Rapid Response™

COVID-19 Antigen *Self-Test* Kit

Product Insert

Nasal Antigen Self-Test

REF COV-19CHC1, COV-19CHC2, COV-19CHC5, COV-19CHC25

INTENDED USE

The Rapid Response™ COVID-19 Antigen Self-Test Kit is an immunochromatographic assay intended for qualitative detection of the SARS-CoV-2 nucleocapsid protein antigen in self-collected direct anterior nasal (nares) swab samples from individuals aged 14 years or older or with adult collected anterior nasal swab samples from individuals aged 2 years or older. This test is intended for individuals suspected of COVID-19 within 7 days of symptom onset when tested at least twice with 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19 infection when tested at least three times with 48 hours between tests. This test is authorized for home use only under the Health Canada Interim Order.

Results are for the identification of SARS-CoV-2 viral nucleoprotein antigen. Antigens are generally detectable in nasal secretions during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the Rapid Response™ COVID-19 Antigen Self-Test Kit should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results should be treated as presumptive, and do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or infection control decisions. Negative results should be considered in the context of a person's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19 and confirmed with a molecular assay.

Individuals who test negative and continue to experience COVID-like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from their healthcare provider.

The Rapid Response™ COVID-19 Antigen Self-Test Kit is intended for home use. The Rapid Response™ COVID-19 Antigen Self-Test Kit is only for use under the Health Canada Interim Order.

PRINCIPLE

The Rapid Response™ COVID-19 Antigen *Self-Test* Kit 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 15 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 devices: foil pouch with test device with encased test strip and desiccant
- Extraction buffer vial: 400 µL of extraction buffer solution
- Individually packed nasal swabs: For specimen collection
- Tube stand: To hold extraction tube upright during test procedure
- Package insert: Complete instructions for Use

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

Materials Required but Not provided

Clock, timer, or stopwatch

WARNINGS AND PRECAUTIONS

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.

- 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.
- Children under 14 years old should be tested by an adult. Do not use on anyone under 2 years old.
- Wear a safety mask or other face-covering when collecting anterior nares swab specimen from a child or another individual.
- Wash hands thoroughly for at least 30 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 result in 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 15 minutes or more than 30 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 of the extraction buffer tube or where the pouch of the test cassette has not been completely sealed.
- Erroneous result may occur if test reagents or components are improperly stored. Immediately use after opening the test device from the pouch.
- Do not use on anyone who is prone to nosebleeds or has had facial or head injury/surgery in the last 6

months.
- 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 prior to testing.
- Do not use the Extraction Buffer if it is discoloured or turbid. Discolouration or turbidity may be a sign of microbial contamination.
- Avoid exposure of your skin, eyes, nose, or mouth to the solution in the extraction tube.
- Extraction solution should not be ingested.
- The chemicals in the reagent solution are 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, contact your local Position Control Centre.

LIMITATIONS OF THE TEST

1. The Rapid Response™ COVID-19 Antigen *Self-Test* Kit 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 *Self-Test* Kit.
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 collected incorrectly or handled.
6. An incorrect result may occur if used lesser or more than 3 drops on the device.
7. Results obtained with this assay, particularly in the case of weak test lines that are difficult to interpret, should be used in conjunction with other clinical information available to the physician.
8. Negative results do not preclude SARS-CoV-2 infection and should be confirmed via molecular assay.
9. The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
10. This device has been evaluated for use with human specimen material only
11. This test and the results from this test do not establish that user has acquired immunity to COVID-19.
12. The BTNX Rapid Response COVID-19 Antigen Self-Test does not differentiate between SARS-CoV and SARS-CoV-2 and between MERS-coronavirus and SARS-CoV-2.
13. Moving the test after the addition of the sample and prior to the recommended reading time may lead to false results.

SERIAL TESTING (REPEAT TESTING) INFORMATION AND LIMITATIONS

- Serial testing (i.e., testing every other day) is more likely to detect COVID-19, both when you do or do not have any symptoms.
- Symptomatic individuals that test negative should repeat testing at least twice over three days with at

least 48 hours between tests and at least three times over five days with at least 48 hours between tests if they are asymptomatic.

