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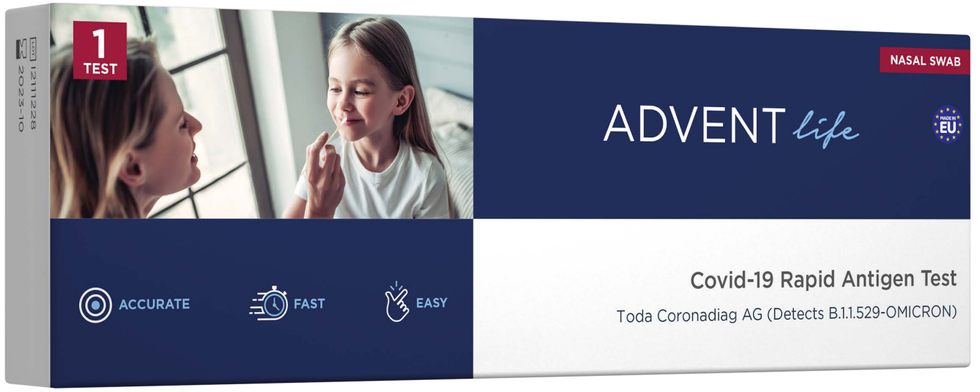
Covid antigen test
(Toda Coronadiag AG, detects B.1.1.529-OMICRON)

FAST

EASY

ACCURATE



ADVENT life
Health in Your Hands

TODA PHARMA

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

Toda Coronadiag Ag is an in vitro diagnostic test for the direct and qualitative detection of SARS-CoV-2 viral nucleoprotein antigens from nasopharyngeal and nasal secretion.

Toda Coronadiag Ag detecting the N protein, can be used to detect any known COVID-19 strain. The test detects SARS-CoV-2 viral antigens through visual interpretation of colour development. Anti SARS-CoV-2 antibodies are immobilised on the test region of the nitrocellulose membrane. Anti SARS-CoV-2 antibodies conjugated to colored particles are immobilised on the conjugated pad. A sample is added to the extraction buffer which is optimised to release the SARS-CoV-2 antigens from the sample.

CLINICAL EVALUATION RESULTS

Sensitivity: 98.60%

Specificity: 100%

Accuracy: 99.50%

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

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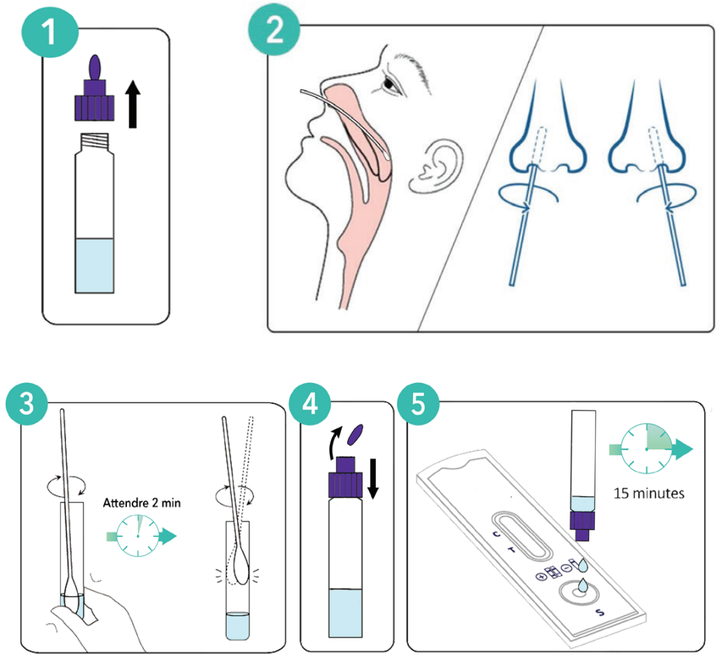
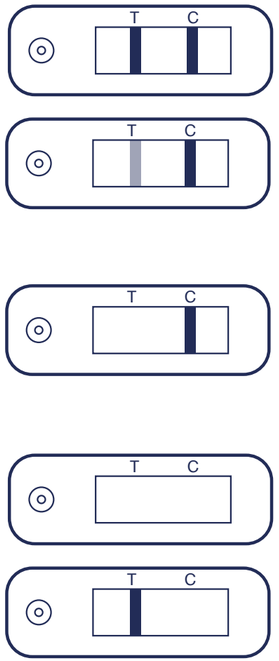
Testing procedure always starts with a good preparation. Place the content of the box on a clean, dry and flat surface (e.g. table). Then the testing follows:

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 definite 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 im-mediately 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

Toda Cotonadiag Ag is for professional in vitro diagnostic use and should only be used for the qualitative detection of SARS-CoV-2 antigen. The intensity of colour in a positive line should not be evaluated as “quantitative”.

As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test but should only be made by the physician after all clinical and laboratory findings have been evaluated. Failure to follow the TEST PROCEDURE and RESULT INTERPRETATION may adversely affect and/or invalidate the test result.

Results obtained with this assay, particularly in the case of weak test lines that are difficult to interpret, should be used in conjunction with other clinical information available to the physician. Negative results do not eclude SARS-CoV-2 infection and should be confirmed via molecular assay. If the test result is negative and clinical symptoms persist, further testing should be carried out. A negative test result may occur if the extracted antigen concentration from a sample is below the sensitivity of the test or if the sample obtained is of poor quality.

IMPORTANT INFORMATION

For in vitro diagnostic use only.

Read the instructions prior to use. Directions should be read and followed carefully. Do not use kit or components beyond the expiration date.

The device contains material of animal origin and should be handled as a potential biohazard. Do not use if pouch is damaged or open.

Test devices are packaged in foil pouches that exclude moisture during storage. Inspect each foil pouch before opening. Do not use devices that have holes in the foil or where the pouch has not been completely sealed. Erroneous result may occur if test reagents or components are improperly stored. Do not use the extraction buffer if it is discoloured or turbid. Discolouration or turbidity may be a sign of microbial contamination.

All patient samples should be handled and discarded as if they are biologically hazardous. All samples must be mixed thoroughly before testing to ensure a representative sample prior to testing.

Failure to bring samples and reagents to room temperature before testing may decrease assay sensitivity. Inaccurate or inappropriate sample collection, storage, and transport may yield false negative test results. Avoid skin contact with buffer.