samples only.

IMPORTANT INFORMATION

The kit performance depends on antigen load and may not correlate with other diagnostic methods performed on the same sample.

Negative test results are not intended to rule in other non-SARS-CoV-2 viral or bacterial infections.

Positive and negative predictive values are highly dependent on prevalence rates. Positive test results are more likely to represent false-positive results during periods of little/no SARS-CoV-2 activity when disease prevalence is low. False-negative test results are more likely when the prevalence of disease caused by SARS-CoV-2 is high.

This device has been evaluated for use with human sample material only.

Monoclonal antibodies may fail to detect or detect with less sensitivity, SARS-CoV-2 viruses that have undergone minor amino acid changes in the target epitome region.

The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection and performance may differ in asymptomatic individuals.

The sensitivity of the test after the first five days of the onset of symptoms has been demonstrated to decrease as compared to a RT-PCR SARS-CoV-2 assay.

Negative results should be treated as presumptive and confirmed with an FDA-authorised molecular assay, if necessary, or clinical management, including infection control.