BTNX INC.

# Rapid Response™

**COVID-19 Antigen Detection Test**
(Anterior Nasal Swab)

REF COV-19COPU

For *in vitro* diagnostic use only.
For prescription use only.

## Intended Use

The Rapid Response™ COVID-19 Antigen Detection Test is a lateral flow immunochromatographic assay intended for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal swabs specimens from individuals with signs and symptoms of upper respiratory infection within the first six (6) days of symptom onset. The test is intended for use as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19) in symptomatic individuals when either: tested at least twice over three days with at least 48 hours between tests; or when tested once, and negative by the Rapid Response™ COVID-19 Antigen Detection Test and followed with a molecular test.
The test does not differentiate between SARS-CoV and SARS-CoV-2.
A negative test result is presumptive, and it is recommended these results be confirmed by a molecular SARS-CoV-2 assay. Negative results do not preclude SARS-CoV-2 infections and should not be used as the sole basis for treatment or other patient management decisions.
Positive results do not rule out co-infection with other respiratory pathogens.
Performance characteristics for SARS-CoV-2 were established from May 2022 to July 2022 when SARS-CoV-2 Omicron was the predominant SARS-CoV-2 variant in circulation. When other SARS-CoV-2 virus variants are emerging, performance characteristics may vary.

## Summary

Coronaviruses belong to the β genus. Coronavirus disease 19 (COVID-19) is an acute respiratory infectious disease in patients infected by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). The virus incubation period typically ranges from 1 to 14 days, and symptoms may appear within 2 to 14 days following exposure. Possible symptoms include fever or chills, fatigue, new loss of taste or smell, shortness of breath or difficulty breathing, cough, nasal congestion or runny nose, sore throat, myalgia, nausea or vomiting, headache, and diarrhea.
This test is for detection of SARS-CoV-2 nucleocapsid protein antigen to aid in the diagnosis of SARS-CoV-2 infection. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection.

## Principle

The Rapid Response™ COVID-19 Antigen Detection Test uses antibodies to detect nucleocapsid protein from SARS-CoV-2 in direct nasal (anterior nares) swabs. If SARS-CoV-2 nucleocapsid antigen is present in the sample a line will form at the test line at "T", which means the test is positive. If SARS-CoV-2 nucleocapsid protein antigen is not in the sample a test line will not appear at "T" which means the test is negative. A control will always appear at "C" on a test that is functioning properly and when the test procedure has been followed.

## Precautions

1. For prescription use only.
2. For *in vitro* diagnostic use only.
3. Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate results.
4. Serial testing should be performed in symptomatic individuals with negative results at least twice over three days (with 48 hours between tests). You may need to purchase additional tests to perform this serial (repeat) testing or follow up testing with a molecular test.
5. Do not use the kit past its expiration date.
6. Do not use if any of the test kit contents or packaging is damaged.
7. Swabs, tubes, and test devices are for single use only. Do not re-use.
8. Do not interchange or mix components from different kit lots.
9. Testing should only be performed using the swabs provided within the kit. Do not touch the swab tip.
10. To obtain accurate results, do not use visually bloody or overly viscous samples.
11. Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
12. Wear appropriate personal protection equipment and gloves when running each test and handling patient specimens. Change gloves between handling of specimens.
13. Dispose of used contents as biohazardous wastes in accordance with federal, state, and local requirements.
14. Do not open the Test Cassette until you are ready to perform the test. Once opened, the test cassette should be used within one hour.
15. Do not read test results before 15 minutes or after 20 minutes. Results read before 15 minutes or after 20 minutes may lead to a false positive, false negative, or invalid results.
16. Do not use the kit to evaluate patient specimens if either the positive control swab or negative control swab fails to give the expected results.
17. Do not move test device during result development.

## Materials

**Materials provided**

- 20 Test Cassettes
- 20 Sterile Swabs
- 20 Pre-filled buffer tubes with flip-top
- 2 Tube Holders
- 1 Instructions for Use
- 1 Quick Reference Guide

**Materials required but not provided**

- Timer
- External Controls: COVID-19 Antigen Control Kit (GCCOV(Ag)-PN10/GCCOV(Ag)-PN20)

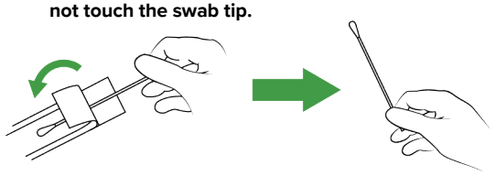
## Storage and Stability

1. The kit can be stored at room temperature or refrigerated (2-30°C/36-86°F) in the original sealed pouch.
2. Do not freeze any of the test kit components.
3. Keep away from direct sunlight.
4. Do not use the test device and reagents after the expiration date.
5. Unused test devices that have been outside of the sealed pouch for more than one hour should be discarded.
6. Close the kit box and secure contents when not in use.

