Rapid Response™ COVID-19 Antigen Rapid Test Cassette
At Home
Product Insert
REF COV-19CSHC, COV-19CSHC1, COV-19CSHC2, COV-19CSHC5, COV-19CSHC25

INTENDED USE

The Rapid Response™ COVID-19 Antigen Rapid Test Cassette - At Home is an *in vitro* immunochromatographic assay intended to detect nucleocapsid protein antigen from SARS-CoV-2 virus that causes COVID-19 in nasal swab samples from individuals suspected of COVID-19 within 7 days of symptom onset and from individuals without symptoms or other epidemiological reasons to suspect COVID-19 infection. This device is authorized for home-use in a non-laboratory setting with direct anterior nasal (nares) swab samples for:

- Unobserved self-collection for individuals aged 18 years or older
- Adult supervised self-collection for individuals for ages 14 or older
- Adult collection from individuals aged 2 years or older

This test is authorized for home use only under the Health Canada Interim Order.

The Rapid Response™ COVID-19 Antigen Rapid Test Cassette - At Home does not differentiate between SARS-CoV and SARS-CoV-2.

People who test positive with the Rapid Response™ COVID-19 Antigen Rapid Test Cassette - At Home should seek follow up care with their physician or healthcare 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. People 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 healthcare provider.

The Rapid Response™ COVID-19 Antigen Rapid Test Cassette - At Home is intended for self-use and/or, as applicable for an adult lay user testing for another person aged 2 years or older in a non-laboratory setting. The Rapid Response™ COVID-19 Antigen Rapid Test Cassette - At Home is only for use under the Health Canada Interim Order.

PRINCIPLE

The Rapid Response™ COVID-19 Antigen Rapid Test Cassette - At Home detects SARS-CoV-2 viral antigens through visual interpretation of colour development. Anti-SARS-CoV-2 antibodies are immobilized on the test region of the nitrocellulose membrane. Anti-SARS-CoV-2 antibodies conjugated to coloured particles are immobilized on the conjugated pad. A sample is added to the extraction buffer which is optimized to release the SARS-CoV-2 antigens from specimen.
Nasal swabs require sample preparation in which the sample is eluted into the extraction buffer solution. The sample is then added to the sample well of the test device to initiate the test. During testing, the extracted antigens bind to anti-SARS-CoV-2 antibodies conjugated to coloured particles. As the specimen migrates along the strip by capillary action and interacts with reagents on the membrane, the complex will be captured by the anti-SARS-CoV-2 antibodies at the test region. Excess coloured particles are captured at the internal control zone.
Test results are interpreted visually 10 minutes after loading the sample to the sample well according to the test instructions. The presence of a coloured line in the test region, “T”, indicates a positive result for the SARS-CoV-2 viral antigens, while its absence indicates a negative result. A coloured line at the control region, “C”, should always appear and serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking is working. No appearance of a coloured lined in the control region indicates an invalid test result.

MATERIALS

Materials Provided

- Individually packed Test Cassette(s): Test cassettes with encased test strip and desiccant
- Prefilled Extraction buffer tube(s)
- Individually packed nasal swab(s)
- Waste bag(s)
- Package insert: Instructions for Use

NOTE: The test kit comes in 1, 2, 5 and 25 test quantities. The number of individual items supplied in the kit will vary depending on the kit quantity.

Materials Required but Not provided

Clock, timer, or stopwatch

WARNINGS AND PRECAUTIONS

- For *in vitro* Diagnostic Use Only.
- Read the Product Insert prior to use. In order to obtain accurate results, directions should be read and followed carefully.
- Do not use kit or components beyond the expiration date which is printed on the outer packaging.
- Do not use the test on anyone under 2 years old. Children aged 2 and up should be tested by an adult. Children 14 and above may test themselves under adult supervision.
- Wear a safety mask or other face-covering when collecting anterior nares swab specimen from a child or another person.
- Wash hands thoroughly for at least 20 seconds before and after handling nasal swab samples.
- Blood or mucus on the swab specimen may interfere with test performance and may yield a false-positive result. Avoid touching any bleeding areas of the nasal cavity when collecting specimen.
- Inadequate or inappropriate sample collection, storage, and transport can yield incorrect results.
- When collecting a nasal swab sample, use only the nasal swab provided in the kit.
- Do not touch the tip (specimen collection end) of the swab. Handle the swab by the non-absorbent end.
- Keep testing kit and kit components away from children and pets before and after use.
- Keep foreign substances and household cleaning products away from the test during the testing process. Contact with foreign substances and household cleaning products may result in an incorrect test result.
- Use appropriate precautions in the collection, handling, storage, and disposal of samples and used kit contents.
- Test devices are packaged in foil pouches that exclude moisture during storage. Inspect each foil pouch before opening.
- Handle all specimens as though they contain infectious agents.
- Do not operate your test outside of operating conditions. Failure to bring specimens and reagents to room temperature before testing may decrease assay sensitivity. Inaccurate or inappropriate specimen collection, storage, and transport may yield false negative test results.
- Do not interpret the test result before 10 minutes or more than 20 minutes after starting the test.
- Do not use if the test device package is damaged.
- Do not use devices that have holes in the foil or where the pouch has not been completely sealed. Erroneous result may occur if test reagents or components are improperly stored. Use test device immediately after removing it from the pouch.
- Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.
- Do not interchange kit contents from different lots.
- Do not re-use any contents in the kit as they are single-use only.
- All specimens must be mixed thoroughly before testing to ensure a representative sample.
- Do not use the Extraction Buffer if it is discoloured or turbid. Discolouration or turbidity may be a sign of microbial contamination.
- Test kit solutions should only be used as directed; do not ingest; do not dip the swab into provided solution or other liquid before inserting the swab into the nose; avoid contact with skin and eyes; keep out of the reach of children and pets.
- The reagent solution contains Proclin-300 (0.03%) which may be hazardous to the skin and eye. Please see the below table for safety recommendations.

