COVID-19 Antigen Test Rx
INSTRUCTIONS FOR USE

For *In Vitro* Diagnostic Use.
For Prescription Use Only.
For use in a CLIA Complexity: Waived Environment.
This CLIA-waived kit configured for testing anterior nasal swab samples.

CLIA COMPLEXITY: WAIVED
A Certificate of Waiver is required to perform this test in a CLIA Waived setting. To obtain CLIA waiver information and a Certificate of Waiver, please contact your state health department. Additional CLIA waiver information is available at the Centers for Medicare and Medicaid website at www.cms.hhs.gov/CLIA.
Failure to follow the instructions or modification to the test system instructions will result in the test being classified as high complexity.

INTENDED USE

The WELLlife™ COVID-19 Antigen Test Rx is a visually read lateral flow immunoassay test intended for the qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of upper respiratory infection. 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 WELLlife™ COVID-19 Antigen Test Rx and followed with a molecular test.
A negative test result is presumptive, and does not preclude SARS-CoV-2 infection; it is recommended these results be confirmed by a molecular SARS-CoV-2 assay.
Positive results do not rule out co-infection with other respiratory pathogens and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.
Performance characteristics for SARS-CoV-2 were established from April 2023 to February 2024 when SARS-CoV-2 Omicron was dominant. When other SARS-CoV-2 virus variants are emerging, performance characteristics may vary.

SUMMARY AND EXPLANATION

Coronaviruses are enveloped RNA viruses that are found broadly among humans, other mammals, and birds. The viruses are known to cause mild symptoms, but sometimes severe respiratory, enteric, hepatic, and neurological diseases can occur. Seven coronavirus species are known to cause human disease, four of which (229E, OC43, NL63 and HKU-1) are quite prevalent and can cause mild cold symptoms, especially in immunocompetent people.[1] There are three other strains that are known to cause severe acute respiratory disease. These strains include severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory syndrome coronavirus (MERS-CoV), and the 2019 Novel Coronavirus (COVID-19). These strains are all zoonotic in origin and have been linked to sometimes fatal respiratory illness. The prevalence of SARS and MERS has been quite low in recent years; the Novel Coronavirus (COVID-19) was recently identified in December 2019. The main manifestations of illness include fever, fatigue, and dry cough. Nasal congestion, runny nose, sore throat, myalgia, and diarrhea are found in a few cases. Infected but asymptomatic people can also be an infectious source. The WELLlife™ COVID-19 Antigen Test Rx can provide rapid detection of SARS-CoV-2 viral antigens from symptomatic patients.

PRINCIPLE OF PROCEDURE

The WELLlife™ COVID-19 Antigen Test Rx is a sandwich immunochromatographic assay that uses antibodies to detect SARS-CoV-2 nucleocapsid antigen extracted from nasal swab specimen.
A nasal swab sample is collected and then inserted into the extraction buffer during which the extraction buffer disrupts the virus particles in the specimen to expose internal viral nucleocapsid antigens. The extracted specimen is added into the sample well of the test cassette. When an adequate volume of the specimen is added the sample well (S) of the test cassette, the specimen migrated by capillary action from the sample well over the conjugated pad and across the nitrocellulose membrane test strip. During the migration the reagents in the conjugated pad are solubilized. If SARS-CoV-2 nucleocapsid antigens are present in the sample, the antigens bind to the specific anntı-SARS-CoV-2 antibody conjugated with dye particles on the conjugated pad and the antigen–antibody complexes captured by the anti-SARS-CoV-2 antibody immobilized at the test line region (T) to form sandwich complexes to generate a visible colored test line. Unbound conjugates continue to migrate across the nitrocellulose membrane and are captured at the control line region (C) to result in a visible colored control line that indicates adequate operations and sample flow during the test. If no SARS-CoV-2 nucleocapsid antigens are present in the sample, the conjugate will only be captured at the control line of the test.
Results are interpreted between 10 and 20 minutes after adding the extracted sample into the sample well. A false negative or false positive result may occur if the test result before 10 minutes or after 20 minutes.