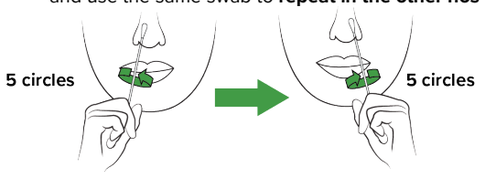
## Collection and Storage of Specimens

**Acceptable specimen type for testing is direct anterior nasal swab specimen. Inadequate specimen collection, improper specimen handling and/or transport may yield false results. Samples should be tested as soon as possible after collection. Based on data generated with the Rapid Response™ COVID-19 Antigen Detection Test, nasal swabs are stable for up to 4 hours at room temperature but should be stored in a sterile container if not tested immediately.**

1. Open the swab pouch by peeling the cover back. Hold the plastic stick end of the swab and remove from pouch. **Do not touch the swab tip.**



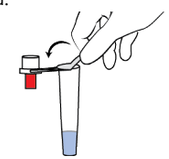
2. To collect the anterior nasal swab sample, tilt the patient's head back 70 degrees and insert the swab tip into nostril, at about **1/2 to 3/4 inches deep**. For children, young children, swab should not be inserted more than 1/2 inch. Rotate the swab along the inside walls of nostril in a complete circle at least **5 times**. Remove swab from nostril and use the same swab to **repeat in the other nostril.**



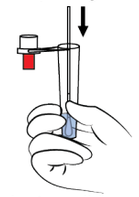

## Test Procedure

**Check expiration on each individual test package or outer box before using.**
**The test should be performed at room temperature (59-86°F; 15-30°C). Allow the test materials to reach room temperature prior to use. Do not open the Test Cassette until you are ready to use.**

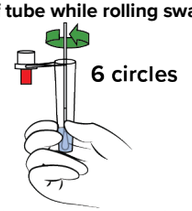
1. While maintaining the tube upright, remove seal from tube. Avoid spilling liquid.



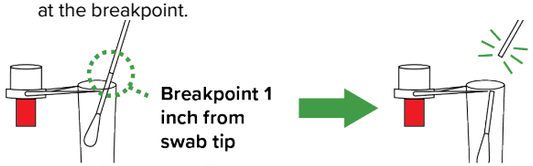
2. Insert swab tip in tube opening.



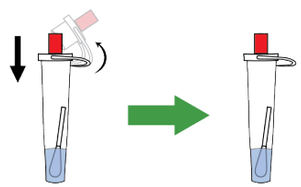
3. Grab swab shaft and mix well by rolling swab in a circular motion **at least 6 times. Press the swab tip against the bottom and sides of tube while rolling swab.**



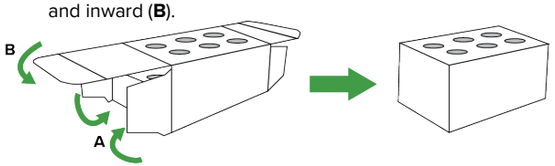

4. While holding the tube in your hand, place the swab's tip near the top of the tube. Gently bend the swab until it snaps at the breakpoint.



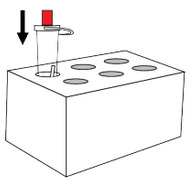

5. Hold tube upright. Close the flip cap of the tube tightly to ensure there is a tight fit so it does not leak. **Do not remove the red cap or swab tip from tube.**



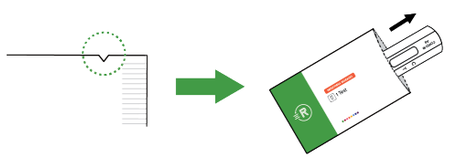
6. Fold tube holder by folding vertical flaps toward center (**A**). Hold vertical flaps in place and hold horizontal flap down and inward (**B**).



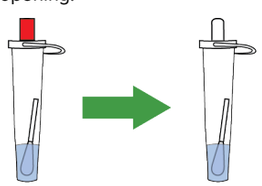

7. Allow the swab to sit in buffer tube for at least 1 minute, but no longer than 30 minutes immediately after specimen collection.