Contact	Risk	First-aid measures
Ingestion	Toxicity	Rinse mouth with water. If irritation or signs of toxicity occur, seek medical attention.
Eye contact	May cause eye irritation	Wash with copious amounts of water for approx. 15 minutes with eyelid held open. If irritation or signs of irritation, pain or toxicity occur, seek medical attention.
Skin contact	May cause skin irritation	Wash affected area with plenty of water. If irritation or signs of toxicity occur, seek medical attention.

- If the reagent solution contacts the skin or eye, flush with plenty of water. If irritation persists, seek medical advice and contact your local Poison Control Centre.

LIMITATIONS OF THE TEST

1. The Rapid Response™ COVID-19 Antigen Rapid Test Cassette - At Home is for *in vitro* diagnostic use and should only be used for the qualitative detection of SARS-CoV-2 antigens in anterior nasal swab specimens only. The intensity of colour in a positive line should not be evaluated as "quantitative or semi-quantitative".
2. Both viable and nonviable SARS-CoV-2 viruses are detectable with the Rapid Response™ COVID-19 Antigen Rapid Test Cassette - At Home.
3. Failure to follow the test procedure in any of the following steps may adversely affect test performance and/or invalidate the test result.
4. A false negative result may occur if the level of antigen in a sample is below the detection limit of the test.
5. A false negative result may occur if the sample was incorrectly collected or handled.
6. An incorrect result may occur if less than or more than 3 drops of fluid are added to the sample well.
7. Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.
8. 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.
9. This device has been evaluated for use with human specimen material only.
10. This test and the results from this test do not establish that user has acquired immunity to COVID-19.
11. The performance of this device has not been assessed in a population vaccinated against COVID-19.

STORAGE AND STABILITY

- Store the Rapid Response™ COVID-19 Antigen Rapid Test at 2~30°C when not in use.
- The test device must remain in the sealed pouch until use.
- **DO NOT FREEZE ANY OF THE CONTENTS OF THE KIT.**
- Do not use after the expiration date.

SPECIMEN COLLECTION AND STORAGE

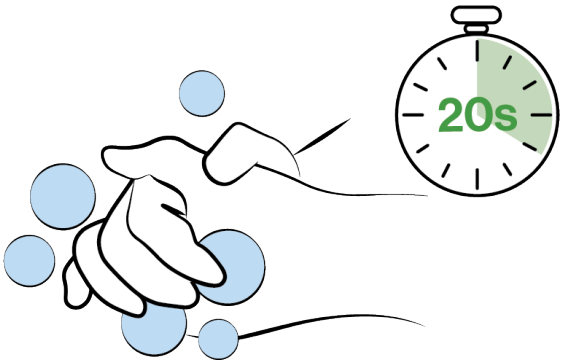
- Acceptable specimen type for testing with the Rapid Response™ COVID-19 Antigen Rapid Test is a direct anterior nasal (nares) swab specimen. It is essential that correct specimen collection and preparation methods be followed. Inadequate specimen collection, improper specimen handling and/or transport may yield false results.
- Use freshly collected specimen for best test performance. Process the test swab sample immediately after collection.
- Do not use specimen that are obviously contaminated with blood, as it may interfere with the flow of sample and with the interpretation of test results.

TEST PROCEDURE

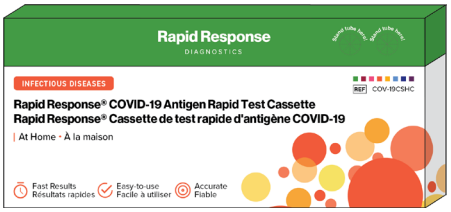
Bring devices, reagents, and specimens and/or controls to room temperature (15~30°C) before use.

Before taking your sample:

1) Before starting the test, wash your hands thoroughly with soap and water or use hand sanitizer. Make sure they are dry before starting. If you are performing more than one test, wash your hands again between each test.

