SARS-CoV-2 Rapid Antigen Test NASAL

Questions	Answers
Purchase - Ordering	
I am a health care professional and I would like to order the test	Roche SARS-CoV-2 Rapid Antigen Test Nasal has been authorized under Health Canada's Interim Order making it available to Canadian healthcare professionals. The Canadian team is currently working on the allocation strategy for the SARS-CoV-2 Rapid Antigen tests Nasal. Please contact laval.covid-19@roche.com or fill the online survey https://www.surveymonkey.com/r/6JJJF65 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 Rapid Antigen Test Nasal	Roche SARS-CoV-2 Rapid Antigen Test Nasal has been authorized under Health Canada's Interim Order making it available to Canadian healthcare professionals. The Canadian team is currently working on the allocation strategy for the SARS-CoV-2 Rapid Antigen tests Nasal. Please contact laval.covid-19@roche.com or fill the online survey https://www.surveymonkey.com/r/6JJJF65 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 Rapid Antigen Test Nasal	Roche SARS-CoV-2 Rapid Antigen Test Nasal has been authorized under Health Canada's Interim Order making it available to Canadian healthcare professionals. The Canadian team is currently working on the allocation strategy for the SARS-CoV-2 Rapid Antigen tests Nasal. Please contact laval.covid-19@roche.com or fill the online survey https://www.surveymonkey.com/r/6JJJF65 to signify your interest and a Roche representative will contact you shortly to provide further information.
I would like to order the SARS-CoV-2 Antigen Controls, how do I proceed?	Roche SARS-CoV-2 Rapid Antigen Controls has been authorized under Health Canada's Interim Order making it available to Canadian healthcare professionals. The Canadian team is currently working on the allocation strategy for the SARS-CoV-2 Rapid Antigen Controls. Please contact laval.covid-19@roche.com or fill the online survey https://www.surveymonkey.com/r/6JJJF65 to signify your interest and a Roche representative will contact you shortly to provide further information.
How many kits can I order?	Please contact laval.covid-19@roche.com or fill the online survey https://www.surveymonkey.com/r/6JJJF65 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 Rapid Antigen Test Nasal has been authorized under Health Canada's Interim Order making it available to Canadian healthcare professionals. The Canadian team is currently working on the allocation strategy for the SARS-CoV-2 Rapid Antigen tests Nasal. Please contact laval.covid-19@roche.com or fill the online survey https://www.surveymonkey.com/r/6JJJF65 to signify your interest and a Roche representative will contact you shortly to provide further information.
What is the SARS-CoV-2 Rapid Antigen Test Nasal product number for ordering?	Roche SARS-CoV-2 Rapid Antigen Test Nasal has been authorized under Health Canada's Interim Order making it available to Canadian healthcare professionals. The Canadian team is currently working on the allocation strategy for the SARS-CoV-2 Rapid Antigen tests Nasal. Please contact laval.covid-19@roche.com or fill the online survey https://www.surveymonkey.com/r/6JJJF65 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 Rapid Antigen Test Nasal ?	Roche SARS-CoV-2 Rapid Antigen Test Nasal has been authorized under Health Canada's Interim Order making it available to Canadian healthcare professionals. The Canadian team is currently working on the allocation strategy for the SARS-CoV-2 Rapid Antigen tests Nasal. Please contact laval.covid-19@roche.com or fill the online survey https://www.surveymonkey.com/r/6JJJF65 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 laval.covid-19@roche.com or fill the online survey https://www.surveymonkey.com/r/6JJJF65 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 Rapid Antigen Test Nasal ?	Please contact laval.covid-19@roche.com or fill the online survey https://www.surveymonkey.com/r/6JJJF65 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 laval.covid-19@roche.com or fill the online survey https://www.surveymonkey.com/r/6JJJF65 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
Where do I buy the control tests?	Controls have been authorized under Health Canada's Interim Order making it available to Canadian healthcare professionals. The Canadian team is currently working on the allocation strategy for the SARS-CoV-2 Rapid Antigen Controls. Please contact laval.covid-19@roche.com or fill the online survey https://www.surveymonkey.com/r/6JJJF65 to signify your interest and a Roche representative will contact you shortly to provide further information. The control box contains 10 positive and 10 negative controls swabs. Product reference number 09396276023.