- The performance of this test was not clinically validated for serial testing in patients with or without symptoms consistent with COVID-19. Serial testing recommendations are supported by the study conducted by the National Institutes for Health (NIH) and the University of Massachusetts Chan Medical School in collaboration with the US FDA.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.

STORAGE AND STABILITY

- Store the Rapid Response™ COVID-19 Antigen *Self-Test* Kit 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

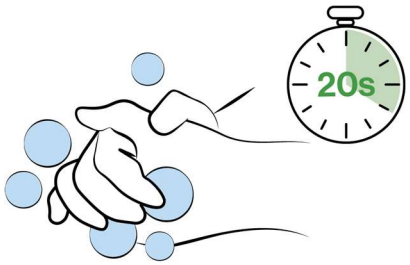
- Acceptable specimen type for testing with the Rapid Response™ COVID-19 Antigen *Self-Test* is a direct anterior nasal (nares) swab specimen. It is essential that correct specimen collection and preparation methods be followed. Inadequate specimen collection, improper specimen handling and/or transport 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.
- Do not use the test if the foil package is visibly damaged.
- Do not open the foil package until you are ready to perform the test. Use the test within 1 hour after opening.

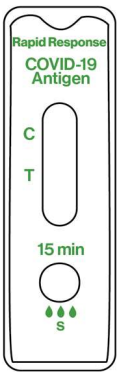
Setting up the test:

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.

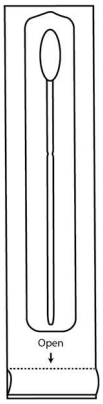


2) Unpack the test components from the kit and make sure that all the packaging is intact.

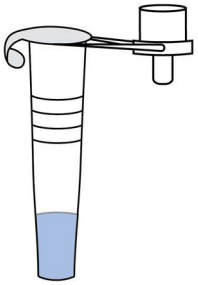
For each test you will need:



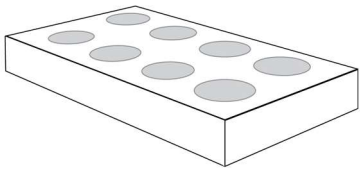
One Test Device



One swab

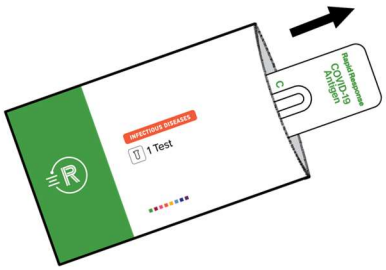


One Extraction Buffer Tube

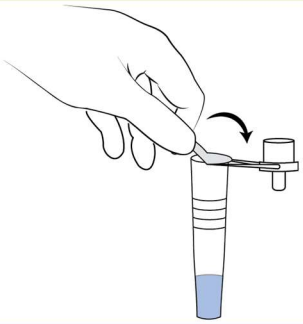


Tube Stand or Outer Box with Tube Holder

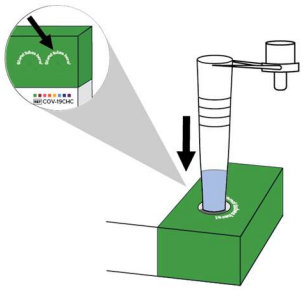
3) Remove the test cassette from the pouch and place it on a clean, flat surface.



4) Peel off the aluminum foil cover of the extraction buffer.

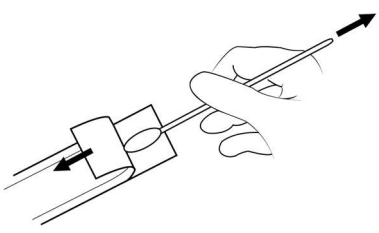


5) Place the extraction buffer tube upright in the tube stand or hole on the packaging.

