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 variants in circulation as of 29 November 2021 (including the Delta variant) are detected by this test without any impact on performance.

Summary
At the end of 2019, a novel virus was discovered in a cluster of pneumonia cases.1 This virus belongs to the large family of Coronavirus, and has been named SARS-CoV-2 because its genetic sequence is closely related to the virus that caused the SARS outbreak in 2003.2 The disease caused by SARS-CoV-2 is called COVID-19 (Coronavirus Disease 2019).3 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 diarrhoea. But it can also cause more serious symptoms such as difficulty in breathing or even death.5,6 Usually, it takes 5 - 6 days for symptoms to develop after an exposure to SARS-CoV-2, but sometimes it can take as long as 14 days.6

Reagents
- COVID-19 - antibody
- anti-chicken-IgY conjugate
- purified chicken-5’-y-iod conjugate.

Precautions and warnings

1. Use the test kit once only. Do not reuse the test strip or buffer.
2. Remove the test device from the sealed pouch only when you are ready to perform the test.
3. Do not use the test kit if the pouch is damaged.
4. In the event of a negative result, the test kit is thoroughly cleaned using a suitable disinfectant.
5. Use only the components of this test kit.
6. Inadequate or improper sample collection may lead to inaccurate or false results.
7. If you suspect the presence of blood on the swab, discard the swab and repeat the test with a fresh one.
8. Do not leave the test kit unattended with children or people with visual impairments. In cases of concern, consult your doctor.
9. Keep the test kit away from children to reduce the risk of accidentally drinking the buffer liquid or swallowing small parts.
10. Do not use any of the test components in the body with the exception of the sample included in the kit. Do not swallow any of the components.

Performing the test
1. Place the test device on a flat surface.
2. Hold a 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.
4. Note: You can continue with the test even if you accidentally drop 5 drops onto the test device.
5. Set the timer and read the result after 15 to 30 minutes.
6. Wash your hands with soap and water or use a hand sanitizer after performing the test.
7. Failure to squeeze the tube can lead to incorrect results due to excess buffer in the swab.
8. Test results that are read before 15 minutes or after 30 minutes may be incorrect.

Interpreting the test results
1. 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. Look carefully at the test. 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 interpreting the test result, where necessary.
   - 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 or 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.

Limitations of the procedure
- The test procedure, precautions and interpretation of results for this test must be followed strictly when carried out.
- 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 adults aged 18 - 68. If the test is to be used on a child or teenager under 12 years of age, the test must be performed by an adult or under adult supervision. For older individuals aged over 65, a helper should also be on hand to provide assistance with testing 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 few days of symptom onset as the antigen in the specimen may be too low to detect for.
- False negative test results may occur if the specimen was collected incorrectly.
- False positive results may occur if the specimen is not mixed well in the tube (step 9 in the test procedure section).
- Antibiotics can generally be detected using nasal swab samples during the acute phase of infection. The test is less reliable in later phases of infections and in asymptomatic individuals.
- The immune response cannot be evaluated using this test. Other test methods are required for that purpose.
- Positive results do not indicate the presence of viral antigens. However, a clinical correlation with the case history and other diagnostic information are required to determine the status of the infection.
- Positive results do not exclude the possibility of a bacterial infection or a co-infection with another virus is present.
- Human coronavirus HUKS could not be tested in the lab. There is a very low probability of cross-reactivity with HUKS.
- False positive results may occur in the presence of SARS-CoV-2 infections.
- Negative results should be viewed as provisional and a PCR test should be performed as confirmation if necessary.
- Negative results do not rule out a SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including decisions about infection control.
- Individuals who have tested negative and continue to show COVID-19-like symptoms should contact their doctor/primary care physician.

Limitations of the procedure
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 (of which, 139 within 7 days post symptom onset) study participants 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 hospital Charité in Berlin and the Schering.

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 of how to perform the test, and performing the test 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 comparative method. Nasal sampling by the self-testers always preceded the combined deep nose/deep throat sample collection for RT-PCR comparison. A SARS-CoV-2 infection was diagnosed (using PCR) by the patient's healthcare professionals or 96 study participants (thereof 83 within 7 days post symptom onset) underwent nasal sampling performed by healthcare professionals and 96 study participants (thereof 83 within 7 days post symptom onset) study participants 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 hospital Charité in Berlin and the Schering.

