

SARS-CoV-2 Antigen Self Test NASAL

Questions	Answers
	Purchase - Ordering
I am a health care professional and I would like to order the test	Roche SARS-CoV-2 Antigen Self Test Nasal is intended for self-use in individuals aged 16 and older. The test may not be used in children younger than 16 or by lay users to test others. This test has been authorized under Health Canada's Interim Order making it available to Canadians, individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection. The Canadian team is currently working on the allocation strategy for the SARS-CoV-2 Antigen Self Test Nasal. Please contact lval.covid-19@roche.com to signify your interest and a Roche representative will contact you shortly to provide further information.
I have not yet received my order and I would like a follow-up on my order	Please contact our Customer Service Support by email: orders.ca@roche.com or by phone: 1-800-363-5887 and a Roche representative will provide further information.
I am a ROCHE customer and would like to order the SARS-CoV-2 Antigen Self Test Nasal	Roche SARS-CoV-2 Antigen Self Test Nasal has been authorized under Health Canada's Interim Order making it available to Canadians, individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection. The Canadian team is currently working on the allocation strategy for the SARS-CoV-2 Antigen Self Test Nasal. Please contact lval.covid-19@roche.com to signify your interest and a Roche representative will contact you shortly to provide further information.
I am not ROCHE customer and would like to order the SARS-CoV-2 Antigen Self Test Nasal	Roche SARS-CoV-2 Antigen Self Test Nasal has been authorized under Health Canada's Interim Order making it available to Canadians, individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection. The Canadian team is currently working on the allocation strategy for the SARS-CoV-2 Antigen Self Test Nasal. Please contact lval.covid-19@roche.com to signify your interest and a Roche representative will contact you shortly to provide further information.
How many kits can I order?	Please contact lval.covid-19@roche.com to signify your interest and a Roche representative will contact you shortly to provide further information.
How do I place an order?	Roche SARS-CoV-2 Antigen Self Test Nasal has been authorized under Health Canada's Interim Order making it available to Canadians, individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection. The Canadian team is currently working on the allocation strategy for the SARS-CoV-2 Antigen Self Test Nasal. Please contact lval.covid-19@roche.com to signify your interest and a Roche representative will contact you shortly to provide further information.
What is the SARS-CoV-2 Antigen Self Test Nasal product number for ordering?	Roche SARS-CoV-2 Antigen Self Test Nasal has been authorized under Health Canada's Interim Order making it available to Canadians, individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection. The Canadian team is currently working on the allocation strategy for the SARS-CoV-2 Antigen Self Test Nasal. Please contact lval.covid-19@roche.com to signify your interest and a Roche representative will contact you shortly to provide further information.
I am not a Health Care Provider, how do I purchase the SARS-CoV-2 Antigen Self Test Nasal?	Roche SARS-CoV-2 Antigen Self Test Nasal has been authorized under Health Canada's Interim Order making it available to Canadians, individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection. The Canadian team is currently working on the allocation strategy for the SARS-CoV-2 Antigen Self Test Nasal. Please contact lval.covid-19@roche.com to signify your interest and a Roche representative will contact you shortly to provide further information.
If I place an order today, when will I receive the kit?	Please contact our Customer Service Support by email: orders.ca@roche.com or by phone: 1-800-363-5887 and a Roche representative will provide further information.
What is the delivery time after placing an order?	Please contact our Customer Service Support by email: orders.ca@roche.com or by phone: 1-800-363-5887 and a Roche representative will provide further information.
How do I know if my order has been prioritized?	Please contact lval.covid-19@roche.com to signify your interest and a Roche representative will contact you shortly to provide further information.
What is the price for the SARS-CoV-2 Antigen Self Test Nasal?	Please contact lval.covid-19@roche.com to signify your interest and a Roche representative will contact you shortly to provide further information.
Is it possible to have a preferential rate for large quantity orders?	Please contact lval.covid-19@roche.com to signify your interest and a Roche representative will contact you shortly to provide further information.
Who should I contact if there was an error in my order (wrong quantities received)	Please contact our Customer Service Support by email: orders.ca@roche.com or by phone: 1-800-363-5887 and a Roche representative will provide further information.
Does ROCHE sell the swabs?	The nasal swabs come with the kit, they are not sold separately.
Format and storage specifications	
What material is provided with the kit	<ul style="list-style-type: none"> • Test device (individually in a foil pouch with desiccant) • Extraction buffer tube • Nozzle cap • Sterile nasal swab • Tube holder • Instructions for use • Quick Reference Guide
How many tests per kit?	5
Are the tests individually wrapped?	The test devices are individually packaged in an aluminum bag with desiccant
Dimensions of the box? (For storage purpose)	Length 16 cm Width 12 cm Height 3 cm Weight 121 g
Refrigerated or at room temperature?	Store the kit at (2-30°C) out of direct sunlight. Do not freeze the kit.
What is the shelf life of the product?	Kit materials are stable until the expiry date printed on the outer box.
