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TODA CORONADIAG AG® COVID-19 RAPID ANTIGEN TEST

FAST

EASY

PRECISE

ABOUT THE IMPORTER

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Advent Life is part of Advent Group - an established leader in health and education with a global presence on five continents through legal entities in Paris, Sofia, Montreal, as well as representatives based in London, Munich, Kuala Lumpur, Vienna and Budapest. Advent Group is a registered distributor of medical devices.

TODA CORONADIAG AG® COVID-19 RAPID ANTIGEN TEST

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.

PRINCIPLE

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The COVID 19 Antigen Rapid Test Device detects SARS-CoV-2 viral antigens through visual interpretation of color development. Anti SARS-CoV-2 antibodies are immobilized on the test region of the nitrocellulose membrane. Anti SARS-CoV-2 antibodies conjugated to colored particles are immobilized on the conjugated pad. A sample is added to the extraction buffer which is optimized to release the SARS-CoV-2 antigens from specimen.

CHARACTERISTICS

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HIGH ACCURACY, SPECIFICITY AND SENSITIVITY:

SPECIFICITY:	**100%**
ACCURACY:	**99.5%**
SENSITIVITY:	**98.6%**

The Toda Coronadiag test has the best performance among the 122 main tests on the European market according to the comparative study by The National Paul Ehrlisch center and 6 national institutes mandated by the German Ministry of Health.
Results in 15 minutes.
Results are easy to read.
Storage at room temperature (2°C-30°C).
1 test in a box.

WHAT'S IN THE PACKAGE

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1 unitary aluminium bag containing the test cassette and a desiccant bag

1 sterile swab

1 reaction vial containing the extraction reagent

1 instruction for use

STEP-BY-STEP INSTRUCTIONS

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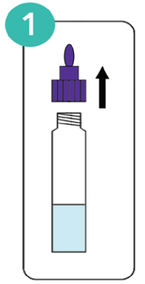
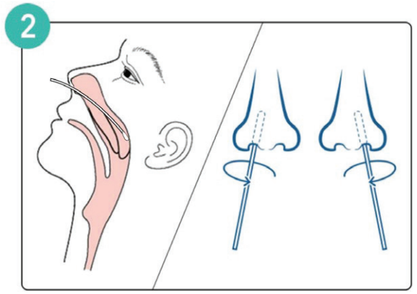
Bring the product, reagents and samples and/or controls to room temperature (15~30°C) before use. For each test, open the pouch just prior testing, remove the test device and place on a clean, flat surface. For best results, the test should be performed within one hour. Be sure that the patients blow their nose before sampling to avoid obtaining a thick sample.

1. Unscrew the blue cap from the diluent bottle containing the extraction reagent.
2. Remove the swab from its packaging.

2a. Insert the swab into the nostril parallel to the roof of the mouth (see Figure 2a) and rotate it against the nasal wall to ensure that it contains cells and mucus

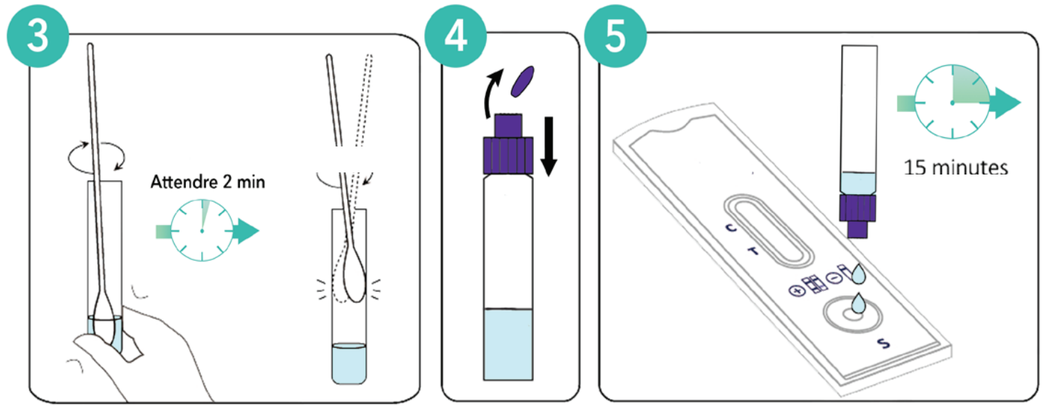
2b. Gently insert the entire absorbent portion of the swab into one nostril until you feel a slight resistance.(See diagram 2b). Gently pinch the upper part of the nostril and rotate the swab around the inside of the nostril, making 5 complete circles. Repeat this process for the other nostril to ensure that you get an adequate sample.





3. Perform the test as soon as possible after collection.
4. Insert the swab into the diluent bottle. Mix thoroughly and press the swab 10-15 times against the sides of the bottle. Allow to stand for 2 minutes. Press the head of the swab against the inside wall of the bottle while removing it to release as much liquid as possible. Dispose of the used swab according to the protocol of the current regulations for the disposal of biohazardous waste.
5. Screw the blue cap back on the diluent bottle and then unscrew the small transparent cap.
6. Turn the vial upside down and place 3 drops of solution into the sample well by gently squeezing the vial.

Read the results after 15 minutes. Do not read the results after 30 minutes



- If the extraction liquid is too viscous, make sure to homogenize the solution and add a 4th drop when depositing in the S well.
- If the migration of the solution does not appear after 1 minute, make sure to add a 4th drop of solution in the S well.

DO NOT ADD MORE THAN 4 DROPS

- Swab samples should be tested as soon as possible after collection. Use freshly collected samples for best test performance.
- If not tested immediately, swab specimens may be stored at 2-8°C for 24 hours after collection.
- Do not use specimens that are obviously contaminated with blood, as this may alter the test results.

RESULTS

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POSITIVE

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region and another band appears in the test region.

NEGATIVE: Only one colored band appears in the control region (C).No apparent colored band appears in the test region (T)

INVALID: Control band fails to appear.

NEGATIVE

*Results from any test which has not produced a control band at the specified read time must be discarded Please review the procedure and repeat with a new test If the problem persists, discontinue using the kit immediately and contact your distributor.

INVALID

IMPORTANT INFORMATION

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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 color in a positive band 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 preclude SARS-CoV-2 infection and should be confirmed via molecular assay.
If the test result is negative and clinical symptoms persist, further investigations 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

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For in vitro diagnostic use only.

Read the package. Insert 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 discolored or turbid. Discoloration or turbidity may be a sign of microbial contamination.

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

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