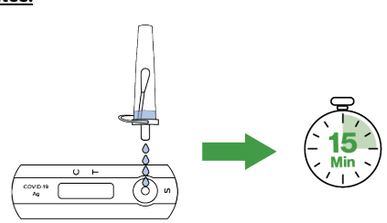
8. Open the test cassette pouch by tearing the area circled below. Place the test cassette on a **flat surface.**



9. **Gently remove red cap from tip.** Ensure tip remains secure within tube opening.

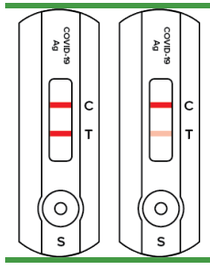


10. Invert the tube and gently squeeze, from the middle of the tube, to add **4 drops** of solution into the sample well, labeled as "S" on the test cassette. **Start timer for 15 minutes.**

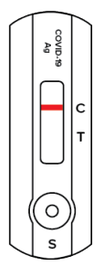



11. **After 15 minutes** read the test results visually in the result window, labeled as "C" and "T" on the test cassette. **Do not read result before 15 minutes or after 20 minutes.**

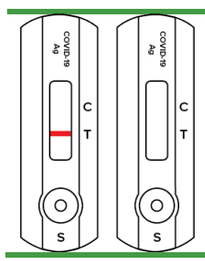
## Results Interpretation




**POSITIVE**
If the Control (C) line and the Test (T) line are visible, the test is positive. Any visible faint red or pink test (T) line with a visible control (C) line should be read as positive. Repeat testing is not needed for individuals with a positive result.




**NEGATIVE**
If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative. A negative test result indicates that the virus that causes COVID-19 was not detected in the sample.
**NOTE:** Negative results are presumptive and may be confirmed with a molecular assay, if necessary, for patient management. Individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours or followed up with a molecular test.




**INVALID**
If a control (C) line is not visible, the test is not valid. Invalid tests should be repeated with a new test.

## Limitations

1. This test is only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
2. The test is intended to only be used with direct anterior nasal swabs and is not validated for use with swabs in viral transport media.
3. This test is only for use with individuals who show symptoms of upper respiratory infection within 6 days of symptom onset.
4. Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals.
5. This test is not for use in at-home test settings.
6. This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
7. This test should not be used beyond the expiration date listed on the packaging. Use of expired tests can lead to incorrect results.
8. Accurate results are dependent on adequate specimen collection, transport, storage, and processing. Failure to observe proper procedures in any one of these steps can lead to incorrect results.
9. Test results should be interpreted in conjunction with other clinical and laboratory information available to the healthcare provider. Results from the device should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.
10. A negative test result does not preclude the possibility of infection with other bacteria or viruses.
11. A negative test result may occur if the level of antigen in the sample is below the detection limit of the test.
12. All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.
13. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
14. Positive test results do not rule out co-infections with other non-SARS viral or bacterial pathogens.
15. Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
16. False positive test results are more likely when prevalence of upper respiratory infection is low in the community.
17. This test detects both viable (live) and non-viable SARS-CoV-2 virus. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample. A false-negative test result may occur if the level of viral antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
18. There is a risk of erroneous results (i.e., false negatives) due to the presence of novel, emerging respiratory viral variants (e.g., specific strains or isolates).
19. The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between May 2022 and July 2022. The clinical performance has not been established in 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.
20. Based on sequence analysis, a potential for cross-reactivity between the SARS-CoV-2 test and HKU1 exists. Wet testing for HKU1 coronavirus was not conducted and therefore, cross-reactivity between SARS-CoV-2 and HKU1 coronavirus cannot be ruled out.

## Performance Characteristics

### Clinical Performance

Clinical performance of the Rapid Response™ COVID-19 Antigen Detection Test was established with 806 anterior nasal swab (ANS) samples prospectively collected from symptomatic subjects between May 2022 and July 2022 at six clinical point of care sites. Samples (ANS for the investigational device and nasopharyngeal (NP) swab for the comparator) were collected from sequentially enrolled subjects presenting with symptoms of upper respiratory infection within 6 days of onset of symptoms. Results obtained with the Rapid Response™ COVID-19 Antigen Detection Test were compared to a composite comparator method of two FDA cleared, highly sensitive RT-PCR assays. A third FDA cleared RT-PCR comparator assay was performed on comparator samples with discordant results between the first and second RT-PCR tests. The final result for the comparator was determined using a 2 out of 3 rules. Testing was performed by operators who had no prior experience in the laboratory and were representative of the intended users. Operators used only the QRI to conduct testing without comprehensive training provided. Of the 806 subjects, 164 were confirmed positive by the comparator and 642 were confirmed negative. The positive percent agreement (PPA) was 85.4% and the negative percent agreement (NPA) was 99.7% (see tables below).