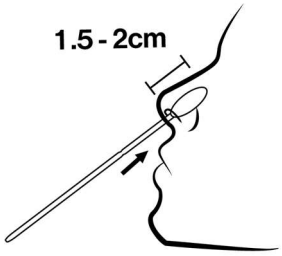


Nasal Swab Collection:

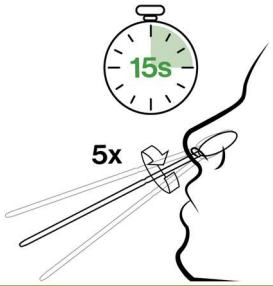
6) Check that the swab wrapper is properly sealed. Only when you are ready to use it, gently peel open the packaging of the swab from the indicated end. Hold swab by the stem as you remove it. Do not touch the padded fabric tip of the swab. If it has been touched, you must discard the swab and use a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



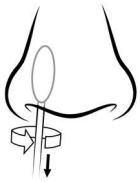
7) Insert the swab about 1.5 – 2cm (1/2 to 3/4 inch) into the nostril. (Collect the anterior nasal swab specimen).



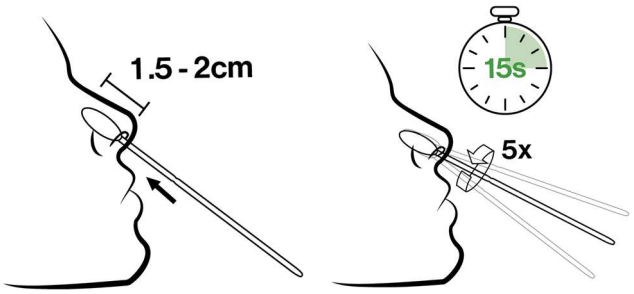
8) Gently twist the swab 5 times against the nasal wall. **Do not just spin the swab**. The swab should remain in the nostril for 15 seconds.



9) Pull the swab out of the nose while twisting it slightly.



10) Repeat the process with the same swab in the other nostril, also for 15 seconds. **WARNING: Inaccurate test results may occur if the nasal swab specimen is not properly collected.**

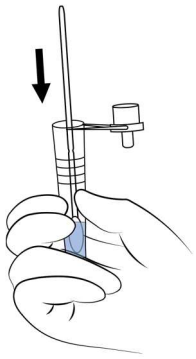


The nasal swab is not sharp and should not hurt. It may feel slightly uncomfortable. If you feel pain, please stop the test, and seek advice from a healthcare provider.

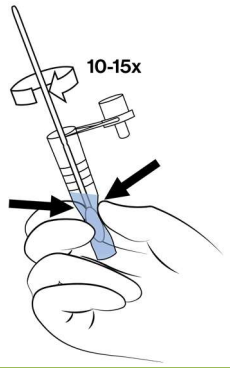
Note: With children, the maximum depth of insertion into the nostril may be less than 2cm (3/4 of an inch), and you may need to have a second person to hold the child's head while swabbing

Running the test:

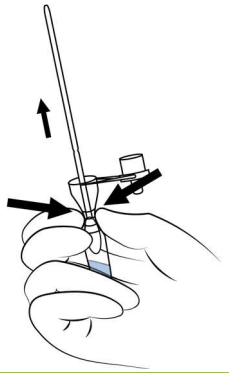
11) Place swab into the tube.



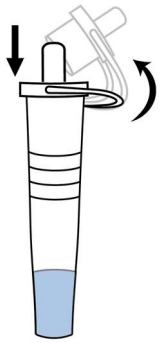
12) Rotate the swab while squeezing the lower part of the tube 10-15 times so that a slight pressure is exerted on the tip of the swab.



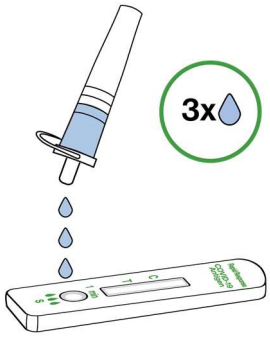
13) Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.



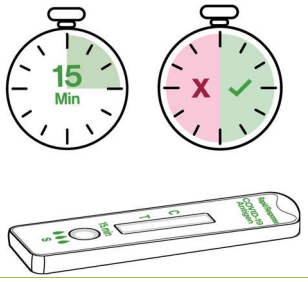
14) Secure the nozzle dropper cap tightly onto the top of the extraction tube.