MATERIALS PROVIDED

Each WELLlife™ COVID-19 Antigen Test Rx contains enough reagents and materials. The following components are included in a kit:

Components	25 Tests/kit
Test Cassette	25
Tube	25
Swab	25
Tube Holder	1
Quick Reference Instructions	1
Instructions for Use	1

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or clock
- WELLlife™ COVID-19 Antigen Test Rx Control Kit (Catalogue No.: WCOV-CON-1, WCOV-CON-5)

WARNINGS AND PRECAUTIONS

- **Do not use this test when individuals have symptoms for more than 5 days or if individuals have no symptoms.**
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- Check the test's expiration date. Do not use kit past its expiration date. Use of expired tests can lead to incorrect results.
- The test device should remain in its original sealed pouch until ready for use to keep all test components dry.
- Do not use if any of the test kit components or packaging is damaged.
- Once opened, the test device must be used immediately.
- Do not use the kit to evaluate patient specimens if either the positive control swab or negative control swab fail to give expected results.
- Do not mix components from different kits or different lots.
- Wear protective clothing such as safety mask or other face covering, laboratory coats, disposable gloves, and eye protection when specimens are collected and evaluated.
- Do not reuse the test cassette, processing solution, or swab.
- Not for use with viral transport media (VTM).
- When collecting a sample, only use the swab provided in the kit.
- Inadequate or inappropriate sample collection, test storage, or test transport may yield false test results.
- Testing should be performed in an area with good lighting.
- **Keep test kit and materials out of the reach of children and pets before and after use. Avoid exposure of your skin, eyes, nose, or mouth to the solution in the tube. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the reagent solution contacts the skin, eyes, nose, or mouth, flush with large amounts of water. If irritation persists, seek medical advice. https://www.poisonhelp.org or 1-800-222-1222.**

Chemical name	Harms (GHS Code) for each ingredient	Concentration
ProClin 300	Causes serious eye irritation (H319) Cause mild skin irritation (H316)	0.02%
Tris-HCl	Causes eye irritation (H320) Causes skin irritation (H315)	1.2%
Tween 20	Causes eye irritation (H319) Causes skin irritation (H315)	0.5%

STORAGE AND STABILITY

- The test kit should be stored in a dry place between 36°F– 86°F (2°C–30°C). The test kit is stable until the expiration date on kit box and pouch. Do not use beyond the expiration date.
- Ensure all kit components are at room temperature 59°F– 86°F (15°C–30°C) before use.
- Keep away from direct sunlight, moisture and heat.
- Do not freeze any of the test kit components.

SAMPLE STORAGE AND TRANSPORTATION

Samples should be tested immediately after collection.

QUALITY CONTROL

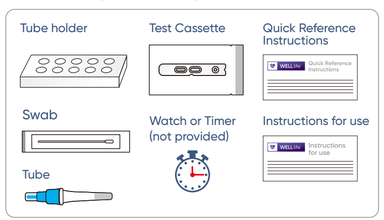
Internal Quality Control
Each WELLlife™ COVID-19 Antigen Test Rx has a built-in internal procedural control. The red line appearing at the "C" position is an internal procedural control. This procedural control line indicates that sufficient flow has occurred, and the functional integrity of the test cassette has been maintained. A distinct pink to red Control line should always appear if the test has been performed correctly. If the Control line does not appear, the test result is invalid, and a new test should be performed. Contact Wondfo USA Co. Ltd., at 1-888-444-3657 or via wondfo@wondfousa.com if you experience a problem.

External Quality Control Procedure
The WELLlife™ COVID-19 Antigen Test Rx Control Kit may be used with the WELLlife™ COVID-19 Antigen Test Rx. The controls are specifically formulated and manufactured to ensure performance of the test and are used to verify an operator's ability to properly perform the test and interpret the results. The external controls should be processed and tested in accordance with the nasal swab test procedure provided in the Instructions for Use or in the Quick Reference Instructions (QRI). Use of Kit Control reagents manufactured by any other source should not be used and will not ensure adequate quality assurance. It is recommended that the positive and negative controls are run once for each untrained operator, once for each new shipment of kits –provided that each different lot received in the shipment is tested – and as deemed additionally necessary by your internal quality control procedures, and in accordance with Local, State, and Federal regulations or accreditation requirements.
If external controls do not perform as expected, testing of individuals should not be performed. Repeat the test or contact Wondfo via email at wondfo@wondfousa.com or call 1-888-444-3657.

STEP BY STEP INSTRUCTIONS

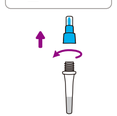
MATERIAL PREPARATION

1. Ensure you have all required testing components. Place the kit components on a flat surface.
NOTE: Ensure all test components are at room temperature (15°C–30°C (59°F–86°F)) before use.

