REF COV-19CSHA
REF COV-19CSHA1
REF COV-19CSHA2
REF COV-19CSHA5
REF COV-19CSHA20
REF COV-19C25B

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.

Intended Use

The Rapid Response™ COVID-19 Antigen Rapid Test Cassette - At Home is a rapid test for the detection of COVID-19 antigens in nasal swab samples. It is an *in vitro* immunochromatographic assay to be used with nasal secretions from individuals suspected of COVID-19 within 7 days of symptom onset. This test is authorized for non-prescription home-use with self-collected, unobserved direct anterior nasal (nares) swab samples from individuals aged 14 years or older or with anterior nasal swab samples from individuals aged 2 years or older when collected by an adult in a non-laboratory setting.
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. Negative results should be treated as presumptive, and do not rule out SARS-CoV-2 infection.
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 you symptoms persist or become more severe, or if you are concerned at any time.

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 $2 \times 10^{2.4}$ $TCID_{50}$/mL.
Clinical Performance:
The Rapid Response™ COVID-19 Antigen Rapid Test Cassette - At Home was evaluated with anterior nasal swabs and compared to RT-PCR. The Rapid Response™ COVID-19 Antigen Rapid Test Cassette – At Home correctly identified 94.5% (86/91) of positive samples and 99.4% (326/328) of negative samples.
Usability Study
Out of 419 participants, 100% of participants feel the overall instructions and procedure were clear and easy to follow. 98.57% of participants did not have difficulty performing the test, 98.09% of participants feel it is easy to interpret the test results. For ease of use, 93.08% of participants selected that the test was easy or very easy.
Contrived Samples Usability Study
Of 100 participants selected to interpret the results of contrived specimens, the rate of correct interpretation is 98%, indicating that lay users can reliably interpret the test results.
Cross Reactivity and Microbial Interference Study:
Potential cross reactivity and microbial interference was evaluated to demonstrate that the organisms listed below do not cause false positives in the absence of SARS-CoV-2 or false negatives in the presence of SARS-CoV-2. 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 cross reactivity or 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, Pooled human nasal wash – representative of normal respiratory microbial flora.
The test cannot differentiate between SARS-CoV-1 and SARS-CoV-2.
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 Rapid Test Cassette - At Home:
3 OTC nasal sprays, 3 OTC mouthwashes, 3 OTC throat drops, 4-acetamidophenol, Acetylsalicylic acid, Albuterol, Chlorpheniramine, Dexamethasone, Dextromethorphan, Diphenhydramine, Doxylamine succinate, Flunisolide, Guaiacol glyceryl ether, Mucin, Mupirocin, Oxymetazoline, Phenylephrine, Phenylpropanolamine, Relenza ® (zanamivir), Rimantadine, Tamiflu ® (oseltamivir), Tobramycin, Triamcinolone.
Variants
Performance evaluation using the recombinant nucleocapsid proteins demonstrated the Alpha, Beta, Gamma, Kappa, Lamda, Delta and Omicron variants were detectable with the Rapid Response™ COVID-19 Antigen Rapid Test Cassette – At Home. Performance may vary depending on variants circulating, including newly emerging strains and their prevalence, which changes over time.

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 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.

Warnings and Precautions

- Read the Product Insert before use. Follow the directions carefully to obtain accurate results. Inadequate or inappropriate sample collection, storage, and transport can result in incorrect results.
- Do not use kits after their expiration date, which is printed on the 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 face-covering when collecting nasal swab specimen from a child or another person.
- Keep foreign substances and household cleaning products away from the test during the testing process as contact with foreign substances and household cleaning products may result in an incorrect test result.
- Test cassettes are packaged in foil pouches that exclude moisture during storage. Inspect each foil pouch before opening. Do not use cassettes if the pouch is damaged, isn't properly sealed or has holes in it.
- The test device must remain in the sealed pouch until use. Use the test immediately after opening the pouch.
- Do not operate the test outside of operating conditions. Failure to bring specimens and reagents to room temperature before testing may decrease assay sensitivity.
- 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.
- 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.
- Each test can only be used once. Do not re-use any contents in the kit except the tube stand.
- 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 before and after use.
- The chemicals in the reagent solution are hazardous to the skin and eye. If the extraction buffer comes in contact with the skin or eyes, flush with plenty of water. If irritation persists, seek medical advice from a doctor or your local medical centre.

