

Important safety information

Warning!


Follow all health and safety regulations.

- Use appropriate personal protective equipment.
- Handle all samples as if they contain infectious agents.
- Observe all precautions and warnings in the Instructions for Use.



Document information


Document version: Initial version

Revision date: January, 2021



SD Biosensor, Inc.
C-4th&5th, 16,
Deogyong-daero 1556beon-gil,
Yeongtong-gu, Suwon-si,
Gyeonggi-do, 16690,
REPUBLIC OF KOREA
Made in Korea





Authorized representative:
MT Promedt Consulting GmbH
Altenhofstrasse 80
D-66386 St. Ingbert, Germany

Distributed by:
Roche Diagnostics GmbH
Sandhofer Strasse 116
D-68305 Mannheim, Germany
www.roche.com

For in vitro diagnostics use only
Not for self testing

© 2020. All rights reserved.

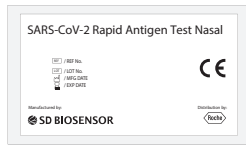
SARS-CoV-2
Rapid Antigen Test Nasal
Quick Reference Guide

This guide is a reference for using the
SARS-CoV-2 Rapid Antigen Test Nasal.
Read the Instructions for Use before using this test.

0 9368221001 (01) 2021-01 EN

1 Preparing for a test

- Carefully read the Instructions for Use for the **SARS-CoV-2 Rapid Antigen Test Nasal.**
- Check the expiry date  on the back of the foil pouch. Do not use the test if the expiry date has passed.
- Open the foil pouch and remove the test device and the desiccant package.
- Ensure that the test device is undamaged and that the desiccant status indicator shows valid (yellow).

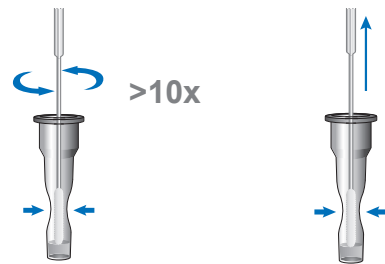
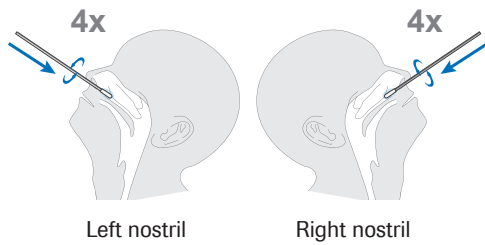


2 Collecting and preparing nasal sample

- Tilt the patient's head slightly back (approx. 70° angle).
- Insert sterile swab into the nostril with the most secretion.
- Insert the sterile swab into the nostril with the most secretion. While rotating the swab, insert the swab 2 cm (slightly less than 1 inch) parallel to the palate (not upwards) towards the throat into the nostril until resistance is met at turbinates. Do not apply pressure.
- Rotate the swab 4 times for about 15 seconds against the nasal wall and remove it from the nostril.
- Repeat step 3 to 4 with the same swab in the other nostril.
Note: Samples must be collected from both nostrils using the same swab.
- Insert the swab into an extraction buffer tube. While squeezing the buffer tube, stir the swab more than 10 times.
- Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

WARNING! Failure to squeeze the tube can lead to incorrect results due to excess buffer in the swab.

8. Press the nozzle cap tightly onto the tube. Continue with **3 Performing a test.**

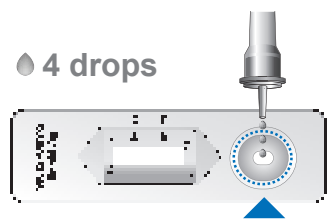


3 Performing a test

- Place the test device on a flat surface and apply 4 drops of extracted sample at a 90° angle to the specimen well of the test device.

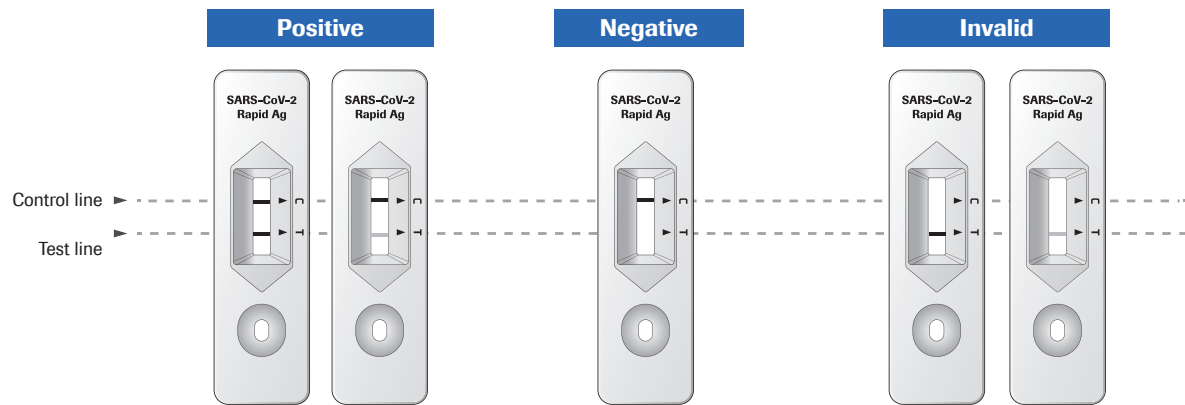
- Read the test result at 15 to 30 min.

WARNING! Risk of incorrect results. Do not read the test result after 30 min.



4 Interpreting results

- A colored line appears in the top section of the result window to show that the test is working properly. This is the control line (C). Even if the control line is faint, the test should be considered to have been performed properly. If no control line is visible the test is invalid.
- In case of a positive result, a colored line appears in the lower section of the result window. This is the test line (T). Even if the test line is very faint or not uniform, the test result should be interpreted as a positive result.



Note: The presence of any test line no matter how faint, together with a control line, should be considered as a positive result.
For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination, and other findings.

5 Performing a QC (as required)

- Put the positive or negative control swab into an extraction buffer tube. Stir the swab more than 5 times.
- Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
- Press the nozzle cap tightly onto the tube.
- Place the test device on a flat surface and apply 3 drops of extracted sample at a 90° angle to the specimen well of the test device.
- Read the test result at 15 to 30 min as described in **4 Interpreting results.**

WARNING! Risk of incorrect results. Do not read the test result after 30 min.