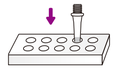


2. Check the expiration date of the test kit before use.
WARNING: The test must not be used beyond the expiration date listed on the packaging. Use of expired tests can lead to incorrect results.

3. Remove the large blue cap from the **TUBE**.

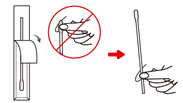


4. Place **TUBE** in the Tube Holder.



SAMPLE COLLECTION

5. Remove the **SWAB** from its wrapper.
Do not touch the tip of the swab.

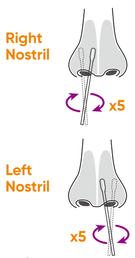


6. Gently insert the entire absorbent tip of the swab (3/4 of an inch) into the nostril.

WARNING: Do not insert the swab any further if you feel any resistance.

7. Firmly and slowly brush against the nasal wall in a circular motion **at least 5 times.** Remove the swab and repeat in the other nostril using the same swab. Take **at least 15 seconds** to collect the specimen and be sure to collect any nasal drainage on the swab.

WARNING: Be sure to rub BOTH nostrils with the same SWAB.



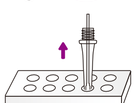
NOTE: With children, you may not need to insert the swab as far into the nostril and you may need another person to steady the child's head while swabbing.

NOTE: Failure to swab properly may cause false negative results.

TEST PROCEDURE

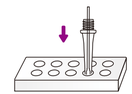
8. Immediately place the **SWAB** into the liquid inside the **TUBE**, and ensure it is touching the bottom of the **TUBE**.

9. Remove the **TUBE** from the tube holder.



10. Stir the swab vigorously **at least 15 times.**

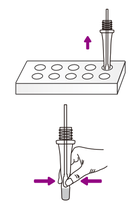
11. Place the tube back into the tube holder. Keep the swab inside of the tube for 1 minute.



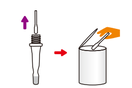
12. Start timer for 1 minute.

13. After 1 minute, take the tube out of the tube holder. **Remove the swab while squeezing the sides of the tube** to express as much liquid as possible from the swab.

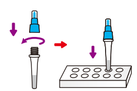
WARNING: Be sure to squeeze the tube while removing the swab.



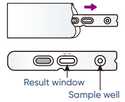
14. Dispose the **SWAB** in the trash.



15. Screw the large blue cap back onto the **TUBE**. Place **TUBE** in the Tube Holder.

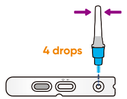


16. Remove the **TEST CASSETTE** from the sealed pouch and lay it flat.



17. Twist to open the small white cap at the top of the **TUBE.**

18. Add **4 drops** of sample into the sample well of the **TEST CASSETTE**.

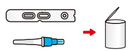


19. Wait **10 minutes.** And then read the result at 10 minutes as described in the next section **Interpretation of Results.**

DISPOSE THE TEST KIT

20. Screw back the small white cap.

21. After the test is completed, dispose of the kit and its components in the trash.



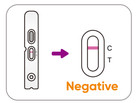
INTERPRETATION OF RESULTS

WARNING: Do not read the result before 10 minutes or after 20 minutes. Results read before 10 minutes or after 20 minutes may result in false or invalid results.
Look carefully for a C line for a valid test result. For positive result, look carefully for a T line.

Positive Result

If the Control (C) line and the Test (T) line are visible, the test result is Positive. Any faint visible pink or purple test (T) line with the control (C) line should be read as positive. **Do not need to repeat testing if you have a positive result at any time.**

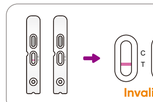
Negative Result



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 Result



If a Control (C) line is NOT visible, DO NOT CONTINUE reading the results. It means that your test result is INVALID.

NOTE: An invalid test result means that the test is unable to determine if individuals are infected with SARS-CoV-2 (COVID-19) or not. The test needs to be repeated with a new kit and sample.
If the problem persists, please call at 1-888-444-3657.

LIMITATIONS

- The clinical performance of this test was established based on the evaluation of a limited number of clinical specimens collected between April, 2023 and February, 2024. The clinical performance has not been established for 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. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.
- 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.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.
- If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- This test is read visually. Because test lines can be very faint, users with conditions affecting their vision – such as far-sightedness, glaucoma, or color blindness–are encouraged to seek assistance to interpret results accurately (e.g., reading glasses, additional light source, or another person). This test has not been validated for use by those with color-impaired vision.
- This test detects both viable (live) and nonviable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample.
- This test does not distinguish between SARS-CoV and SARS-CoV-2.
- The test results should be interpreted in conjunction with other clinical and laboratory data available to the healthcare provider.
- A false negative test result may occur if the level of viral antigen in a sample is below the detection limit of the test; therefore, a negative test result does not eliminate the possibility of SARS-CoV-2 infection.