Format and storage specifications	
What material is provided with the kit	• Test device (individually in a foil pouch with desiccant) • Extraction buffer tube • Nozzle cap • Sterile nasal swab • 1 QC positive swab and 1 QC negative swab • Paper stand • Instructions for use • Quick Reference Guide
How may tests per kit?	25
Are the tests individually wrapped?	The test strips are individually packaged in an aluminum bag with desiccant
Dimensions of the box? (For storage purpose)	Lenth 270 mm Width 150 mm Height 74 mm Weight 380 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
How do we store the samples?	Samples should be tested as soon as possible after collection. Specimen in extraction buffer are stable for up to 1 hour at room temperature (20±5 °C), up to four hours when stored refrigerated at 5±3 °C. If stored frozen at -20°C, specimen in extraction buffer are stable for only one (1) freeze/thaw cycle. Dry swab specimen are stable for 60 minutes at room temperature (20±5 °C).
What is included in the SARS-CoV-2 Antigen Control kit?	Each kit of SARS-CoV-2 Antigen Control contains (product code 09396276023) • Positive control : 10 QC positive swabs • Negative control : 10 QC negative swabs • Instructions for use
Technical information about the test	
What is the type of test?	The SARS CoV 2 Rapid Antigen Test Nasal is rapid lateral flow immunoassay for the qualitative detection of antigens specific to SARS CoV 2 present in the human nasal samples. This product is strictly intended for professional use in laboratory and Point of Care environments.
Do you provide a viral transport medium?	Our kit includes the extraction buffer solution tube. However, other transport media can be used. Use only the following MTVs: Copan UTM™ universal transport medium, BD™ universal viral transport, STANDARD™ transport medium.
What is the test procedure?	Tilt patient's head back slightly. While rotating the swab, insert swab approximately one inch (about 2 cm) into nostril until resistance is met at turbinates. Slowly rotate the swab in a circular path against the nasal wall at least 4 times for a minimum of 15 seconds. Repeat in other nostril using the same swab. Insert the swab from patient into an extraction buff er tube. While squeezing the buff er 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. Press the nozzle cap tightly onto the tube. Apply 4 drops of extracted specimen to the specimen well of the test device. Read test result at 15-30 minutes. The entire procedure is detailed in the Quick Reference Guide included with the test.
Do you need an instrument to run the SARS-CoV-2 Rapid AntigenTest Nasal?	No. The test comes as a separate single use test kit, presenting a visualized qualitative test result without an instrument needed. The test is ready for use without additional equipment.
Do you have a package insert ?	Yes, a Package Insert and a Quick guide are available. Link: https://www.rochecanada.com/en/products/diagnostics-products/documentation/canadian-package-inserts.html
Do you have comparative studies of the SARS-CoV-2 Rapid Antigen Test Nasal with the RT PCR tests?	Yes, the methodological insert includes the results of a a clinical study carried out with 696 patient samples Clinical performance of the SARS-CoV-2 Rapid Antigen Test Nasal was evaluated using nasal swab samples from 696 subjects in a prospective study at a clinical center in Germany. The study cohort included adults at high risk for SARS-CoV-2 infection according to clinical suspicion. 311 subjects underwent nasal sampling performed by healthcare professionals and 385 subjects followed instructions to obtain a nasal swab sample by themselves. Self-collection was performed under the supervision of healthcare workers without interference or assistance. Test procedures and result reading were always performed by healthcare professionals. RT-PCR tests (Roche cobas® SARS-CoV-2 and TibMolbiol SARS-CoV-2 E-gene assay) using combined nasopharyngeal/oropharyngeal swab samples were used as the comparator methods. Nasal sampling always preceded the combined NP/OP sampling. Look for the clinical performance section.