Limitations

The test 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.
The intensity of colour in a positive line should not be evaluated as "quantitative or semi-quantitative".
The test can detect both viable and nonviable SARS-CoV-2 virus.
Test should be performed within 7 days of symptom onset. Test results may be less reliable in the later stages of infection and false negative results may occur. The amount of antigen in a sample may decrease as the duration of illness increases.
Repeat testing is recommended (between 24-48 hours after your first test) if there is an ongoing suspicion of infection, if you are in a high risk setting or where there is an occupational risk or other requirement for repeat testing.
Failure to follow the test procedure in any of the steps may adversely affect test performance and/or invalidate the test result.
An incorrect result may occur if more than or less than 3 drops are used on the cassette.
A false negative result may occur if the level of antigen in a sample is below the detection limit of the test.
A false negative result may occur if the sample was collected incorrectly or handled.
Negative results may not mean that a person is not infectious. If symptoms are present, the person must seek immediate further testing by PCR.
This is a presumptive test only. Speak to your healthcare provider about the need for confirmatory testing of positive results by a laboratory PCR test and/or follow-up clinical care.
Negative results do not rule out infection with another type of respiratory virus.
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.
The performance of this device has not been assessed in a population vaccinated against COVID-19.
This test and the results from this test do not establish that user has acquired immunity to COVID-19.
The accuracy of this test may be less reliable in asymptomatic individuals.

Storage and Stability

- Store the Rapid Response™ COVID-19 Antigen *Self*-Test Kit at 2-30°C when not in use.
- **DO NOT FREEZE ANY OF THE CONTENTS OF THE KIT.**

Quality Control

Internal Procedural Controls
The Rapid Response™ COVID-19 Antigen Rapid Test Cassette - At Home has built-in procedural controls. Each test cassette 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.

Contact Information and Support

For assistance, call (02) 9061 0577 from 9 am to 7 pm (AEST), 7 days per week. For information on the correct use of this test and for interpretation of the test results or visit the website www.surescreen.net.au. You may also contact BTNX technical support at suppport@btnx.com

You can contact the Therapeutic Goods Administration (TGA) to report poor performance or usability issues in the self-test environment via the online Users Medical Device Incident Report, email iris@tga.gov.au or call 1800 809 361.

Information regarding available support services can be obtains from your local state or territory health department at:

Australian Capital Territory Department of Health	Coronavirus helpline (8am to 8pm daily): 02 6207 7244	https://health.act.gov.au/
New South Wales Department of Health	General enquiries: 1300 066 055 Coronavirus hotline (24/7): 137 788	https://www.health.nsw.gov.au
Northern Territory Department of Health	General enquiries: 08 8922 8044 Coronavirus hotline: 1800 020 080	https://health.nt.gov.au/
Queensland Department of Health	General enquiries: 13 432 584 Coronavirus hotline: 134 268	https://www.health.qld.gov.au/
South Australian Department of Health	General enquiries: 1300 232 272 Coronavirus hotline (9am to 5pm daily): 1800 253 787	https://www.sahealth.sa.gov.au/
Tasmanian Department of Health	General enquiries: 1300 135 513 Public Health Hotline (coronavirus): 1800 671 738	http://www.health.tas.gov.au
Victorian Department of Health	Department of Health and Human Services: 1300 650 172 Victorian coronavirus hotline (24/7): 1800 675 398	https://www.coronavirus.vic.gov.au
Western Australia Department of Health	General enquiries: 08 9222 4222 Coronavirus hotline: 13COVID (8am to 6pm, Mon-Fri): 1800 595 206	https://www.healthywa.wa.gov.au/

Glossary of Symbols

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

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

Scan for More Resources
Or visit:
https://www.btnx.com/covid19homeau

Australian Sponsor:
Surescreen Australia Pty Limited
Unit 4, 181-187 Taren Point Road
Caringbah NSW 2229 Australia
Tel: (02) 9061 0577 from 9AM to 7PM (AEST)
Email: admin@btnx.com.au

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Effective date: (2022-05-04)

Rapid Response™

COVID-19 Antigen Rapid Test Cassette

At Home

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

Warning: Keep the testing kit and kit components away from small children and pets before and after use.

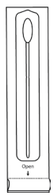
1. Setting Up the Test

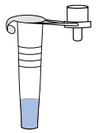
Before starting the test, wash your hands thoroughly with soap and water or use hand sanitizer. Make sure they are dry before starting.

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

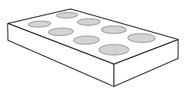
For each test you will need:


One Test Cassette


One Swab


One Extraction Buffer Tube


One Waste Bag

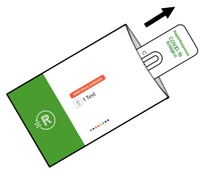

Tube Stand


Instructions
(This Document)

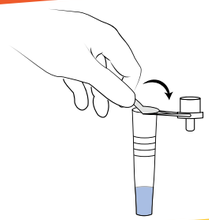

Stopwatch or Timer
(Not provided)

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

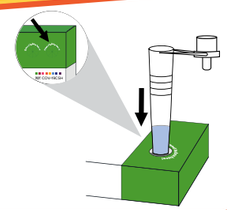
Do not touch the sample well or test region of the test.



