The SARS-CoV-2 Antigen Self Test Nasal is a so-called lateral flow test for the qualitative detection of SARS-CoV-2 nucleocapsid antigen in human nasal samples. This test is used to detect antigens of the SARS-CoV-2 virus in individuals suspected of having COVID-19. It is designed as a self-test for patients. For best performance, it is recommended this test be used within 7 days post-onset of symptoms.

Any COVID-19 vaccination as of 29 November 2021 (including the Delta variant) are detected by this test without any impact on performance.

### Summary

At the end of sequence is closely related to the virus that caused the SARS outbreak in 2002-2013. The disease caused by SARS-CoV-2 is COVID-19 (Coronavirus Disease 2019). The course of SARS-CoV-2 infections can vary widely. Some infected individuals do not have any symptoms, others experience relatively mild symptoms such as fever, cough, loss of taste or smell, or diarrhea. But it can also cause more serious symptoms such as difficulty in breathing or even death. Usually, it takes 3-6 days for symptoms to develop after an exposure to SARS-CoV-2, but sometimes it can take as long as 14 days.

### Materials provided
- Test device (packaged in foil pouch 1 including desiccant package)
- Test device (packaged in foil pouch 2)
- Sterile swab
- Tube holder
- Instructions for Use and Quick Reference Guide

### Test preparation and sample collection

Carefully read the Instructions for the Use of the SARS-CoV-2 Antigen Self Test Nasal. Please also see the Quick Reference Guide (with illustrations) before performing the test.

#### Preparing for a test

Prior to starting the procedure, the test device and reagents must be equilibrated to operating temperature (15 - 30 °C / 59 - 86 °F).

1. Wash your hands with soap and water or use a hand sanitizer before performing the test.
2. Check the expiry date on the back of the foil pouches. Do not use the test if the expiry date has passed.
3. Open one of the foil pouches by tearing along the tear-line and take out the test device and the desiccant package.
4. Use the test device and reagents must be kept at room temperature, protected from light, and against humidity and moisture. Do not open the desiccant package.

#### Collecting and preparing a nasal sample

1. Open the foil pouch 2 by tearing along the tear-line and take out one of the tubes with the liquid and the nozzle cap and place it in the table.
2. Open the seal of the tube carefully without splashing the liquid inside the tube. Place the tube in the tube holder.
3. Blot your nose once using a tissue.
4. Remove the swab from the packaging. Ensure you touch only the handle of the swab and not the soft tip at the tip.
5. Slightly tilt your head backwards.
6. Insert the swab with the soft pad at the front into your nostril. Slowly slide the swab approx. 2 cm forward (parallel to the roof of your mouth - not upwards) until you encounter resistance. Do not apply any pressure.
7. Rotate the swab 4 times (for a total of approx. 15 seconds) against the lining of the nasal wall before removing the swab from the nostril.
8. Repeat steps 6 and 7 in your right nostril using the same swab.
9. Insert the swab into the tube until the soft pad is in the liquid. Squeeze the tube at the bottom and hold it tight. Stir the swab more than 10 times to transfer the biological material from the swab to the liquid.
10. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

#### Performing the test

1. Place the test device on a flat surface.
2. Hold the tube upright above the circular well on the test device (not over the rectangular result window).
3. Drop exactly 4 drops onto the circular well. Gently squeeze the sides of the tube together if necessary.

#### Note:
You can continue with the test even if you accidentally drop 5 drops onto the test device.
4. Set the timer and read the test result after 15 to 30 minutes.
5. Wash your hands with soap and water or use a hand sanitizer after performing the test.

#### Interpreting the test results - invalid test result:

If a control line (C) is visible (regardless of how faint it is) and a test line (T) is not visible, this means that the result is negative. Look carefully at the result. The test should be considered positive if two lines are visible - even if they are faint. A positive test result means it is very likely that you have COVID-19.

**Refer to your state or territory health department information for guidance on confirmation testing, where necessary.**

#### Positive test result:

If a test line (T) is visible together with a control line (C), this means that the result is positive. Look carefully at the result. The test should be considered positive if two lines are visible - even if they are faint. A positive test result means it is very likely that you have COVID-19.