**Table 1. Rapid Response™ COVID-19 Antigen Detection Test Results versus RT-PCR Composite Comparator for Symptomatic Patients**

| Rapid Response™ COVID-19 Antigen Detection Test | Composite Comparator | | Total |
|---|---|---|---|
| | Positive | Negative | |
| Positive | 140 | 2 | 142 |
| Negative | 24 | 640 | 664 |
| **Total** | **164** | **642** | **806** |

Positive Percent Agreement (PPA) = (140/164) = 85.4% (95% CI: 79.1% - 90%)
Negative Percent Agreement (NPA) = (640/642) = 99.7% (95% CI: 98.9% - 99.9%)

**Table 2. Patient Demographics**

| Subject Age Group | Number of samples tested | Antigen Positives | Composite Comparator Positives | % Positive (by Comparator) |
|---|---|---|---|---|
| 2-13 years of age | 75 | 11 | 13 | 17.3% |
| 14-24 years of age | 118 | 17 | 19 | 16.1% |
| 25-64 years of age | 514 | 91 | 110 | 24.4% |
| ≥65 years of age | 99 | 21 | 22 | 22.2% |
| **Total** | **806** | **140** | **164** | **20.3%** |

**Table 3. Clinical Performance in Subjects on Different Symptomatic Days**

| Days Post COVID-19 Symptoms | Number of samples tested | Antigen Positives | Composite Comparator Positives | PPA (%) |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| Day 0 | 26 | 3 | 3 | 100.0% |
| Day 1 | 92 | 14 | 16 | 87.5% |
| Day 2 | 213 | 36 | 46 | 78.3% |
| Day 3 | 219 | 31 | 39 | 79.5% |
| Day 4 | 150 | 27 | 29 | 93.1% |
| Day 5 | 75 | 17 | 19 | 89.5% |
| Day 6 | 31 | 12 | 12 | 100.0% |
| **Total** | **806** | **140** | **164** | **85.4%** |

## Analytical Sensitivity: Limit of Detection (LoD)

LoD studies determine the lowest detectable concentration of SARS-CoV-2 at which approximately 95% of all (true positive) replicates test positive. Heat inactivated SARS- CoV-2 virus, isolate 2019-nCoV/USA-WA1/2020, was spiked into negative clinical matrix composed of pooled nasopharyngeal swab specimens in PBS/saline and serially diluted. A preliminary LoD test was performed by spiking 50 µL of each diluted sample onto the sample collection swab head in triplicate. The confirmatory LoD test was performed at the selected preliminary LoD concentration and at concentrations above and below the preliminary LoD with an additional 20 replicates on the Rapid Response™ COVID-19 Antigen Detection Test. The Limit of Detection is 5.75 x $10^3$ $TCID_{50}$/mL (2.875 x $10^2$ $TCID_{50}$/swab). Furthermore, the LoD was established using the 1st WHO International Standard for SARS-CoV-2 Antigen (NIBSC 21/368) in real clinical matrix of pooled swab specimens. Initially, a preliminary LoD was performed in range finding studies, and a confirmatory LoD test was then conducted to confirm the preliminary LoD concentration and additional dilutions bracketing the preliminary concentration. It was determined that the LoD of the 1st WHO International Standard for SARSCoV-2 Antigen (NIBSC 21/368) for the Rapid Response™ COVID-19 Antigen Detection Test was determined to be 250 IU/mL (12.5 IU/swab).

## Inclusivity

Inclusivity testing was conducted with the currently available commercial stock strains of SARS-CoV-2 Alpha, Beta, Gamma, Delta, Kappa, and Omicron variants.