15) 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



16) Set a timer and read the results at 15 minutes. **Do not read the result before 15 minutes or after 30 minutes.**

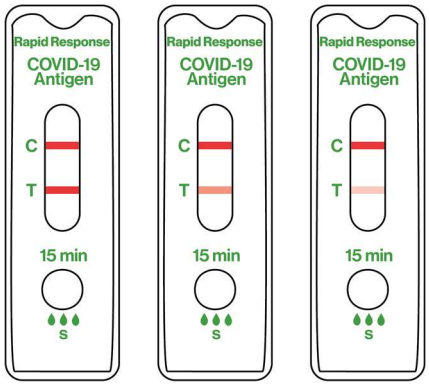


Wash hands thoroughly with soap and water or use hand sanitizer when you are done.

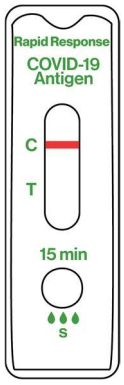
DISPOSAL

Dispose of all used test kit components and samples in household trash.

RESULT INTERPRETATION



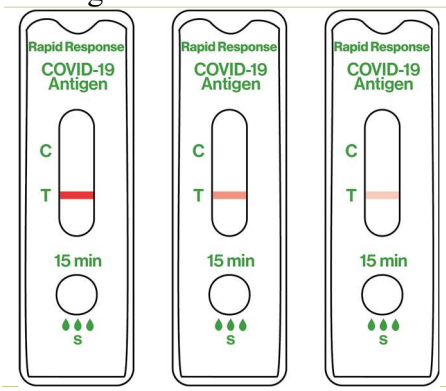
POSITIVE: COVID-19 Detected
If a test line (T) is visible together with a control line (C), this means that the result is positive. Look carefully at the result: The test should be considered positive.
If two lines are visible - even if they are faint. A positive test result means that the virus that causes COVID-19 was detected in your sample, and 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 molecular PCR test to confirm the result. There is a very small chance that this test can give a result that is incorrect (a false positive). You do not need to perform repeat testing if you have a positive result at any time.



NEGATIVE: COVID-19 Not Detected.
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.
To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if you have symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.**

A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If all repeat tests are negative and you are concerned you have COVID-19, you may choose to test again using an antigen test or consult with your health care provider regarding molecular testing.



INVALID: If a control line (C) is not visible, even if the test line is 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 Quick Reference Instructions and repeat the test. If your test result is still invalid, please contact a doctor or visit a COVID-19 test center.

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

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

QUALITY CONTROL

Internal Procedural Controls

The Rapid Response™ COVID-19 Antigen *Self-Test* Kit 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 *Self-Test* Kit 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 cause 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. You may need to pursue another method of follow-up testing. If you are concerned about your COVID-19 infection status after testing or think you may need follow up testing, please contact 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 $2x10^{2.4}$ $TCID_{50}$/mL.

Clinical Study of Rapid Response™ COVID-19 Antigen *Self-Test*:
The performance of the Rapid Response™ COVID-19 Antigen *Self-Test* Kit was established in a, randomized, blinded clinical study conducted at multiple sites in the U.S. between November 2021 and February 2022 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 asymptomatic individuals and those who were symptomatic (within 7 days from symptom onset) and were suspected of COVID-19. Two samples from each patient were collected – one for PCR and another for the Rapid Antigen test. 97 positive specimens and 208 negative specimens were confirmed by RT-PCR out of which the Rapid Response™ COVID-19 Antigen *Self-Test* Kit correctly identified 92.8% of positive specimens and 99.5% of negative specimens respectively. The study was based on testing only once. **However, clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causes COVID-19 when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach is recommended to minimize the risk of incorrect results.** This test was not clinically validated for serial testing. The serial testing recommendations are supported by the study conducted by the National Institutes for Health (NIH) and the University of Massachusetts Chan Medical School in collaboration with the US FDA.