### Limitations of the procedure

- The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
- The test should be used for the detection of SARS-CoV-2 antigen in human nasal swab samples.
- This is a qualitative test, therefore quantitative values of SARS-CoV-2 antigen concentration cannot be determined.
- The test cannot determine if you are infectious.
- The SARS-CoV-2 Antigen Self Test Nasal for patient self-testing was evaluated in a study of symptomatic individuals aged 18 to 68. If the test is to be used on a child or teenager under 18 years of age, the test must be performed by an adult or under adult supervision. For older adults aged over 61, a helper should also be on hand to provide assistance with test and result interpretation.
- False negative test results (i.e., an existing infection is not detected) may occur if testing is not performed within the first 3 days of symptom onset as the antigen level in the specimen may be too low for the test to detect.
- False positive test results may occur if the specimen was collected incorrectly.

### Specific performance data

**Limit of detection**

The test is highly sensitive with a limit of detection of less than 50 copies/mL.

### Clinical evaluation

The clinical performance of the SARS-CoV-2 Antigen Self Test Nasal for patient self-testing was evaluated using nasal swab samples collected from 146 (of which, 139 within 7 days post symptom onset) study subjects in a prospective study at a clinical centre in Germany. The clinical evaluations were performed independently from the manufacturer and distributor within a collaboration between the university hospitals Charité in Berlin and Cologne.

The study cohort included symptomatic adults (aged 18 to 68) who were clinically suspected of having a SARS-CoV-2 infection.

In the patient self-testing group, the study participants followed written instructions with illustrations for the self-testing procedure and performing the tests themselves. The samples were collected and the tests performed under the observation of healthcare professionals, who did not intervene at any stage. PCR tests using combined deep nose/deep throat swab samples were used as a reference method. Nasal sampling by the self-testers always preceded the combined nose/deep throat sample collection for RT-PCR comparison. A SARS-CoV-2 infection was diagnosed (using RT-PCR) if 0.4% or more of the sample DNA was positive by quantitative real-time PCR.

The clinical performance of the SARS-CoV-2 Antigen Self Test Nasal was also evaluated for professional testing following patient self-collection and professional collection of nasal swab samples in the same clinical centre. 229 adults who were clinically suspected of having a SARS-CoV-2 infection were included in the prospective study. 133 study participants (hereof 126 within 7 days post symptom onset) underwent nasal sampling performed by healthcare professionals and 96 study participants (hereof 83 within 7 days post symptom onset) followed instructions for collecting their nasal swab samples themselves. Self-collection was performed under the supervision of healthcare professionals. PCR tests were performed as described above.
Test sensitivity and specificity
In the self-testing study, the SARS-CoV-2 Antigen Self Test Nasal correctly identified 91.2 % (CI: 76.3 % - 98.1 %) of infected study participants with a relatively high viral load (Ct ≤ 30). Individuals with a viral load are considered to be at higher risk of being infectious and transmitting the virus to others.

For all study participants, the antigen rapid test correctly identified 82.5 % (CI: 67.2 % - 92.7 %) of infected study participants and 100.0 % (CI: 96.5 % - 100.0 %) of non-infected study participants.

In all 3 cohorts together, 110 PCR-positive and 263 PCR-negative study participants were evaluated using the SARS-CoV-2 Antigen Self Test Nasal. For patients with relatively high viral load (Ct ≤ 30), the relative sensitivity was 91.1 % (95 % CI: 83.8 % - 95.8 %, N=101). For all samples, the overall relative sensitivity and the overall relative specificity were 86.4 % (95 % CI: 78.5 % - 92.2 %) and 99.6 % (95 % CI: 97.9 % - 100.0 %), respectively.

For patients tested within 7 days post symptom onset (DPSSO), the relative sensitivity was 87.4 % (95 % CI: 79.4 % - 93.1 %) and the relative specificity was 99.6 % (95 % CI: 97.7 % - 100.0 %).