**Table 4. Results of Inclusivity Testing**

| SARS-CoV-2 Variant | Lowest Concentration with 9/9 Positive Results ($TCID_{50}$/mL) |
|---|---|
| B.1.1.7 (Alpha) | $1.00\times10^2$ |
| B.1.351 (Beta) | $3.83\times10^2$ |
| B.1.617.2 (Delta) | $1.10\times10^2$ |
| P1 (Gamma) | $6.30\times10^2$ |
| B.1.617.1 (Kappa) | $1.90\times10^2$ |
| B.1.1.529 (Omicron) | $2.51\times10^2$ |

## Analytical Specificity: Cross Reactivity (Exclusivity) and Microbial Interference

Various microorganisms were evaluated for cross-reactivity and microbial interference by wet testing with the Rapid Response™ COVID-19 Antigen Detection Test. Human coronavirus HKU1 was not tested for cross-reactivity due to a lack of availability. The samples were tested in triplicate, and no cross-reactivity and no microbial interference were observed. Microbial concentrations and results are outlined in **Table 5.**

**Table 5. Results of Microorganisms Tested for Cross-Reactivity and Microbial Interference**

| Microorganism | Concentration Tested | Cross-Reactivity | Interference |
|---|---|---|---|
| Human coronavirus 229E | 8.00 × $10^5$ $TCID_{50}$/mL | No | No |
| Human coronavirus OC43 | 7.00 x $10^6$ $TCID_{50}$/mL | No | No |
| Human coronavirus NL63 | 2.93 x $10^4$ $TCID_{50}$/mL | No | No |
| MERS-coronavirus | 7.0 × $10^5$ $TCID_{50}$/mL | No | No |
| Adenovirus 21 | 2.39 x $10^6$ $TCID_{50}$/mL | No | No |
| Adenovirus 10 | 1.14 x $10^6$ $TCID_{50}$/mL | No | No |
| Human Metapneumovirus | 3.95 x $10^5$ $TCID_{50}$/mL | No | No |
| Parainfluenza virus Type 1 | 2.23 x $10^6$ $TCID_{50}$/mL | No | No |
| Parainfluenza virus Type 2 | 2.23 x $10^5$ $TCID_{50}$/mL | No | No |
| Parainfluenza virus Type 3 | 4.00 x $10^6$ $TCID_{50}$/mL | No | No |
| Parainfluenza virus Type 4a | 4.00 x $10^3$ $TCID_{50}$/mL | No | No |
| Influenza virus, Type A (H1N1) | 4.00 x $10^8$ $CEID_{50}$/mL | No | No |
| Influenza virus, Type A (H3N2) | 7.00 x $10^5$ $TCID_{50}$/mL | No | No |
| Influenza virus, Type B | 7.00 x $10^5$ $TCID_{50}$/mL | No | No |
| Enterovirus 68 | 2.23 x $10^6$ $TCID_{50}$/mL | No | No |
| Enterovirus 71 | 4.00 x $10^7$ $TCID_{50}$/mL | No | No |
| Respiratory syncytial virus | 2.23 x $10^6$ $TCID_{50}$/mL | No | No |
| Rhinovirus 60 | 8.00 x $10^5$ $TCID_{50}$/mL | No | No |
| Haemophilus influenzae | 1.74 x $10^8$ CFU/mL | No | No |
| Streptococcus pneumoniae | 3.35 x $10^8$ CFU/mL | No | No |
| Streptococcus pyogenes | 5.98 x $10^8$ CFU/mL | No | No |
| Candida albicans | 1.19 x $10^8$ CFU/mL | No | No |
| Bordetella pertussis | 4.90 x $10^9$ CFU/mL | No | No |
| Mycoplasma pneumoniae | 6.75 x $10^7$ CCU/mL | No | No |
| Chlamydia pneumoniae | 4.25 x $10^7$ CFU/mL | No | No |
| Legionella pneumophila | 9.20 x $10^9$ CFU/mL | No | No |
| Staphylococcus aureus | 5.0 × $10^6$ CFU/mL | No | No |
| Staphylococcus epidermidis | 1.75 x $10^8$ CFU/mL | No | No |
| Pooled human nasal wash | N/A | No | No |

In-silico analysis was conducted for SARS-coronavirus, Human coronavirus HKU1, Mycobacterium tuberculosis, Pneumocystis jirovecii (PJP) and MERS coronavirus.

No sequence was found with significant homology with N protein sequence in both Mycobacterium tuberculosis and Pneumocystis jirovecii genomes, suggesting no cross-reactivity would not occur; however, cross-reactivity cannot be ruled out. Homologous N protein sequences were identified in SARS-coronavirus, Human coronavirus HKU1, and MERS coronavirus; therefore, cross-reactivity cannot be ruled out. The N protein sequence of SARS coronavirus shares 79.01%- 97.61% sequence identity indicating that cross-reactivity is likely.

## Endogenous Interfering Substances

To assess endogenous interference, potentially interfering substances which may be present in respiratory samples were tested to determine if interference may occur on the Rapid Response™ COVID-19 Antigen Detection Test. A summary of the results is shown in **Table 6**.