What is the shelf life of the product once opened?	Use the test immediately after opening the pouch. Make sure that the test device is not damaged and that the status indicator of the desiccant is valid (yellow).
My kit arrived frozen, can I still use it?	No. Do not freeze the kit and do not use if frozen
My kit was left on a hot delivery dock, can I still use it?	Store the kit between 2-30°C out of direct sunlight. If these conditions are not respected, the kit cannot be used
Do we need to get swabs?	The nasal swabs are in the kit, there are not sold separately
Technical information about the test	
What is the type of test?	<p>SARS-CoV-2 Antigen Self Test Nasal is a lateral flow immunoassay intended for qualitative detection of SARS-CoV-2 nucleocapsid protein antigen in human nasal samples from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection. The SARS-CoV-2 Antigen Self Test Nasal is intended for self-use in individuals aged 16 and older. The test may not be used in children younger than 16 or by lay users to test others.</p> <p>Prep work 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. 1. Rigorously tear along the tear-line and take out the test device and the desiccant package. Use the test immediately after opening the pouch. 4. Ensure that the test device is intact and that there are no green beads in the desiccant package. Do not open the desiccant package.</p> <p>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 one nozzle cap and place them on the table. 2. Open the seal of the tube carefully without spilling the liquid inside the tube. Place the tube in the tube holder. 3. Blow your nose once using a tissue. 4. Remove the swab from the packaging. Ensure that you only touch the handle of the swab and not the soft pad at the tip. 5. Slightly tilt your head backwards. 6. Insert the swab with the soft pad at the front into your left 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 it 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. Dispose the swab and seal the tube securely with the nozzle cap.</p> <p>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 or seal 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. The entire procedure is detailed in the Quick Reference Guide included with the test.</p>
Do you need an instrument to run the SARS-CoV-2 Antigen Self Test Nasal?	No. The test comes as a separate single use test kit, presenting a visual/and/or qualitative test result without an instrument needed. The test is ready for use without additional equipment.
Do you have a package insert?	https://www.roche.ca/roche/en/products/diagnostics/products/documentation/sars-cov-2-rapid-antigen-self-test.html
Do you have comparative studies of the SARS-CoV-2 Antigen Self Test Nasal with the RT-PCR tests?	Yes, the clinical performance of the test was measured in three clinical studies. The overall relative sensitivity of the SARS-CoV-2 Antigen Self Test Nasal was 91.2% (CI ± 3.0); 94.9% and 100% in the three different studies. The overall relative specificity was 100%, 100% and 98.4% in the three studies, which represents the ability of the test to correctly identify patients without the virus.
Do you have a rapid test?	Yes, this is a SARS-CoV-2 Antigen Self Test Nasal
Is your kit reliable?	Yes, the overall relative sensitivity of the SARS-CoV-2 Antigen Self Test Nasal was 91.2% (CI ± 3.0); 94.9% and 100% in the three different studies. The overall relative specificity was 100%, 100% and 98.4% in the three studies, which represents the ability of the test to correctly identify patients without the virus. In one comparative independent self-testing study where patients followed written and illustrated instructions to sample, test, and read-out the results themselves, a majority of study participants considered the procedures easy to perform.
Do you have a RDT (Rapid Diagnostic Test)?	Yes, the SARS-CoV-2 Antigen Self Test Nasal is considered a RDT.
How is the test interpreted?	<p>Interpreting the test results</p> <p>• 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. You may have performed the test incorrectly. Carefully read the Instructions for Use and repeat the test. If your test result is still invalid, please contact your doctor or a COVID-19 test center.</p> <p>• 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. Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. Your doctor may require you to undergo a PCR test to confirm the result.</p> <p>• 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.</p>
What is the performance of the test?	The clinical performance of the test was measured in three clinical studies. The overall relative sensitivity of the SARS-CoV-2 Antigen Self Test Nasal was 91.2% (CI ± 3.0); 94.9% and 100% in the three different studies. The overall relative specificity was 100%, 100% and 98.4% in the three studies, which represents the ability of the test to correctly identify patients without the virus. In one comparative independent self-testing study where patients followed written and illustrated instructions to sample, test, and read-out the results themselves, a majority of study participants considered the procedures easy to perform.
What happens if I read my result after the deadline?	As mentioned in the methodological insert "Do not read test results after 30 minutes." Test results that are read before 15 minutes or after 30 minutes may be incorrect.
When opening the packaging, is there a time limit to use the test?	The test should be used immediately after opening the pouch.
Is it a saliva test or oropharyngeal test?	No, it consists of a nasal test
I would like to have the user guide in English	https://www.roche.ca/roche/en/products/diagnostics/products/documentation/sars-cov-2-rapid-antigen-self-test.html
Do you have a video or presentation for test usage?	https://www.roche.ca/roche/en/products/diagnostics/products/documentation/sars-cov-2-rapid-antigen-self-test.html
What is the time between the sample and the test?	The sample should be tested as soon as possible after collection.