### Antigen positive/ negative sample

<table>
<thead>
<tr>
<th>Antigen positive/ negative</th>
<th>Self testing</th>
<th>Self collection</th>
<th>Professional collection*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample</td>
<td>33 out of 40</td>
<td>105 out of 105</td>
<td>31 out of 34</td>
</tr>
</tbody>
</table>

### Antigen negative/ PCR positive

<table>
<thead>
<tr>
<th>Antigen negative/ PCR positive</th>
<th>Sample</th>
<th>Relative sensitivity (95% confidence interval)</th>
<th>Relative specificity (95% confidence interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self testing</td>
<td>100 %</td>
<td>99.0 % (97.9 % - 100 %)</td>
<td></td>
</tr>
<tr>
<td>Self collection</td>
<td>100 %</td>
<td>99.0 % (97.9 % - 100 %)</td>
<td></td>
</tr>
<tr>
<td>Professional collection*</td>
<td>100 %</td>
<td>99.0 % (97.9 % - 100 %)</td>
<td></td>
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</tbody>
</table>

### Combined**, 95 out of 110

<table>
<thead>
<tr>
<th>Sample</th>
<th>Relative sensitivity (95% confidence interval)</th>
<th>Relative specificity (95% confidence interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n.a.</td>
<td>91.1% (83.2% - 95.8%)</td>
<td>n.a.</td>
</tr>
<tr>
<td>n.a.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### DPSSO ≤ 7**, 90 out of 103

<table>
<thead>
<tr>
<th>Sample</th>
<th>Relative sensitivity (95% confidence interval)</th>
<th>Relative specificity (95% confidence interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n.a.</td>
<td>97.4% (93.1% - 100 %)</td>
<td>n.a.</td>
</tr>
</tbody>
</table>

### Cross-reactivity & microbial interference:

**Ct values are commonly used to estimate the amount of the viral material in samples. A low Ct value suggests the presence of high viral load, while a high Ct value suggests the presence of low viral load.

**One sample (PCR negative) was excluded from the analysis because the PCR test result was not available.

***Ct values are commonly used to estimate the amount of the viral material in samples. A low Ct value suggests the presence of a lot of viral material, and a high Ct value suggests the presence of lower levels of viral material.

### Analytical performance

1. **Cross-reactivity & microbial interference:** There was no cross-reactivity or interference with the following microbes: Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, MERS-coronavirus, Adenovirus Type 1, Adenovirus Type 2, Adenovirus Type 5, Adenovirus Type 6, Adenovirus Type 7A, Adenovirus Type 11, Adenovirus Type 14, Adenovirus Type 40, Human Metapneumovirus Type 3 B1, Human Metapneumovirus 16 Type A 1, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4A, Influenza A H1N1 pdm/Hongkong/483/15, Influenza A H1N1 pdm/Michigan/45/15, Influenza A H3N2 Singapore/INMF96-0019/16, Influenza A H3N2 South Australia/55/16, Influenza A H3N2 Hong Kong/85/87, Influenza A H3N2 Victoria/263/11, Influenza A H3N2 Malaysia/381/09, Influenza B Yamagata/16/88, Influenza B Victoria/287/89, Influenza B Texas/61/17, Influenza B Florida/02/2004, Enterovirus type 6B 02/2014 Isolate 4, Respiratory syncytial virus A, Respiratory syncytial virus B, Rhinovirus 1A, Rhinovirus 16, Rhinovirus 42, Haemophilus influenzae (NCCP 13815), Haemophilus influenzae (NCCP 13819), Haemophilus influenzae (NCCP 14381), Haemophilus influenzae (NCCP 14582), Streptococcus pneumoniae Type 1 (KCCM 41500), Streptococcus pneumoniae Type 3 (KCCM 41506), Streptococcus pneumoniae Type 5 (KCCM 41507), Streptococcus pyogenes (ATCC 12349), Candida albicans (ATCC 10231), Bordetella pertussis (NCCP 13671), Mycoplasma pneumoniae (ATCC 15513), Chlamydia pneumoniae (ATCC 20282), Legionella pneumophila (ATCC 33151), Staphylococcus aureus (ATCC 25923), Staphylococcus epidermidis (KCCM 35494).

### Symptoms

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard:

- **RET** Reference number
- **LOT** Batch code
- **SN** Serial Number
- **IN** in vitro diagnostic medical device
- **SI** Systems on which reagents can be used
- **CI** Global Trade Item Number
- **M** Manufacturer
- **D** Warning
- **K** Contains sufficient for <n> tests
- **A** Use-by date
- **D** Distributor
- **T** Temperature limit
- **O** Do not use if package is damaged

### Distribution in Australia by:
Roche Diagnostics Australia Pty Limited, 2 Julius Avenue, North Ryde, NSW, 2113
Tech Support: 1800 497 069, Hours: 9am-7pm AEST / 8am 4pm AEDT, 7 days per week
https://www.roche.com/covid-safety
Roche order number: 09445323

In the event you are experiencing problems with the test, please contact Roche Diagnostics Australia.
Additionally, you may wish to report poor performance or usability issues directly to the Therapeutic Goods Administration (TGA) via the Medical Device Incident Reporting scheme, email: info@tga.gov.au or call 1800 809 361.

