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: 2.0

L29SCR3EN01R1

Issue date: 2020.12

Revision date: December, 2020

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

EC REP 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

IVD

CE

For in vitro diagnostics use only
Not for self testing

© 2020. All rights reserved.

SARS-CoV-2 Rapid Antigen Test

Quick Reference Guide

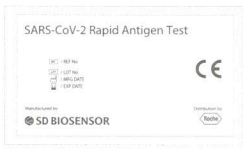
This guide is a reference for using the **SARS-CoV-2 Rapid Antigen Test**.
Read the Instructions for Use before using this test.

0 932776200 1 (02) 2020-12 EN

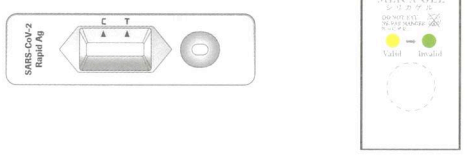
1 Preparing for a test

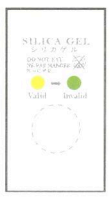
1. Carefully read the Instructions for Use for the **SARS-CoV-2 Rapid Antigen Test**.

2. Check the expiry date on the back of the foil pouch. Do not use the test if the expiry date has passed.



3. Open the foil pouch and remove the test device and the desiccant package.
4. Ensure that the test device is undamaged and that the desiccant status indicator shows valid (yellow).

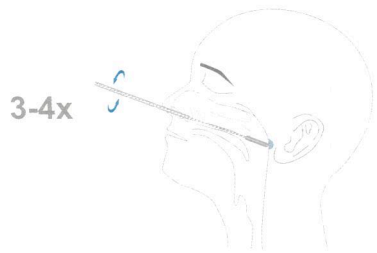




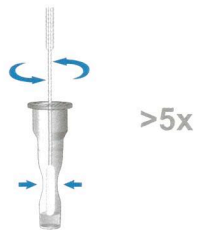
5. Perform a QC as required according to the Instructions for Use of the QC material and according to your local guidelines.

2a Collecting and preparing a sample (Nasopharyngeal swab)

1. Insert a sterile swab into the nostril of the patient and then rotate the swab 3-4 times against the nasopharyngeal surface. Withdraw the swab from the nasal cavity.



2. Insert the swab into an extraction buffer tube. While squeezing the buffer tube, stir the swab more than 5 times.



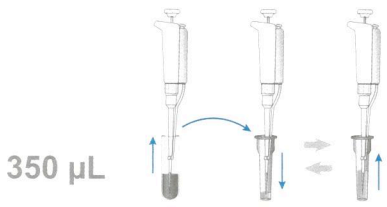
3. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

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

Note: When collecting a combined NP/OP sample be sure to follow the procedures described in the Instructions for Use.

2b Preparing a sample from viral transport media

1. Using a micropipette, collect 350 µL of sample from the collection cup or viral transport medium (VTM). Mix the sample with the extraction buffer as shown.

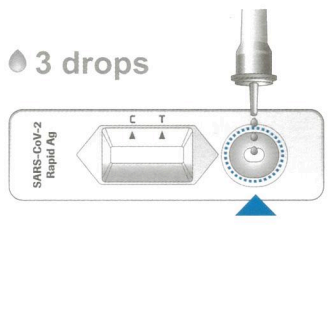


2. Press the nozzle cap tightly onto the tube. Continue with **3 Performing a test**.

Note: When using supplemented HBSS be sure to follow the procedures described in the Instructions for Use.

3 Performing a test

1. 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.

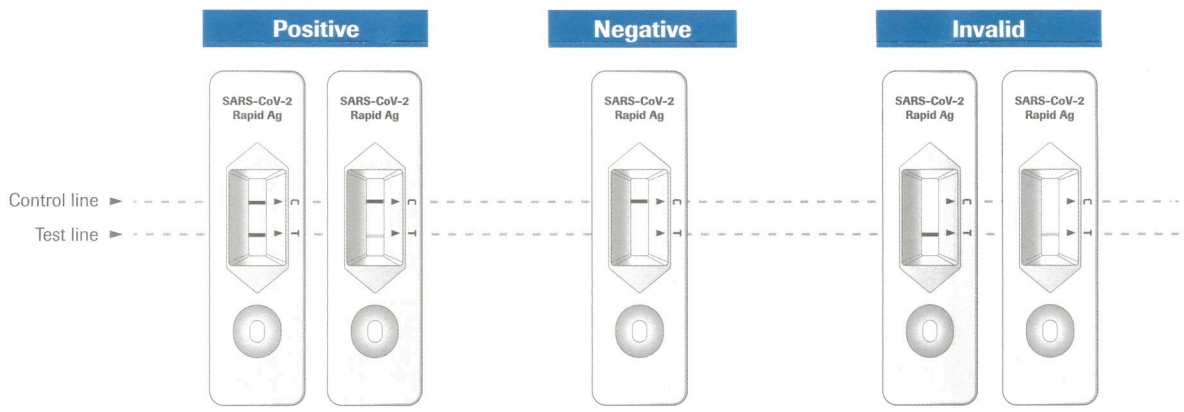


2. Read the test result at 15 to 30 min.

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

4 Interpreting results

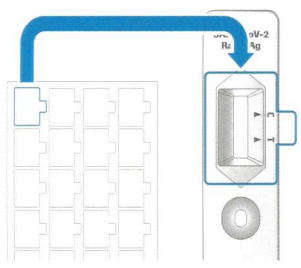
1. A colored line appears in the top section of the result window to show that the test is working properly. This is the control line (C). Even if the control line is faint, the test should be considered to have been performed properly. If no control line is visible the test is invalid.
2. In case of 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.



Ensuring test performance

Observe the following to ensure best test performance:

1. If the test site is subject to strong ventilation, attach the provided film to the result window of the test device before applying the sample. This ensures sufficient migration of the sample.



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.**