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

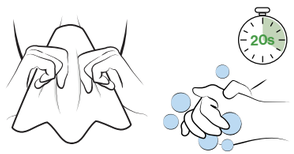


Place the extraction buffer tube upright in the tube stand or hole on the packaging.

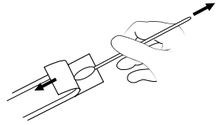


2. Nasal Swab Collection

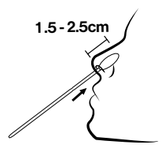
Gently blow your nose into a tissue to remove excess mucus and discard used tissue in the garbage. Wash or sanitize your hands again.



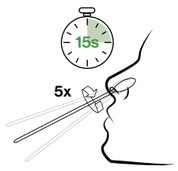
Open the packaging of the swab from the indicated end and hold swab by the stem. Do not touch the padded tip of the swab.



Insert the swab about 1.5-2.5cm 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 about 15 seconds.

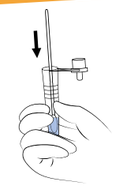


Pull the swab out while twisting and repeat in the other nostril using the same swab.

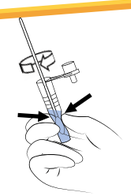
The nasal swab is not sharp and should not hurt. It may feel slightly uncomfortable. If you feel pain, please stop the test, and seek advice from a healthcare provider.

3. Running the Test

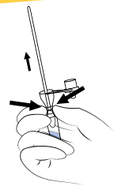
Pick up the extraction buffer tube and place the swab specimen into the buffer.



Swirl the swab, mixing well. Squeeze the swab 10-15 times by compressing the walls of the tube against the swab.



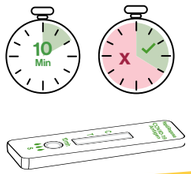
Remove the swab while squeezing the tube to squeeze as much liquid out of the swab as possible. Throw the used swab in the provided waste bag



Attach nozzle to sample extraction tube.

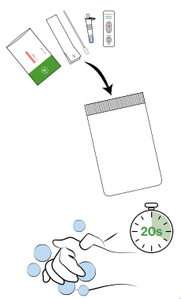
Invert the tube and add 3 drops of the extracted sample into the sample well (S) of the test cassette by gently squeezing the tube.

Start the timer. Wait for coloured line(s) to appear. Read the results at 10 minutes. Do not interpret the results more than 20 minutes after adding the sample.



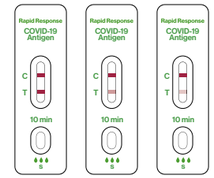
When the test is done **and you have recorded your results**, dispose of all used test kit components and samples in the waste bag provided and dispose of with household trash. Wash hands thoroughly with soap and water or use hand sanitizer when you are done.

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.



Results Interpretation

POSITIVE: COVID-19 Detected

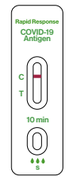


Two coloured lines appear on the membrane. One line appears in the control region (C) and another line appears in the test region (T).

IMPORTANT: Look very closely! <u>Any faint coloured line</u> in the test region should be considered positive.

A positive result indicates that antigens from SARS-CoV-2 were detected in the specimen, and you are likely to be infected. If you test positive, you should presume you are contagious and self isolate. Refer to your local COVID support services for guidance and the necessity for additional PCR testing.

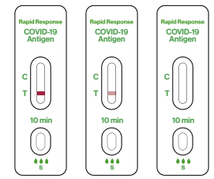
NEGATIVE: COVID-19 Not Detected.



Only one coloured line appears, in the control region (C). No apparent coloured line appears in the test region (T).

A negative result indicates that antigens from SARS-CoV-2 were not detected in the specimen. Negative results are considered presumptive and do not rule out SARS-CoV-2 infection. Continue to monitor for symptoms of COVID-19 and re-test in 24 - 48 hours if symptoms persist. Individuals who test negative and continue to experience COVID-19 symptoms such as fever, cough and/or shortness of breath may still be infected with SARS-CoV-2 and must seek further testing. Refer to your local COVID support services for guidance.

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.

NOTE:
1. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control line failure.
For questions or to report a problem, please call technical support at (02) 9061 0577, 9AM-7PM (AEST) or email support@btnx.com

Scan for More Resources
Or visit:
https://www.btnx.com/covid19homeau

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