I would like to know if specific training is required to perform the test on patients.	<p>The SARS-CoV-2 Antigen Self Test Nasal may not be used to test others. It is intended for self-use in individuals aged 16 and older. The test may not be used in children younger than 16 or by lay users to test others. No specific training is necessary. It is an easy to use test, requiring just few handling steps.</p> <p>=> Please refer to the methodological insert and the quick user guide. => If you have any questions, please do not hesitate to contact us. => A video is available: https://www.roche.ca/roche/en/products/diagnostics/products/documentation/sars-cov-2-rapid-antigen-self-test.html</p>
After how long does it take for the result to be obtained?	The result should be read 15 to 30 min after the test. In the methodological insert it is stated in the section Performing the test: Test results that are read before 15 minutes or after 30 minutes may be incorrect.
Is it possible to do several antigen (Ag) tests from the same sample?	No, the kit consists of as many sampling consumables as there are tests. (5 per kit), so a single test for a single sample.
What is the expiration date of the product?	Kit materials are stable until the expiry date printed on the outer box
Are the swabs included in the box?	Yes
Is it possible to use a different swab than the one provided in the kit?	No, it is not possible to use a swab other than the one in the reagent box.
Why is this new test called antigen test?	This test is intended to detect the antigen of the SARS-CoV-2 virus (nucleocapsid protein) in individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection.
What are the antigens detected?	SARS-CoV-2 Antigen Self Test Nasal is a lateral flow immunoassay intended for qualitative detection of SARS-CoV-2 nucleocapsid protein antigen.
We would like on-site training for the use, is this possible?	<p>The SARS-CoV-2 Antigen Self Test Nasal is intended for self-use in individuals aged 16 and older. The test may not be used in children younger than 16 or by lay users to test others. No specific training is necessary. It is an easy to use test, requiring just few handling steps.</p> <p>=> Please refer to the methodological insert and the quick user guide. => If you have any questions, please do not hesitate to contact us. => A video is available: https://www.roche.ca/roche/en/products/diagnostics/products/documentation/sars-cov-2-rapid-antigen-self-test.html</p>
What is the expiration date of the product?	Kit materials are stable until the expiry date printed on the outer box
Technical information on the results	
What is the intended use of the SARS-CoV-2 Rapid Antigen Test Nasal?	<p>SARS-CoV-2 Antigen Self Test Nasal is a lateral flow immunoassay intended for qualitative detection of SARS-CoV-2 nucleocapsid protein antigen in human nasal samples from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection. Persons who test positive with the SARS-CoV-2 Antigen Self Test Nasal should seek follow-up care with their physician or health care provider as additional testing and public health reporting may be necessary. Positive results do not rule out bacterial infection or co-infection with other viruses. Persons who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow-up care with their physician or health care provider. All test results will be reported to health care providers and relevant public health authorities in accordance with local, provincial and federal requirements. The SARS-CoV-2 Antigen Self Test Nasal is intended for self-use in individuals aged 16 and older. The test may not be used in children younger than 16 or by lay users to test others.</p>
Should a negative test result be confirmed?	<p>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.</p>
How to interpret the results?	<p>• 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 kit. You may have performed the test incorrectly. Carefully read the Instructions for Use and repeat the test. If your test result is still invalid, please contact your doctor or a COVID-19 test center.</p> <p>• 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. Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. Your doctor may require you to undergo a PCR test to confirm the result.</p> <p>• 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.</p>
Does a positive test need to be confirmed by PCR testing?	Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. Your doctor may require you to undergo a PCR test to confirm the result.
The result of my rapid antigen test and that of the lab are different. What should I do?	Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. Your doctor may require you to undergo a PCR test to confirm the result.
What is the impact of the SARS-CoV-2 variants on the SARS-CoV-2 Antigen Self Test Nasal?	For our SARS-CoV-2 Rapid Antigen Self Test Nasal, in-vitro testing of the Alpha, Beta, Delta, Gamma and Delta variants has been performed and we can confirm that the test is suitable for detecting these SARS-CoV-2 variants. Concerning the Omicron VOC, in-silico analysis conducted at CD Biosensor showed no expected impact on performance from the mutation concerning this variant. Further wet-lab testing for confirmation is currently in progress. We will perform testing of other new variants and not both independently and in collaboration with our partner SD Biosensor. We will share our findings, as soon as these investigations have concluded. Since the recognition site of the new materials used in our SARS-CoV-2 Rapid Antigen Self Test Nasal are the C-terminal domain of the nucleocapsid protein and therefore different from mutation sites, we expect our products are theoretically able to detect these variants.
Who do I contact if I require additional technical assistance?	Contact the Roche Care Center by phone at 1-877-273-3433 or by email at lval.techn@roche.com
Regulatory and medical	
Who do I contact if I have a complaint with the product?	Contact the Roche Care Center by phone at 1-877-273-3433 or by email at lval.techn@roche.com
Is this test approved by Health Canada?	This test is approved for use under an Interim Order from Health Canada
What is the authorization number (Health Canada) of the product?	The Interim Order number is 333956