Rapid Response™ COVID-19 Antigen *Self-Test* Kit Clinical Evaluation with Nasal Swabs:

		RT-PCR		Total
		Positive	Negative	
Rapid Response™ COVID-19 Antigen *Self-Test* Kit	Positive	90	1	91
	Negative	7	207	214
Total		97	208	305

Positive Percent Agreement: 92.8% (95%CI: 85.8%-96.5%)*
Negative Percent Agreement: 99.5% (95%CI: 97.3%-99.9%)*
Overall Agreement: 97.4% (95%CI: 94.9%-98.7%)*
*95% Confidence Interval

Cumulative PPA by Days since symptom onset

Days Since Symptom Onset	Cumulative RT-PCR Positive(+)	Cumulative Rapid Response COVID-19 Antigen *Self-Test* Positive(+)	PPA	95%CI
0	0	0	/	/
1	22	20	90.9%	72.2%-97.5%
2	38	34	89.5%	75.9%-95.8%
3	49	45	91.8%	80.8%-96.8%
4	57	53	93.0%	83.3%-97.2%
5	64	59	92.2%	83.0%-96.6%
6	69	64	92.8%	84.1%-96.9%
7	73	68	93.2%	84.9%-97.0%
Asymptomatic	24	22	91.7%	74.2%-97.7%

Serial-testing clinical performance:
A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total

of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.
At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.
Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 – 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.
Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing.
Performance of the antigen test with serial testing in individuals is described in following table.

Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

DAYS AFTER FIRST PCR POSITIVE TEST RESULT	ASYMPTOMATIC ON FIRST DAY OF TESTING			SYMPTOMATIC ON FIRST DAY OF TESTING		
	Ag Positive/PCR Positive (Antigen Test Performance % PPA)					
	1 Test	2 Tests	3 Tests	1 Test	2 Tests	3 Tests
0	9/97 (9.3%)	35/89 (39.3%)	44/78 (56.4%)	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	17/34 (50.0%)	23/34 (67.6%)	25/32 (78.1%)	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	16/21 (76.2%)	15/20 (75.0%)	13/15 (86.7%)	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	20/28 (71.4%)	21/27 (77.8%)	16/18 (88.9%)	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	13/23 (56.5%)	13/22 (59.1%)	4/11 (36.4%)	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	5/9 (55.6%)	5/8 (62.5%)		4/9 (44.4%)	3/7 (42.9%)	

1 Test= one (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.
2 Tests= two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.
3 Tests= three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

Cross Reactivity:
Cross reactivity with the following organisms has been studied. Samples positive for the following organisms were found negative when tested with the Rapid Response™ COVID-19 Antigen *Self-Test* Kit.

HCoV-HKU1	Influenza A (H5N1)	Coxsackie virus A16

HCoV-OC43	Influenza A (H7N9)	Norovirus
HCoV-NL63	Influenza A (H7N7)	Mump virus
HCoV-229E	Influenza B Victoria lineage	*Legionella pneumophila*
Measles virus	Influenza B Yamagata lineage	*Mycoplasma pneumoniae*
Streptococcus pneumoniae	Respiratory syncytial virus	*Chlamydia pneumoniae*
Epstein-Barr virus	Adenovirus	*Streptococcus pyogenes*
Bordetella Para pertussis	Parainfluenza 1/2/3 virus	*Streptococcus agalactiae*
Influenza A (H1N1) pdm09	Human metapneumovirus	Group C *Streptococcus*
Influenza A (H3N2)	Rhinovirus	*Staphylococcus aureus*
H. influenza	C. albicans	S. epidermidis
Enterovirus	Parainfluenza type 4	

Microbial Interference Study:
Potential microbial interference was evaluated to demonstrate that false negatives will not occur when SARS-CoV-2 is present in a specimen with other microorganisms. Low concentration of SARS-CoV-2 (3 X LOD) was spiked into the higher concentrations of interfering organism, and it was found that there is no microbial interference for following organisms.