**Table 6. Results of Potential Interfering Substances**

| Substance | Concentration | Cross-Reactivity | Interference |
|---|---|---|---|
| Whole Blood | 4% | No | No |
| Human Leukocytes | 1 × $10^7$ cells/mL | No | No |
| Mucin | 0.5% | No | No |
| Chloraseptic (Menthol/Benzocaine) | 3 mg/mL | No | No |
| Naso GEL (NeilMed) | 5% v/v | No | No |
| CVS Nasal Drops (Phenylephrine) | 15% v/v | No | No |
| Afrin (Oxymetazoline) | 15% v/v | No | No |
| CVS Nasal Spray (Cromolyn) | 15% v/v | No | No |
| Zicam | 5% v/v | No | No |
| Homeopathic (Alkalol) | 15% v/v | No | No |
| Sore Throat Phenol Spray | 15% v/v | No | No |
| Tobramycin | 4 µg/mL | No | No |
| Mupirocin | 10 mg/mL | No | No |
| Fluticasone Propionate | 15% v/v | No | No |
| Tamiflu (Oseltamivir Phosphate) | 5 mg/mL | No | No |

## Hook Effect

The Hook Effect study tested up to 5.75 × $10^6$ $TCID_{50}$/mL of heat-inactivated SARS-CoV-2 (USA-WA1/2020) on the Rapid Response™ COVID-19 Antigen Detection Test. The test results show that there was no detectable hook effect even for the highest concentrated virus sample.

## Precision/Reproducibility

A reproducibility study was performed to evaluate reproducibility of the Rapid Response™ COVID-19 Antigen Detection Test. The study was performed at three external, CLIA-waived testing sites consisting of three replicates each of positive (prepared at 3x LoD), low positive (prepared at 1x LoD), and negative samples tested by three (3) untrained operators over 5 days, i.e., 3 replicates × 3 operators × 3 sites × 5 days= 135 replicates per concentration and a total of 405 data points collected. Three (3) test lots were used in this study, so lot-to-lot variability was also assessed. Fifty (50) µL of the prepared sample were applied to kit swabs, shipped and stored frozen at -4° F (-20°C) until testing. The results were ≥90% agreement between expected and read result within run, by lot, by operator, by day, between sites and overall.

**Table 7. Results of Multisite Precision Study (Reproducibility)**

| Site | Negative | | Weak Positive | | Positive | |
|---|---|---|---|---|---|---|
| | Correct Reads/Total | PPA | Correct Reads/Total | PPA | Correct Reads/Total | PPA |
| 1 | 44/45 | 97.8% | 45/45 | 100.0% | 45/45 | 100.0% |
| 2 | 45/45 | 100.0% | 45/45 | 100.0% | 45/45 | 100.0% |
| 3 | 45/45 | 100.0% | 45/45 | 100.0% | 45/45 | 100.0% |
| **Total** | **134/135** | **99.2%** | **135/135** | **100.0%** | **135/135** | **100.0%** |

## Bibliography


1. Julien Favresse, Constant Gillot, Maxime Oliveria, Julie Cadrobbi, Marc Elsen, Christine Eucher, Kim Laffineur, Catherine Rosseels, Sandrine Van Eeckhoudt, Jean-Baptiste Nicolas, Laure Moiremont, Jean-Michael Dogné and Jonathan Douxfils. Head-to-Head Comparison of Rapid and Automated Antigen Detection Tests for the Diagnosis of SARS- CoV-2 Infection J. Clin. Med. 2021, 10, 265.
2. Ignacio Torres, Sandrine Poujois, Eliseo Albert, Gabriela Álverez, Javier Colomina and David Navarro. Point-of-care evaluation of a rapid antigen test for diagnosis of SARS-CoV-2 infection in symptomatic and asymptomatic individuals February 11, 2021
3. Public Health England. SARS-CoV-2 lateral flow antigen tests: evaluation of VOC1 (Kent UK) and VOC2 (South Africa) Published12 February 2021


## Glossary of Symbols

Consult instructions for use

Test per Kit

Keep Dry

Store between 36°F to 86°F

Use by

Do Not Reuse

LOT Lot Number

IVD For *in vitro* diagnostic use only

REF Catalogue #

Keep away from sunlight

℞ Only Prescription Use Only

UDI Unique Device Identifier

**Technical Support:**
For questions or technical support, please contact our Technical Support 1-888-339-9964 or email support@btnx.com.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