PERFORMANCE CHARACTERISTICS

ANALYTICAL PERFORMANCE

Lot-to-Lot Precision
Precision was assessed by measuring repeatability using three levels of samples including negative samples, weak positive sample and a positive sample. Samples were prepared in negative clinical nasal swab matrix (NCM), blinded and randomized. 50uL were pipetted onto each swab and swabs were processed per the IFU. The following results were obtained from three kit lots testing each sample in duplicate per run by three operators and two runs per day over 20 days (3 lots × 3 operators × 2 replicates/sample × 2 runs/day/operator × 20 days). A total of 720 tests were run per panel member.

Sample Level	% Agreement with Expected Result			
	Lot 1	Lot2	Lot 3	Total
Negative	240/240 (100%)	240/240 (100%)	240/240 (100%)	720/720 (100%)
Weak positive (1.5 x LoD)	240/240 (100%)	240/240 (100%)	240/240 (100%)	720/720 (100%)
Positive (3 x LoD)	240/240 (100%)	240/240 (100%)	240/240 (100%)	720/720 (100%)

In addition, a supplemental precision study was conducted testing negative samples and a sample below the LoD (0.9 x LoD) to demonstrate potential lot variability. These samples were tested with three lots by two operators for two replicates per run and two run per day over three days (3 lots × 2 operators × 2 replicates/sample × 2 runs/day/operator × 3 days).

Sample Level	Number of positive samples/total tested (%)			
	Lot 1	Lot2	Lot 3	Total
Negative	0/24 (0%)	0/24 (0%)	0/24 (0%)	0/72 (0%)
0.9 x LoD SARS-CoV-2	20/24 (83.33%)	20/24 (83.33%)	24/24 (100%)	64/72 (88.89%)

Site-to-Site Reproducibility
A multisite precision study was performed at three external CLIA-waived testing sites to evaluate reproducibility of the WELLlife™ COVID-19 Antigen Test Rx. Testing consisted of three replicates each of positive (3x LoD), weak positive (1x LoD), low positive (0.8x LoD), high negative (0.1x LoD) and negative samples tested by three (3) untrained operators per site over 5 days, i.e., 3 replicates × 3 operators × 3 sites × 5 days = 135 replicates per concentration for a total of 675 total data points collected. Fifty (50) µL of the prepared sample were applied to kit swabs, shipped and stored frozen until testing.

Site	Operator	True Negative	High Negative	Low Positive	Weak Positive	Moderate Positive
A	n=3	45/45	45/45	40/45	44/45	45/45
B	n=3	45/45	45/45	40/45	45/45	45/45
C	n=3	45/45	45/45	39/45	45/45	45/45
Total		135/135	135/135	119/135	134/135	135/135
%Agreement		100%	100%	88.2%	99.3%	100%
95% CI		97.2%-100%	97.2%-100%	81.6%-92.6%	95.9%-99.9%	97.2%-100%

Limit of Detection (Analytical Sensitivity)
The Limit of Detection (LoD) of the WELLlife™ COVID-19 Antigen Test Rx was determined by evaluating different dilutions of two (2) variants of inactivated SARS-CoV-2 in pooled negative nasal swab matrix. A 10-fold dilution series was made to determine the preliminary LoD, which was measured using three (3) device lots in triplicate measurements (n=3/lot). 50uL were pipetted onto each swab and swabs were processed per the IFU. The LoD was confirmed using 20 replicates for each of the same three (3) lots. The lowest viral concentration that was detected greater than or equal to 95% of the time (i.e., concentration at which at least 19 out of 20 replicates tested positive) was determined to be the LoD for that strain. The LoD was the same for all three lots tested.