HCoV-HKU1	Influenza A (H5N1)	Coxsackie virus A16
HCoV-OC43	Influenza A (H7N9)	Haemophilus influenzae
HCoV-NL63	Influenza A (H7N7)	Candida albicans
HCoV-229E	Influenza B Victoria lineage	Mycobacterium tuberculosis
Measles virus	Influenza B Yamagata lineage	Norovirus
Streptococcus pneumoniae	Respiratory syncytial virus	Mump virus
Epstein-Barr virus	Adenovirus	Legionella pneumophila
Bordetella Para pertussis	Parainfluenza 1/2/3 virus	Mycoplasma pneumoniae
Influenza A (H1N1) pdm09	Human metapneumovirus	Chlamydia pneumoniae
Influenza A (H3N2)	Rhinovirus	Streptococcus pyogenes
Group C Streptococcus	Staphylococcus aureus	Streptococcus agalactiae
H. influenza	C. albicans	S. epidermidis
Enterovirus	Parainfluenza type 4	Pooled human nasal wash – representative of normal respiratory microbial flora

Interfering Substances
The following substances, naturally present in respiratory specimens or that 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 *Self-Test* Kit.

Substance	**Concentration**	**Substance**	**Concentration**
3 OTC nasal sprays	10%	Guaiacol glyceryl ether	20 mg/ml
3 OTC mouthwashes	10%	Mucin	1%
3 OTC throat drops	10%	Mupirocin	250 µg/ml
4-acetamidophenol	10 mg/ml	Oxymetazoline	10 mg/ml
Acetylsalicylic acid	20 mg/ml	Phenylephrine	10 mg/ml
Albuterol	20 mg/ml	Phenylpropanolamine	20 mg/ml
Chlorpheniramine	5 mg/ml	Relenza ® (zanamivir)	20 mg/ml
Dexamethasone	5 mg/ml	Rimantadine	500 ng/ml
Dextromethorphan	10 mg/ml	Tamiflu ® (oseltamivir)	100 mg/ml
Diphenhydramine	5 mg/ml	Tobramycin	40 mg/ml
Doxylamine succinate	1 mg/ml	Triamcinolone	14 mg/ml

Flunisolide	3 mg/ml	Naso GEL (NeilMed)	5% v/v
Nasal Spray (Oxymetazoline)	15% v/v	Nasal Spray (Cromolyn)	15% v/v
Zicam	5% v/v	Homeopathic (Alkalol)	1:10 dilution
Sore Throat Phenol spray	15% v/v	Fluticasone Propionate	5% v/v
Hand & Body lotion (Cerave)	0.5% (w/v)	Hand Sanitizer with Aloe, 62% ethyl alcohol	5% v/v
Hand Lotion (Eucerin)	5% w/v	Hand soap liquid gel (soft soap)	10% w/v
Hand Sanitizer 80% ethanol, fast drying	15% v/v		

High Dose Hook Effect
No high dose hook effect was observed when tested with up to a concentration of 1 x $10^{6.4}$ $TCID_{50}$/mL of heat inactivated SARS-CoV-2 virus with the Rapid Response™ COVID-19 *Self-Test* Kit.

Usability Study
A usability study was conducted as a part of the clinical trial to evaluate whether lay-users can understand the instructions provided and successfully perform the test procedure for Rapid Response™ COVID-19 Antigen *Self-Test* Kit, including nasal specimen collection, extracting the specimen, adding it to the test cassette, and correctly interpret the results. A total of 305 participants enrolled in the study and were asked to complete a questionnaire after completing their tests.
The participants correctly completed 5029 of a possible 5285 steps (96.99%) in the questionnaire with a further breakdown as follows:

- 96.75% confirming the IFU is easy to understand
- 95.42% confirmed the sampling is clear
- 97.05% confirming the sample extraction process is clear
- 97.40% confirmed it is easy to read the results and

100% of the participants have consistent test results as of the observers. 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.

GLOSSARY OF SYMBOLS

	Consult instructions for use		Test per Kit		Catalogue number
	Store between 2°C to 30°C		Use by date		Do Not Reuse
	In vitro diagnostic medical device		Lot Number		Manufacturer

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