To contact your local state/territory health department click on the following link: https://www.health.gov.au/about-us/contact-us/local-state-and-territory-health-departments

### References

### Notes

Human coronavirus HKU1 has not been tested. There can be cross-reaction with human coronavirus HKU1 even though the percentage identity of the nucleocapsid protein sequence of HKU1 with the nucleocapsid protein sequence of SARS-CoV-2 was 31.6 %, which is considered as low homology.

### Symbols

Roche Diagnostics mark on the product or packaging has no bearing on the product registration in Australia.

### Contact details and websites of the local state and territory health departments.

#### Local state and territory health departments

- **Australian Capital Territory Department of Health**
  - Business hours: 02 5124 9213
  - Coronavirus hotline (8am to 8pm daily): 02 6207 3244

- **New South Wales Department of Health**
  - General enquiries: 1300 066 055
  - Coronavirus hotline (Service NSW, 24/7): 1300 671 738

- **Northern Territory Department of Health**
  - General enquiries: 08 8922 8888
  - Coronavirus hotline (National helpline): 1800 002 080

- **Queensland Department of Health**
  - 13HEALTH 13 452 584
  - Coronavirus helpline: 134COVID 134 268

- **South Australian Department of Health**
  - General enquiries: 1300 232 272
  - Coronavirus hotline (9am to 5pm daily): 1800 253 787

- **Tasmanian Department of Health**
  - General enquiries: 1300 135 513
  - Public Health Hotline (coronavirus): 1800 675 398

- **Victorian Department of Health**
  - Department of Health and Human Services Victoria
  - Department of Health and Human Services Victorian
  - Department of Health and Human Services Victorian
  - 1300 650 172
  - Coronavirus hotline: 1300 066 055
  - General enquiries: 1300 232 272
  - Coronavirus hotline (9am to 5pm daily): 1800 253 787

- **Western Australian Department of Health**
  - WA Health
  - General enquiries: 1300 23 22 22
  - Coronavirus helpline: 13COVID (8am to 6pm, Mon-Fri) 1800 595 206

### Please scan the QR code below for more information including the "how-to-use" video and frequently asked questions:
SARS-CoV-2 Antigen Self Test Nasal
Quick Reference Guide for Patients

1 Preparing for a test

1. Carefully read the Instructions for Use for patients for the SARS-CoV-2 Antigen Self Test Nasal.
2. Wash your hands with soap and water or use a hand sanitizer before performing the test.

2 Collecting and preparing nasal sample

1. Open the seal of the tube carefully without accidentally dropping liquid onto the swab.
2. Hold the tube upright above the circular well and take out one of the tubes with liquid.

3 Performing a test

1. Place the test device on a flat surface.
2. Hold the tube upright above the circular well and take out one of the tubes with liquid.
3. Drop exactly 4 drops onto the circular well. Gently squeeze the sides of the tube together if necessary. Note: You can continue with the test even if you accidentally drop 5 drops onto the test device.

4 Interpreting results

**Invalid test result**: If a control line (C) is not visible, the result must be considered invalid. The test is not working correctly and you should perform another test using a different test kit.

**Positive test result**: If a test line (T) is visible together with a control line (C), this means that the result is positive. Look carefully at the test line. The test should be considered positive if two lines are visible - even if they are faint. A positive test result means it is very likely that you have COVID-19. Please click here for your State and Territory COVID Support Services for contact on confirmation testing where necessary. Anyone who tests positive is encouraged to contact their GP for support as required.

**Negative test result**: If a control line (C) is visible (regardless of how faint it is) and a test line (T) is not visible, this means that the result is negative. It is unlikely that you have COVID-19. However, even if your test is negative, continue to observe all hygiene and safety measures. If you suspect that you have an infection (i.e., if you have prolonged symptoms or if your symptoms are worsening), contact your doctor/primary care physician. You may have another infection, or your test result may be false. You may repeat the test after 1–2 days, as COVID-19 cannot be detected with complete accuracy during all stages of an infection.