Variant	Virus Strain	LoD	
		$TCID_{50}$/mL	$TCID_{50}$/swab
Original	USA-WA1/2020	1.0×10^2	50.0
Omicron BA.5	USA/COR-22-063113/2022	3.33×10^3	166.7
Omicron XBB	hCoV-19/USA/CA-STANFORD-109_S21/2022	1.0×10^4	500

WHO Standard Testing
The Limit of Detection (LoD) of the WELLlife™ COVID-19 Antigen Test Rx was determined by using different dilutions of 1st WHO International Standard for SARS-CoV-2 antigen (NIBSC code: 21/368) in pooled negative nasal swab matrix. 50uL were pipetted onto each swab and swabs were processed per the IFU. The LoD was determined for three different reagent lots as the lowest virus concentration that was detected ≥ 95% of the time (i.e., concentration at which at least 19 out of 20 replicates tested positive). The LoD was the same for all three lots tested.

WHO Standard		LoD	
		IU/mL	IU/swab
SARS-CoV-2 antigen	NIBSC code: 21/368	2.00×10^2	10

Inclusivity (Analytical Reactivity)
Analytical reactivity for WELLlife™ COVID-19 Antigen Test Rx was demonstrated using six (6) additional strains of SARS CoV-2 virus and one (1) SARS-CoV-2 JN.1 clinical specimen, in an LoD-like study. For six (6) additional strains of SARS CoV-2 virus, a 10-fold dilution series was made to determine the preliminary analytical reactivity concentration, which was measured using three (3) device lots and in triplicate measurements (n=3). The preliminary analytical reactivity concentration was confirmed using 20 replicates in triplicate using the same three (3) lots. 50uL were pipetted onto each swab and swabs were processed per the IFU. The lowest viral concentration that was detected greater than or equal to 95% of the time (i.e., concentration at which at least 19 out of 20 replicates tested positive) was determined to be the analytical reactivity concentration for that strain. For JN.1 variant testing, one (1) clinical specimen was serially diluted and tested with 5 replicates per dilution/concentration. The lowest concentration that detected 5 positive out of 5 samples represents analytical reactivity concentration for JN.1. The analytical reactivity of the WELLlife™ COVID-19 Antigen Test Rx with the variants is shown in table below:

Variant	Virus Strain	Lowest Reactivity Concentration
Alpha	England/204820464/2020	1.0×10^1 $TCID_{50}$/mL
Beta	South_Africa/KRISP-K005325/2020	1.0×10^1 $TCID_{50}$/mL
Gamma	Japan/TY7-503/2021	1.0×10^1 $TCID_{50}$/mL
Delta	USA/PHC658/2021	1.0×10^1 $TCID_{50}$/mL
Omicron B.1.1.529	USA/MD-HP20874/2021	1.0×10^1 $TCID_{50}$/mL
Omicron BA.2.3	USA/MD-HP24556/2022	3.33×10^1 $TCID_{50}$/mL
JN.1	Clinical specimen	Ct=279 (2.28× 10^5 GE/mL)

Analytical Specificity: Cross-Reactivity and Microbial Interference
To demonstrate that the device does not react with related viruses, other infectious pathogens, and normal flora that are reasonably likely to be encountered in nasal swab specimens cross-Reactivity and Microbial Interference of the WELLlife™ COVID-19 Antigen Test Rx was evaluated by testing 30 microorganisms diluted into negative clinical nasal swab matrix and a sample of pooled nasal wash. Each microorganism was tested in three (3) replicates in the absence and presence of SARS-CoV-2 (USA/COR-22-063113/2022) at 2-3xLoD. None of the organisms and viruses evaluated demonstrated cross-reactivity or microbial interference in this assay at the concentrations tested.