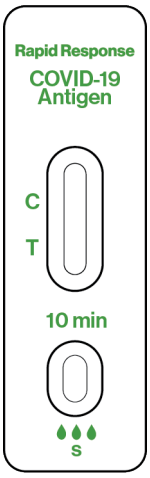


For each test you will need:

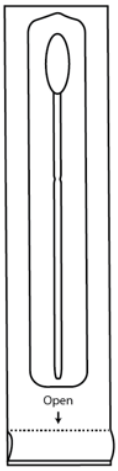


Outer box with tube holder

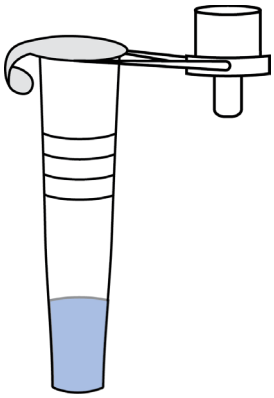
Instructions for use (this pamphlet)



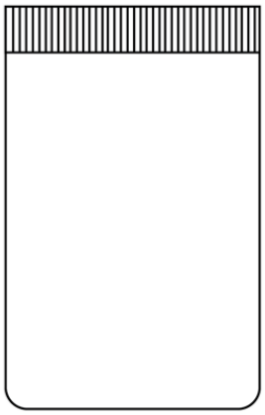
Test Cassette (in sealed pouch)



Swab



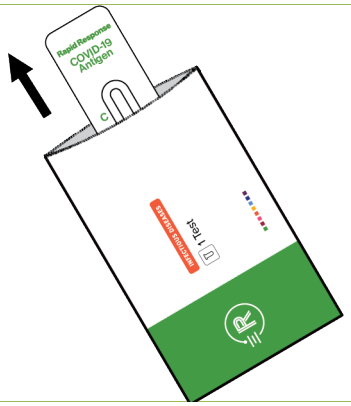
Extraction Buffer Tube



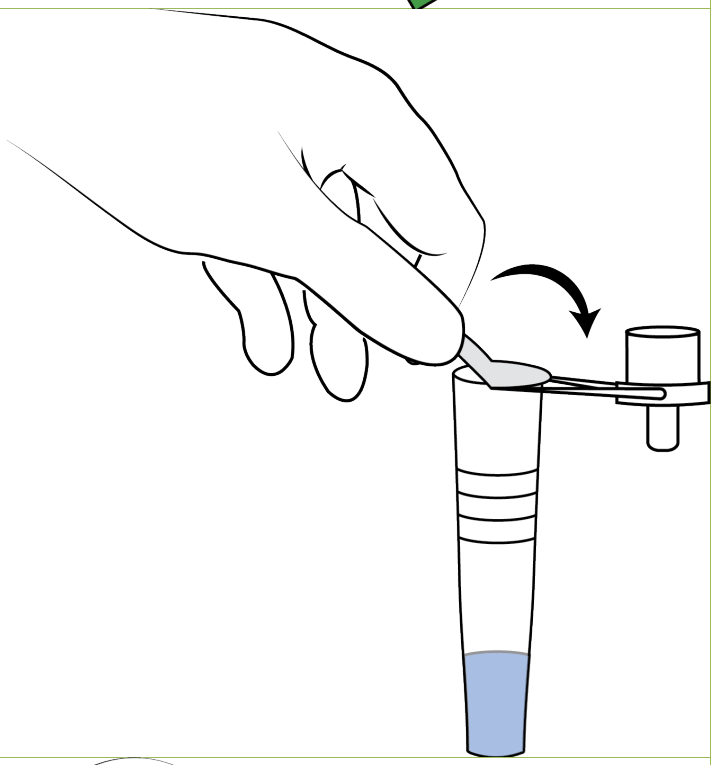
Waste Bag

Tube stand

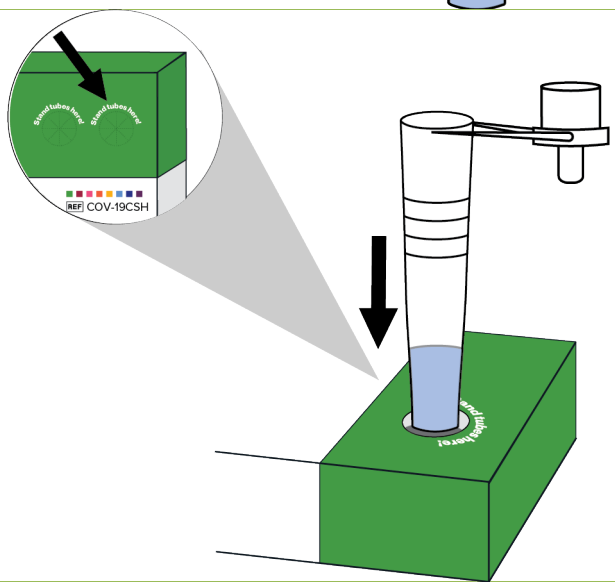
2) Unpack the test components from the kit and make sure that all the packaging is intact. Remove the test cassette from the pouch and place it on a clean, flat surface.



3) Tear the aluminum foil off the top of the extraction buffer tube.



4) Place the extraction buffer tube upright in the tube stand or hole on the packaging.



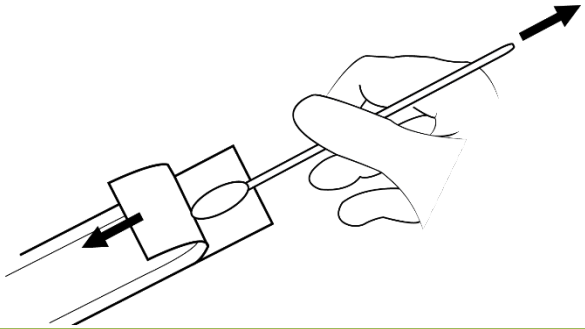
Nasal Swab Collection:

5) Gently blow your nose into a tissue to remove excess mucus and discard used tissue in the garbage. Wash your hands again.