Do you have a rapid test ?	Yes, this is a SARS-CoV-2 Rapid Antigen Test Nasal
Is your kit reliable?	For patients for whom days post symptom onset was known, and was 0-5 days, the relative sensitivity in comparison to RT-PCR was 86.7 % for professionally collected nasal samples (95 % CI: 75.4 % - 94.1 %) and 88.9 % for self-collected nasal samples (95 % CI: 77.4 % - 95.8 %). The relative specificity in comparison to RT-PCR was 99.1 % for professionally collected nasal samples (95 % CI: 96.9 % -99.9 %) and 99.0 % for self-collected nasal samples (95% CI: 97.2 % -99.8 %)
Do you have a RDT (Rapid Diagnostic Test)?	Yes, the SARS-CoV-2 Rapid Antigen Test Nasal is considered a RDT.
How is the test interpreted?	•A colored line appears in the top section of the result window to show that the test is working properly. This line is the control line (C). Even if the control line is faint or not uniform, the test should be considered to be performed properly. If no control line is visible the test result should be considered as invalid. • In case of a positive result, a colored line appears in the lower section of the result window. This line is the test line of the SARS-CoV-2 antigen (T). Even if the test line is very faint or not uniform the test result should be interpreted as a positive result.
What is the performance of the test?	For patients for whom days post symptom onset was known, and was 0-5 days, the relative sensitivity in comparison to RT-PCR was 86.7 % for professionally collected nasal samples (95 % CI: 75.4 % - 94.1 %) and 88.9 % for self-collected nasal samples (95 % CI: 77.4 % - 95.8 %). The relative specificity in comparison to RT-PCR was 99.1 % for professionally collected nasal samples (95 % CI: 96.9 % -99.9 %) and 99.0 % for self-collected nasal samples (95% CI: 97.2 % -99.8 %)
What happens if I read my result after the deadline?	As mentioned in the methodological insert "Do not read test results after 30 minutes. They could be wrong."
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.rochecanada.com/en/products/diagnostics-products/documentation/canadian-operator-manuals.html
Do you have a video or presentation for test usage?	https://www.rochecanada.com/en/products/diagnostics-products/documentation/canadian-operator-manuals.html
What is the time between the sample and the test?	The sample should be tested as soon as possible after collection. Samples in Extraction Buffer can be stored for up to 1 hour at room temperature or up to 4 hours at 2-8 ° C prior to analysis. If stored frozen at -20°C, specimen in extraction buffer are stable for only one (1) freeze/thaw cycle.
If the sample has been refrigerated for less than 4 hours should I wait for it to come to room temperature before proceeding with the analysis?	When using viral transport medium (VTM), it is important to ensure that the VTM containing the sample is warmed to room temperature. Cold samples will not flow correctly and can lead to erroneous or invalid results. Several minutes will be required to bring a cold sample to room temperature.
I would like to know if specific training is required to perform the test on patients.	No specific training is necessary. It is a an easy to use test, requiring just few handling steps. => 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.rochecanada.com/en/products/diagnostics-products/documentation/canadian-operator-manuals.html
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 warnings and precautions: Section: 2. The test results should be read between 15 and 30 minutes after application of a sample to the sample well. Do not read the test results after 30 minutes. It may give false results.
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. (25 per kit), so a single test for a single sample.
Are there any control solutions?	A control kit including positive and negative quality controls is available separately from Roche (Material: 09338322190 SARS-CoV-2 Antigen Control).
What is the expiration date of the product?	Kit materials are stable until the expiry dat 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 suspected of having COVID-19.
What are the antigens detected?	The SARS-CoV-2 Rapid Antigen Test Nasal is a lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 nucleoprotein antigen present in the human nasal samples. This test is intended to detect specific antigen from the SARS-CoV-2 virus in individuals suspected of COVID-19.
