REF COV-19C25B
REF COV-19CSHC
REF COV-19CSHC1
REF COV-19CSHC2
REF COV-19CSHC5
REF COV-19CSHC25

Rapid Response™

COVID-19 Antigen Rapid Test Cassette

At Home

Instructions for Use

For *in vitro* Diagnostic Use Only.
A rapid test for the detection of COVID-19 antigens in nasal swab samples.

Unfold leaflet and flip this sheet over for instructions.

Warning

This test is intended to be used as an aid in the clinical diagnosis of a current COVID-19 infection. Do not use this test as the only guide to manage your illness. Please consult your healthcare provider if your symptoms persist or become more severe, or if you are concerned at any time. Individuals should provide all results obtained with this product to their healthcare provider for public health reporting.

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 collecting 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 a 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.

FAQ

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.

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 yeild 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

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.

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.

Glossary of Symbols

Consult instructions for use
Test per Kit
REF Catalogue number
Do not use if package is damaged
Store between 2°C to 30°C
Use by date
Do Not Reuse
Keep away from sunlight
IVD *In vitro* diagnostic medical device
LOT Lot Number
Manufacturer
Keep dry

Scan
for more detailed instructions found in the complete Instructions for Use
Or visit:
https://www.btnx.com/covid19athome

BTNX, Inc.
570 Hood Rd, Unit 23
Markham, ON, L3R 4G7, Canada
Technical Support: 1-888-339-9964

BTNX INC.

Document Number: INS006_02_COV-19CSHC(03-2022)
Effective date: (2022-03-04)

Rapid Response™

COVID-19 Antigen Rapid Test Cassette
At Home

Bring cassettes, reagents, and samples to room temperature (15~30°C) before use.

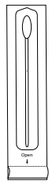
1. Setting Up the Test

Before starting the test, wash your hands thoroughly with soap and water or use hand sanitizer. Make sure they are dry before starting.

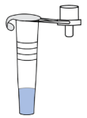
Unpack the test components from the kit and make sure that all the packaging is intact.

For each test you will need:

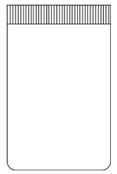
One Test Cassette



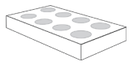
One Swab



One Extraction Buffer Tube



One Waste Bag



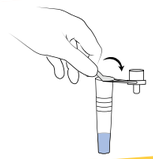
Tube Stand or Outer Box with Tube Holder

Instructions (This Document)

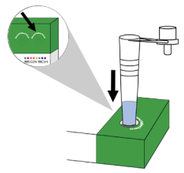
Stopwatch or Timer (Not Provided)

Remove the test cassette from the pouch and place it on a clean, flat surface.

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



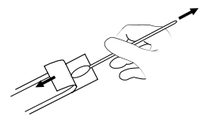
Place the extraction buffer tube upright in the tube stand or hole on the packaging.



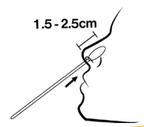
2. Nasal Swab Collection for Adults

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, as blood may interfere with the test.

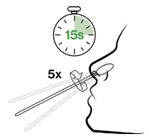
Check that the swab wrapper is properly sealed. Only when you are ready to use it, gently peel open the packaging of the swab from the indicated end and hold swab by the stem. **Do not touch the padded fabric tip of the swab. If it has been touched you must discard the swab and use a new one.**



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



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 **a minimum of about 15 seconds.**



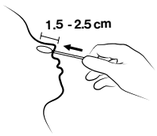
Pull the swab out while twisting and repeat in the other nostril using the same swab. When you are done swabbing, do not return the used swab to the swab packaging.

2. Nasal Swab Collection for Children

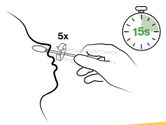
Children under 14 should be tested by an adult. Follow the guidelines below on how to test on a child.

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. Both the child and the adult conducting the test should wash their hands with soap and water or use sanitizer for 20 seconds.

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



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.

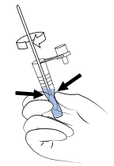


Slowly pull the swab out while twisting and repeat in the other nostril using the same swab. Do not return the swab into the original paper packaging.

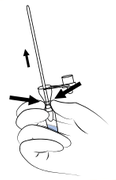
The nasal swab is not sharp and should not hurt. It may feel slightly uncomfortable. If you feel pain, please stop the test, and seek advice from a healthcare provider.

3. Running the Test

Pick up the extraction buffer tube and place the swab with the sample into the liquid inside the extraction buffer tube.
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.

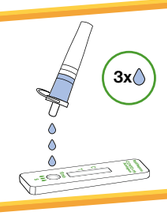


Remove the swab while squeezing the tube to squeeze as much liquid out of the swab as possible. Throw the used swab away in the waste bag provided in the kit.

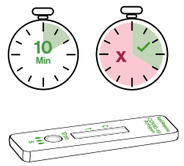


Secure the nozzle dropper cap tightly onto the top of the extraction tube.

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.

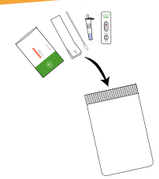


Start a timer and wait for ten (10) minutes before reading the results. Do not move the test cassette once the test has started running.
You must wait the full 10 minutes before reading the test results. Do not read or interpret the results after 20 minutes.



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.

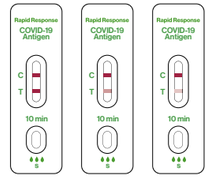
For kits with more than one test, you should **keep the tube stand and the instructions until you have used all of the tests in your kit.**



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

Results 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 coloured line in the test region should be considered positive.

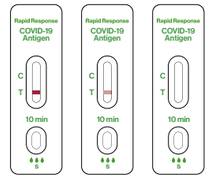
A positive test result for COVID-19 indicates that antigens from SARS-CoV-2 were detected, and the person is very likely to be infected with the virus and presumed contagious. If you test positive with the Rapid Response™ COVID-19 Antigen Rapid Test Cassette – At Home, you should self-isolate and seek follow-up care with your healthcare provider. Your healthcare provider will work with you to determine how best to care for you based on your test result(s) along with your medical history, and your symptoms.

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).

A negative test result for COVID-19 indicates that antigens from SARS-CoV-2 were not detected. Negative results do not rule out SARS-CoV-2 infection. All negative results are considered presumptive, and may require additional molecular testing to confirm that you do not have COVID-19. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. If you test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath, you are advised to continue following local guidelines for self-isolation and seek follow up care with your healthcare provider. Your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently travelled) in deciding how to care for you.

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**

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

Document Number: INS006_02_COV-19CSHC(03-2022)
Effective date: (2022-03-04)