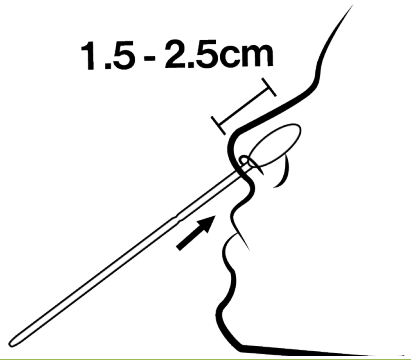
Avoid using bloody samples.

6) Check that the swab wrapper is properly sealed. Only when you are ready to use it, gently peel open the packaging of the swab from the indicated end and hold swab by the stem.

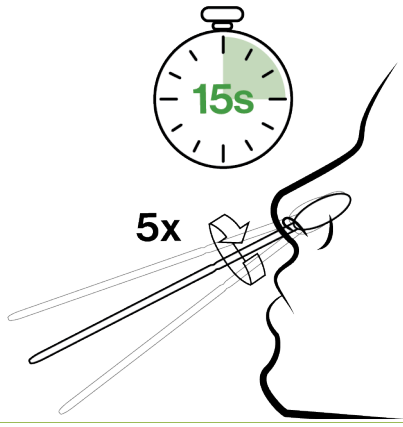
Do not touch the padded fabric tip of the swab. If it has been touched you must discard the swab.



7) Insert the entire absorbent tip of the swab about 1.5 – 2.5 cm (1/2 to 1 inch) inside the nostril.

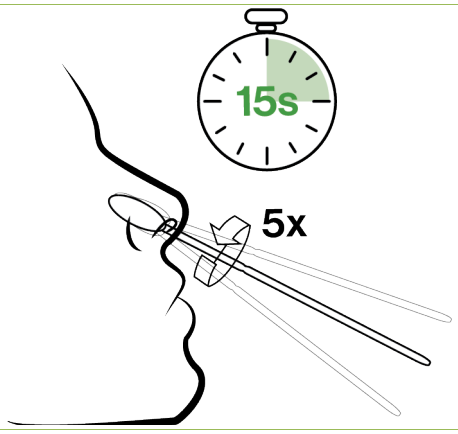


8) Using a wide circular motion, roll and twist the swab against the inside of your nostril at least 5 times. Make sure to swab all around the nasal cavity. Swab each nostril for about 15 seconds.



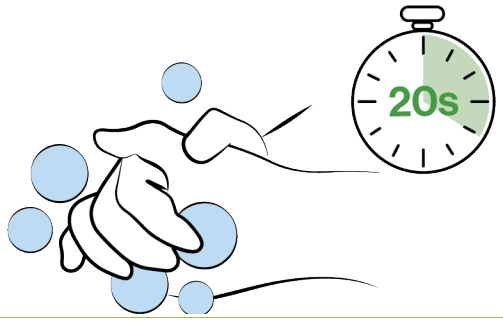
9) Pull the swab out while twisting and repeat in the other nostril using the same swab.

When you are done swabbing, do not return the used swab to the swab packaging.

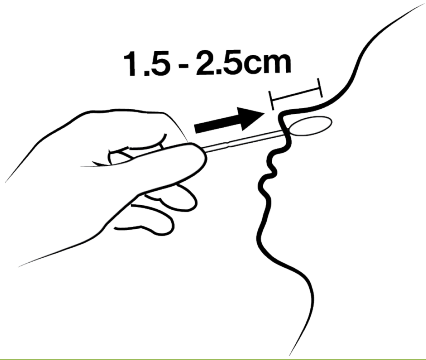


Collecting a nasal swab from someone else or from a child:
Children under 14 should be tested by an adult. Follow the guidelines below on how to test on a child.

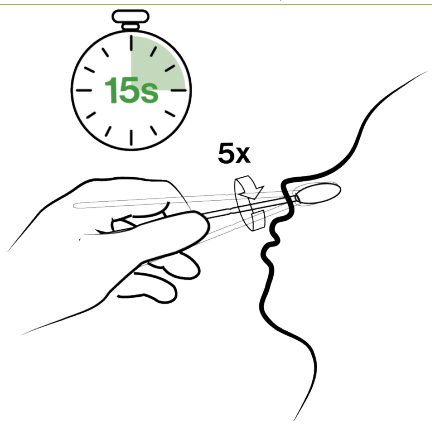
10) Show the child the test kit and explain what you are going to do. Following the same procedure as for self-collection, have the child blow their nose and both the child and the adult conducting the test should wash their hands with soap and water or use sanitizer for 20 seconds.



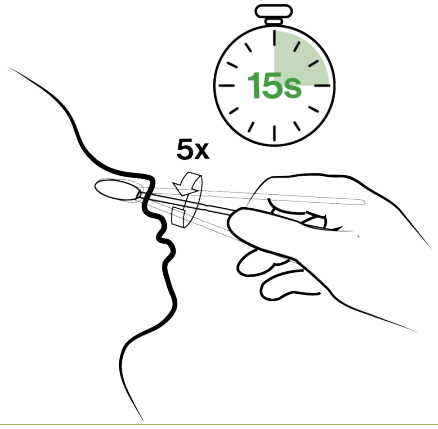
11) While the child is still, insert the fabric swab about 1.5-2.5cm into the nostril until you feel some resistance. Be conscious that the depth for swabbing may be less than for an adult.