We would like on-site training for the use, is this possible?	Unfortunately no. It is a an easy to use test, requiring just few handling steps. => Please refer to the methodological insert and the quick user guide. => If you have any questions, please do not hesitate to contact the Roche Care Center at 1-877-273-3433 => A video is available: https://www.rochecanada.com/en/products/diagnostics-products/documentation/canadian-operator-manuals.html
Do we have to run control tests?	A control kit, including both positive and negative quality controls is available separately (Material: 09338322190 SARS-CoV-2 Antigen Control). The SARS-CoV-2 Antigen Control is intended for use as an external quality control material to monitor the performance of the SARS-CoV-2 Rapid Antigen Test Nasal and is optional. **Use recommendations:** Customers can perform positive and negative controls: • Once for each new lot • Once for each untrained operator • Once for each new shipments of test kits • As required by test procedure instructions, in accordance with local, state, and federal regulations.
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?	The SARS-CoV-2 Rapid Antigen Test Nasal is a lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 nucleoprotein antigen in human nasal samples from individuals who are suspected of COVID-19 by their healthcare provider within the first 5 days of the onset of symptoms. The SARS-CoV-2 Rapid Antigen Test Nasal is intended for use by trained laboratory personnel and healthcare professionals for laboratory use or point of care testing and for self-collection under the supervision of a healthcare worker. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. This assay is not intended to be used for diagnostics. This assay is not intended for home testing (or self-testing).
Should a negative test result be confirmed?	• A negative result may occur if the concentration of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly. Therefore a negative test result does not eliminate the possibility of SARS CoV 2 infection, and should be confirmed by viral culture or a molecular assay or ELISA, if necessary for patient management. Negative test results are not intended to rule in or rule out other coronavirus infection.
How to interpret the results?	• A colored line appears in the top section of the result window to show that the test is working properly. This line is the control line (C). Even if the control line is faint or not uniform, the test should be considered to be performed properly. If no control line is visible the test result should be considered as invalid. • In case of a positive result, a colored line appears in the lower section of the result window. This line is the test line of the SARS CoV 2 antigen (T). Even if the test line is very faint or not uniform the test result should be interpreted as a positive result.
Does a positive test need to be confirmed by PCR testing?	Please refer to your Provincial Public Health authorities for their recommendations regarding test usage and results management.
The result of my rapid antigen test and that of the lab are different. What should I do?	Please refer to your Provincial Public Health authorities for their recommendations regarding test usage and results management.
What is the impact of the SARS-CoV-2 variants on the SARS-CoV-2 Rapid Antigen Test Nasal?	For our SARS-CoV-2 Rapid Antigen Test Nasal, in-vitro testing of the Alpha, Beta, Gamma, Delta and Omicron variants has been performed and we can confirm that the test is suitable for detecting these SARS-CoV-2 variants. We will perform testing of other new variants and our test both independently and in collaboration with our partner SD Biosensor. We will share our findings, as soon as these investigations have concluded. The performance of the device has not been assessed on specimens from individuals who have been infected with emerging variants of SARS-CoV-2 of public health concern.
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 laval.techinfo@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 laval.techinfo@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 328889
Potential Risks	
What are the potential risks associated with the misuse or accidental ingestion or spillage of the SARS-CoV-2 Rapid Antigen Test NASAL test kit solutions on the skin?	Health Canada has determined that the kits are safe and effective when used as intended. Solution provided contains sodium azide as a preservative which may be toxic if ingested. If accidental ingestion occurs, seek medical advice. If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, seek medical advice. In the event of a spillage, ensure that it is cleaned thoroughly using a suitable disinfectant What to do: - Keep rapid antigen test kits and solutions out of the reach of children and pets. - Do not swallow the solutions, and avoid eye and skin contact. - Wash hands thoroughly after use. - If spillage occurs, rinse well with water. - Follow all instructions for proper disposal. - Report any health product-related side-effects or complaints to Health Canada. - Contact your local Poison Information and Control Centre in cases of accidental ingestion or direct skin exposure to test kit solutions.