Despite mixed results, the study participants' testing was performed in the supervision of healthcare professionals. PCR tests were performed as described above.
1. Cross-reactivity & microbial interference:

There was no cross-reactivity and interference with the following microbes: Human coronavirus 229E, Human coronavirus OC43, MERS-coronavirus, Adenovirus Type 1, Adenovirus Type 2, Adenovirus Type 5, Adenovirus Type 6, Adenovirus Type 7 A, Adenovirus Type 229E, Human coronavirus NL63, Human coronavirus H1N1 pdm/Michigan/45/15, Human coronavirus B Malaysia/2506/04, Human coronavirus Lee/40, Human coronavirus B Massachusetts/2/12, Human coronavirus B Michigan/46/15, Human coronavirus B Hong Kong/86/98, Human coronavirus B Victoria/361/11, Influenza A H1N1, Influenza A H1N1 Hong Kong/86/98, Influenza A H1N2 Victoria/361/11, Influenza B Massachusetts/2/12, Influenza B Malaysia/290/04, Influenza B Lee/46, Influenza B Yamagata/16/88, Influenza B Victoria/2/87, Influenza B Texas/61/11, Influenza B Colorado/16/17, Influenza B Florida/02/06, Enterovirus type 68 09/2014 Isolate 4, Respiratory syncytial virus A, Respiratory syncytial virus B, Rhinovirus 1A, Rhinovirus A16, Rhinovirus B42, Human coronavirus (KCV1385), Haemophilus influenzae (NCCP 13851), Haemophilus influenzae (NCCP 13681), Haemophilus influenzae (NCCP 14681), Streptococcus pneumoniae Type 1 (KCCM 41566), Streptococcus pneumoniae Type 2 (KCCM 40410), Streptococcus pneumoniae Type 3 (KCCM 41569), Streptococcus pneumoniae Type 5 (KCCM 41575), Streptococcus pyogenes (ATCC 12534), Candida albicans (ATCC 10231), Bordetella pertussis (NCCP 13371), Mycoplasma pneumoniae (ATCC 15531), Chlamydia pneumoniae (ATCC VR-2822), Legionella pneumophila (ATCC 33153), Staphylococcus aureus (NCCP 13441), Staphylococcus epidermidis (KCCM 3468). Cross-reactivity was observed for SARS-CoV.

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

2. Studies of exogenous/ endogenous interference substances studies:

There was no interference with the following substances at indicated concentrations: Chloroquine (Menthis Baroanei) 1.5 mg/mL, Nase GEL (WelMed) 5% v/v, CVS Health Nasal Drops (Phenylephrine) (15 % v/v), Afrin (Oxymetazoline) (15 % v/v), CVS Health Oxytetracycline (15 % v/v), CVS Health Nasal Spray (Cromolyn) (15 % v/v), Zicam (5 % v/v), Hameopathic (Alkali) (1:10 dilution), Sore Throat Phenol Spray (15 % v/v), Tobramycin (4 μg/mL), Mupirocin (20 mg/mL), CVS Health Flucloxacine Propionate (5 % v/v), Tamiflu (Oseltamivir Phosphate) (5 mg/mL), Whole Blood (4 %), Milk (0.5 %).

A point (period/stop) is always used in this Instructions for Use as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

References


Symbols

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

**Self Testing**: Only carried out by the user.

**Self collection**: The test is performed by the user.

**Collection** [136]: The test is performed by a collector.

***Combined***: The test is performed by both the user and a collector.

DPSO ≤ 7**: Used for the calculation of sensitivity and specificity. The value is obtained from the negative control portion of the test.

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.

DDD **Ct value**: Used for the calculation of the overall relative sensitivity and the overall relative specificity.

The CE mark on the product or packaging has no bearing on the product registration in Australia. Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 11144-1 (2015) standard:

- Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 11144-1 (2015) standard:
  - **Self Testing**: Only carried out by the user.
  - **Self collection**: The test is performed by the user.
  - **Collection**: The test is performed by a collector.
  - **Combined***: The test is performed by both the user and a collector.
  - **DPSO ≤ 7**: Used for the calculation of sensitivity and specificity. The value is obtained from the negative control portion of the test.
  - **Ct value**: Used for the calculation of the overall relative sensitivity and the overall relative specificity.

Please scan the QR code below for more information including the “how-to-use” video and frequently asked questions.