12) Using a circular motion, gently roll and twist the swab against the inside of their nostril at least 5 times for about 15 seconds. Make sure to swab all around the nasal cavity



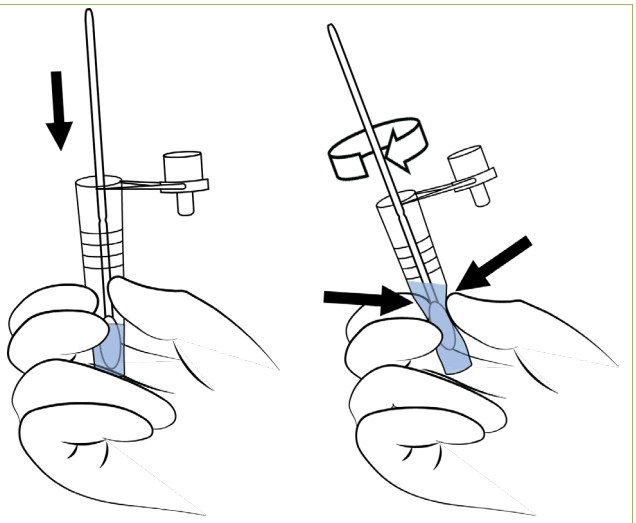
13) Slowly pull the swab out while twisting and repeat in the other nostril using the same swab. Do not return the swab into the original paper packaging.



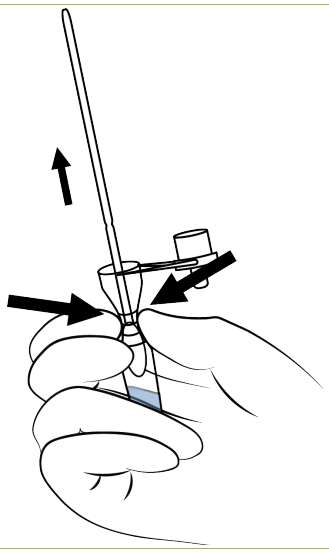
Note: You do not have to push the swab far into the nostril. The nasal swab is not sharp and should not hurt. It may feel slightly uncomfortable. If you feel pain, please stop the test, and seek advice from a healthcare provider.

Processing the Sample:

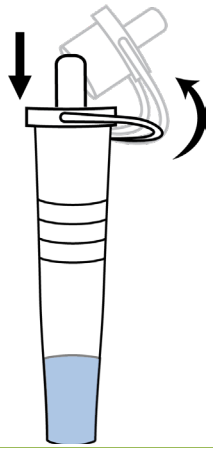
14) Pick up the extraction buffer tube and place the swab with the sample into the liquid inside the extraction buffer tube.
15) While holding the tube, swirl the swab, rotating for at least 10 seconds to mix well. Squeeze the swab 10-15 times by pinching the tube, compressing the walls of the tube against the swab while rotating the swab.



16) Remove the swab while squeezing the tube to squeeze as much liquid out of the swab as possible. Throw the used swab away in the waste bag provided in the kit.

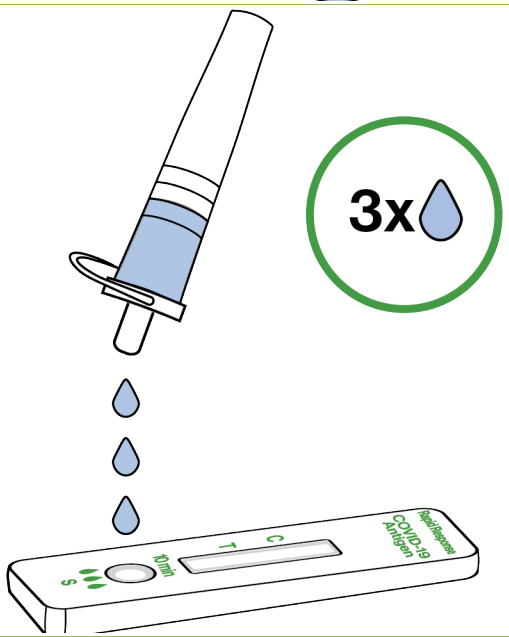


17) Secure the nozzle dropper cap tightly onto the top of the extraction tube.



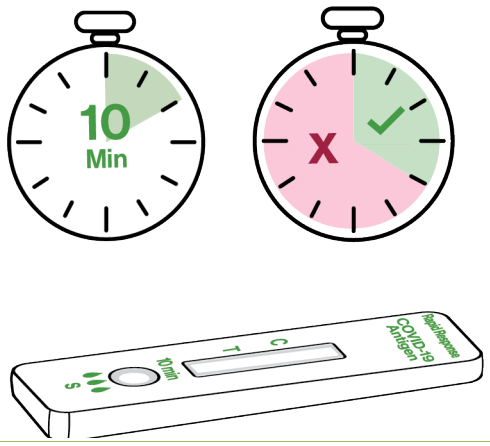
18) Invert the tube and add 3 drops of the extracted solution into the sample well (S) of the test cassette by gently squeezing the tube. Make sure that the liquid is coming out, not air bubbles.

Afterwards, place the extraction tube in the plastic waste bag provided.

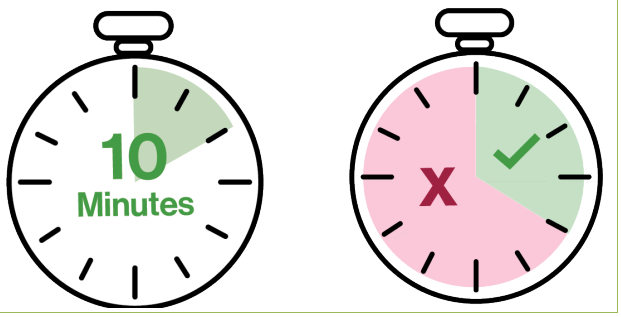


19) Start a timer and wait for ten (10) minutes before reading the results.

Do not move the test cassette once the test has started running.

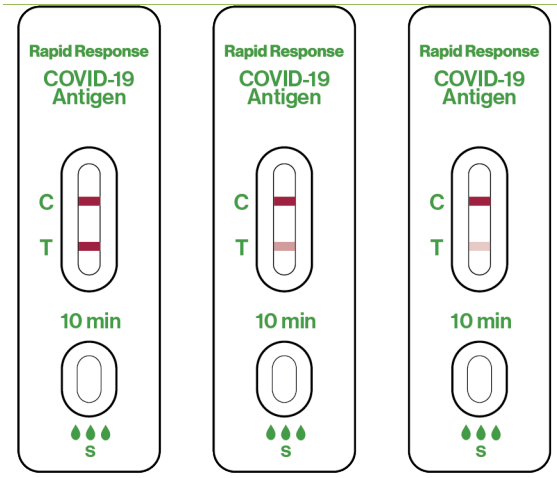


You must wait the full 10 minutes before reading the test results.
Do not read or interpret the results after 20 minutes.



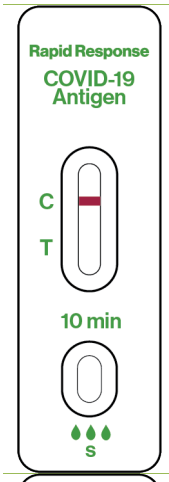
Wash hands thoroughly with soap and water or use hand sanitizer when you are done.

RESULT INTERPRETATION



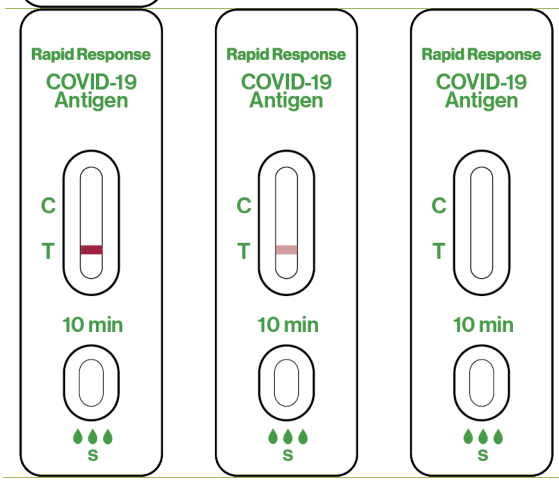
POSITIVE: COVID-19 Detected
Two coloured lines appear on the membrane. One line appears in the control region (C) and another line appears in the test region (T).
IMPORTANT: Look very closely! Any faint colored line in the test region should be considered positive.

A positive test result for COVID-19 indicates that antigens from SARS-CoV-2 were detected, and the person is very likely to be infected with the virus and presumed contagious. Test results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in making a final diagnosis and patient management decisions. Patient management should follow current health guidelines. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.



NEGATIVE: COVID-19 Not Detected.
Only one coloured line appears, in the control region (C). No apparent coloured line appears in the test region (T).

Negative results do not rule out SARS-CoV-2 infection. All negative results are considered presumptive, and confirmation with a molecular assay, if necessary for patient management, may be performed. The amount of antigen in a sample may decrease as the duration of illness increases. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19 and confirmed with a molecular assay, if necessary, for patient management.



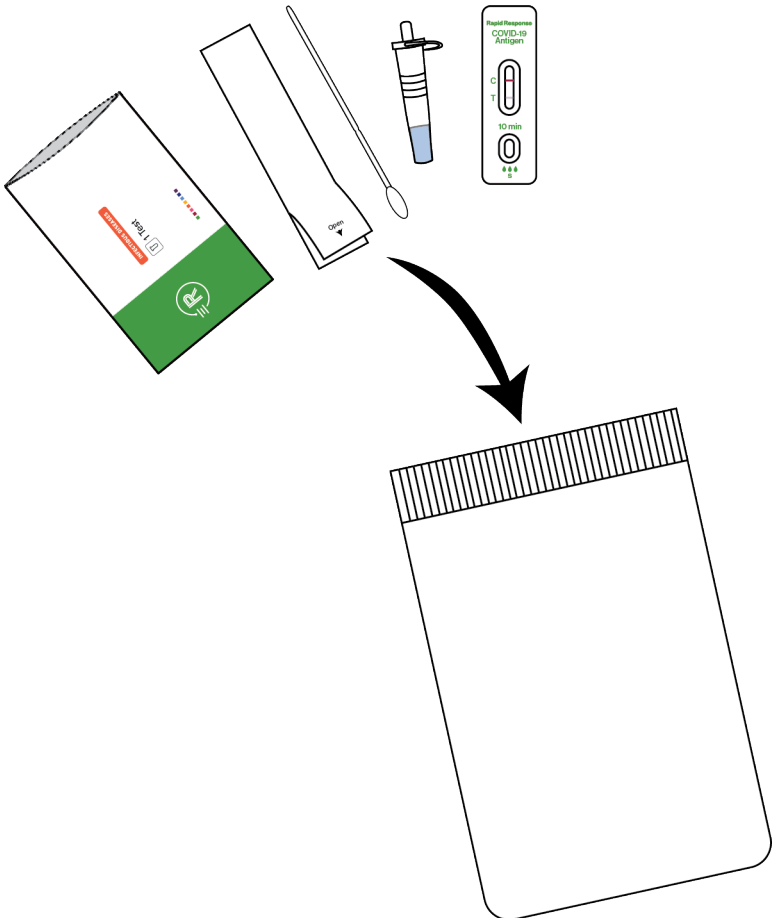
INVALID: Control line fails to appear. Results from any test which has not produced a control line at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, consult a healthcare professional.
If you still have symptoms, you should self-isolate at home and avoid contact with others prior to retesting.

NOTE:
1. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control line failure.

2. For questions or to report a problem, please call technical support at 1-888-339-9964 (MON-FRI 9AM – 5PM EST) or email support@btnx.com

DISPOSAL

Once your test is complete and you have your results, put all used contents in the waste bag provided and throw it out with regular trash.
For kits with more than one test, you should keep the tube stand and the instructions until you have used all of the tests in your kit.
Wash hands thoroughly.



QUALITY CONTROL

Internal Procedural Controls
The Rapid Response™ COVID-19 Antigen Rapid Test Cassette - At Home has built-in (procedural) controls. Each test device has an internal standard zone to ensure proper sample flow. The user should confirm that the coloured line located at the "C" region is present before reading the result.

FREQUENTLY ASKED QUESTIONS

What are the risks and benefits of this test?
Potential risks include:
- Possible discomfort during sample collection.
- Possible incorrect results (see Result Interpretation section).

Potential benefits include:
- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

What is the difference between an antigen and molecular test?
There are different kinds of tests for diagnosing COVID-19. Molecular tests (also known as PCR tests)

detect genetic material from the virus. Antigen tests, such as this one, detect proteins from the virus. Antigen tests are very specific for the virus but are not as sensitive as molecular tests. This means that while positive results are highly accurate, negative results do not rule out infection.

What if I have a positive test result?

If you have a positive test result, it is very likely that you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. There is a very small chance that this test can give a positive result that is wrong (a false positive result). If you test positive with the Rapid Response™ COVID-19 Antigen Home Test you should self-isolate and seek follow-up care with your healthcare provider. Additional testing may be necessary.

What if I have a negative test result?

A negative test result means that proteins from the virus that causes COVID-19 were not detected in your sample. It is possible for this test to give a negative result that is incorrect (a false negative result) for some people with COVID-19. You could still have COVID-19 even though the test is negative. The amount of antigen in a sample may decrease over time and would then be more likely to be negative compared to a molecular assay.

If you test negative but continue to have COVID-19 symptoms, seek follow up care from your healthcare provider.

Can this test detect variants?

Yes, the test can detect different variants. Detailed information available on request.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity (Limit of Detection):

The limit of detection was determined with a quantified SARS-CoV-2 virus and has been evaluated at 1000 $TCID_{50}$/mL.

Clinical Study of Rapid Response™ COVID-19 Antigen Rapid Test Cassette – At Home

The performance of the Rapid Response™ COVID-19 Antigen Rapid Test Cassette – At Home was established in an "all comers" style, randomized, blinded clinical study conducted at six sites in the U.S. between February 2021 and March 2021 compared to an FDA EUA approved RT-PCR molecular assay as a comparator method. Participants without laboratory experience self-tested in a simulated home use environment where they could not see or hear the other participants and were provided the instructions for use and no further training. Anterior nasal swabs were collected from individual asymptomatic and symptomatic individuals (within 7 days from symptom onset) who were suspected of COVID-19. Two samples from each patient were collected – one for PCR and another for the Rapid Antigen test. 91 positive specimens and 328 negative specimens were confirmed by RT-PCR.

Table 1: Rapid Response™ COVID-19 Antigen Rapid Test Cassette - At Home Clinical Evaluation with Nasal Swabs:

		RT-PCR		Total
		Positive	Negative	
Rapid Response™ COVID-19 Antigen Rapid Test Cassette - At Home	Positive	86	2	88
	Negative	5	326	331
Total		91	328	419

Relative Sensitivity: 94.51% (95% CI*: 87.64% - 98.19%)*
Relative Specificity: 99.39% (95% CI*: 97.81% - 99.93%)*
Relative accuracy: 98.33% (95% CI*: 96.59% - 99.33%)*
*Confidence Interval

Cross Reactivity and Microbial Interference.

Cross reactivity and Microbial interference with the following organisms has been studied. Cross

reactivity studies were done to show that the following organisms will not produce a false positive result in the absence of SARS-CoV-2. The same substances were tested in the presence of inactivated SARS-CoV-2 to demonstrate that the organisms will not cause false negatives results. Low concentration of SARS-CoV-2 was spiked into the higher concentrations of interfering organism. No cross reactivity or microbial interference was observed for samples positive for the following organisms when tested with the Rapid Response™ COVID-19 Antigen Rapid Test Cassette - At Home:

Adenovirus -Type 7A	Enterovirus	Human Metapneumovirus (hMPV)
Influenza A H1N1 (New Cal/20/99)	Influenza B (Florida/02/06)	Parainfluenza virus 1
Parainfluenza virus 2	Parainfluenza virus 3	Parainfluenza virus 4
Respiratory syncytial virus-Type A	Rhinovirus (Type 1A)	Bordetella pertussis
Candida albicans	Haemophilus influenzae	Legionella pneumophila
Mycobacterium tuberculosis	Mycoplasma pneumoniae	Pneumocystis jirovecii (PJP)-S. cerevisiae Recombinant
Pseudomonas aeruginosa	Staphylococcus epidermis	Streptococcus pneumoniae
Streptococcus pyogenes	Streptococcus salivarius	Human coronavirus 229E
Human coronavirus OC43	Human coronavirus NL63	MERS-coronavirus
Staphylococcus aureus	Chlamydophila pneumoniae	Streptococcus dysgalactiae subsp.
Streptococcus agalactiae (Z019)	Streptococcus agalactiae (Z023)	Streptococcus constellatus
Pooled human nasal wash		

To estimate the likelihood of cross-reactivity with SARS-CoV-2 virus in the presence of organisms that were not available for wet testing, In silico analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology. Homology exists with HKU1 nucleocapsid protein, although it is relatively low, cross reactivity cannot be ruled out. But for with SARS-COV, homology is high for SARS-CoV-2 nucleocapsid protein and cross-reactivity cannot be ruled out.

Interfering Substances

The following substances, naturally present in respiratory specimens or which may be artificially introduced into the respiratory tract were evaluated at the concentrations listed below. None of them were found to affect test performance of the Rapid Response™ COVID-19 Antigen Rapid Test Cassette - At Home in the presence or in the absence of SARS-CoV-2 virus:

Substance	**Conc.**	**Substance**	**Conc.**
Whole Blood	4%	Sucrets (Dyclonine hydrochloride)	1.5mg/ml
Mucin	0.50%	Chloraseptic (Benzocaine/Menthol)	1.5mg/ml
Ricola (Menthol)	1.5mg/ml	ZICAM Nasal Gel (Oxymetazoline hydrochloride)	10% v/v
Fisherman's Friend (Menthol)	1.5mg/ml	ZICAM Cold Remedy (Galphimia glauca/ Luffa operculate/Sabadilla)	5% v/v
Oseltamivir phosphate	5 mg/ml	Sore Throat Spray (Phenol/Glycerin)	15% v/v
Mupirocin	10mg/ml	Equate Nasal Drops (Phenylephrine hydrochloride)	15% v/v
Tobramycin	4 µg/ml	HealthGuard Nasal Spray (Cromolyn)	15% v/v
Naso GEL (NeilMed)	5% v/v	Afrin (Oxymetazoline hydrochloride)	15% v/v
Nasal wash (Alkalol)	10% v/v	Allergy relief nasal spray (Fluticasone Propionate)	5% v/v

High Dose Hook Effect

No high dose hook effect was observed when tested with up to a concentration of 1.15×10^7 $TCID_{50}$/mL of inactivated SARS-CoV-2 virus with the Rapid Response™ COVID-19 Rapid Test Cassette - At Home.

Usability Study

A study was conducted to evaluate whether lay-users can understand the instructions provided and successfully perform the test procedure for Rapid Response™ COVID-19 Antigen Rapid Test Cassette - At Home, including nasal specimen collection, extracting the specimen, adding it to the test cassette, and correctly interpret the results.

A total of 104 participants were enrolled in the lay user study and were instructed to self-collect nasal samples. The lay users were then asked to complete the required procedural steps and interpret the test results unassisted in a simulated personal use setting. The performance and usability was evaluated at

different levels using a questionnaire based survey for both the observer and the lay users. The digital scale used was with 1-very easy, 2-easy, 3-neutral, 4-somewhat difficult, and 5-difficult. 90.4% of participants rated the comprehensibility of the instructions as 'very easy' to 'easy' corresponding to a very good average score of 1.55. 94.8% of the study participants also predominantly rated the test execution as 'very easy' to 'easy' corresponding to average score of 1.41. All of the 104 participants correctly interpreted the results of their tests. 93% of participants between 21 and 75 years of age were able to correctly interpret the prepared weak positives. This shows that the product is easy to use for non-medically trained users in all phases of operation and that the risk of incorrect handling of the product or incorrect interpretation of the results by the user is minimal.

For the most up to date information on COVID-19, please visit:
https://www.canada.ca/en/public-health/services/diseases/coronavirus-disease-covid-19/testing-screening-contact-tracing/information-patients-guide-self-testing.html

GLOSSARY OF SYMBOLS

Consult instructions for use	Tests per Kit	Catalogue #
Store between 2-30°C	Use by date	Do Not Reuse
In vitro diagnostic medical device	Lot Number	Manufacturer
Do not use if package is damaged	Keep away from sunlight	Keep dry

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