Microorganism	Final Concentration	Cross-Reactivity (no analyte) (# pos reps/total reps)	Interference (3xLoD SARS-CoV-2) (# pos reps/total reps)
Human coronavirus 229E	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Human coronavirus OC43	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Human coronavirus NL63	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
MERS-coronavirus	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Coronavirus HKU 1**	Ct = 20.5 Ct = 22	0/3	3/3
SARS-CoV Nucleocapsid Protein (His Tag)**	0.25 ng/mL	0/3	3/3
Human Adenovirus 1	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Human Metapneumovirus (hMPV-S) Type B1	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus Type 1	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus Type 2	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus Type 3	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus Type 4A	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Enterovirus	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Respiratory syncytial virus	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Rhinovirus	5.62 x 10^4 $TCID_{50}$/mL	0/3	3/3
Influenza A/Victoria/4897/22	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Influenza A/Darwin/6/21	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Influenza B/Washington/02/19	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Influenza B/Florida/04/06	1.17 x 10^3 $TCID_{50}$/mL	0/3	3/3
Haemophilus influenzae type b	2 x 10^6 CFU/mL	0/3	3/3
Bordetella pertussis	2 x 10^6 CFU/mL	0/3	3/3
Candida albicans	2 x 10^6 CFU/mL	0/3	3/3
Chlamydia pneumoniae	2 x 10^6 IFU/mL	0/3	3/3
Legionella pneumophila	2 x 10^6 CFU/mL	0/3	3/3
Mycoplasma tuberculosis	2 x 10^6 CFU/mL	0/3	3/3
Mycoplasma pneumoniae	2 x 10^6 CCU/mL	0/3	3/3
Staphylococcus aureus MRSA	2 x 10^6 CCU/mL	0/3	3/3
*Staphylococcus epidermidis**	2 x 10^6 CFU/mL	0/3	3/3
Streptococcus pneumoniae	2 x 10^6 CFU/mL	0/3	3/3
Streptococcus pyogenes	2 x 10^6 CFU/mL	0/3	3/3
Pneumocystis jirovecii (PJP) - S. cerevisiae†	2x10^6 CFU/mL	0/3	3/3
Pooled human nasal wash	NA	0/3	3/3

** Two different clinical samples were tested in replicates of three.*
 # Tested with 2xLoD of SARS-CoV-2 Omicron Variant lineage BA.5 while the other potential cross-reactants/interferents were tested at 3xLoD.
*** Recombinant protein/strains were tested as the live or inactivated strains were hard to obtain.*

Endogenous Interfering Substances
Forty-two (42) potentially interfering substances, diluted in negative nasal swab matrix, were tested with the WELLlife™ COVID-19 Antigen Test Rx. Each substance was tested in three (3) replicates in the absence and presence of heat-inactivated SARS-CoV-2 (isolate USA/COR-22-063113/2022) at 2-3xLoD. The endogenous and exogenous interfering substances do not cross-react or interfere with the performance of the device at the concentrations tested.

Interfering Substances	Concentration	Cross-Reactivity (no analyte) (# pos reps/total reps)	Interference (3xLoD SARS-CoV-2) (# pos reps/total reps)
Whole Blood	2.5%	0/3	3/3
Mucin	2.5mg/mL	0/3	3/3
Chlorasceptic sore throat lozenges (Benzocaine)	3mg/mL	0/3	3/3
Chlorasceptic sore throat lozenges (Menthol)	3mg/mL	0/3	3/3
NeilMed (Sodium chloride with preservatives)*	15% v/v	0/3	3/3
CVS Nasal Drops (Phenylephrine)	15% v/v	0/3	3/3
Afrin (Oxymetazoline)	15% v/v	0/3	3/3
CVS Nasal Spray (Cromolyn)	15% v/v	0/3	3/3
Zicam	15% v/v	0/3	3/3
Homeopathic (Alkalol)	15% v/v	0/3	3/3
Sore Throat Phenol Spray	5% w/v	0/3	3/3
Tobramycin	4 µg/mL	0/3	3/3
Mupirocin	10 mg/mL	0/3	3/3
Fluticasone Propionate	15% v/v	0/3	3/3
Tamiflu (Oseltamivir Phosphate)	5mg/mL	0/3	3/3
Biotin	3.5 µg/mL	0/3	3/3
Menthol	0.015% w/v	0/3	3/3
Bleach	0.01% v/v	0/3	3/3
Dish Soap	1% v/v	0/3	3/3
Laundry Detergent	1% v/v	0/3	3/3
Multisurface Cleaner	1% v/v	0/3	3/3
Hand Soap	1% v/v	0/3	3/3
Laundry Detergent	1% w/v	0/3	3/3
Bar Soap	1% w/v	0/3	3/3
Multipurpose Cleaner	1% v/v	0/3	3/3
Hand Sanitizer	1% v/v	0/3	3/3
Aspirin	15 mg/mL	0/3	3/3
Motrin (Ibuprofen)	50 mg/mL	0/3	3/3
Naproxen	20 mg/mL	0/3	3/3
Budesonide*	15% v/v	0/3	3/3
Flunisolide*	15% v/v	0/3	3/3
Triamcinolone*	15% v/v	0/3	3/3
Dexamethasone*	5 mg/mL	0/3	3/3
Beclomethasone*	15% v/v	0/3	3/3
Remdesivir*	5 mg/mL	0/3	3/3
Molnupiravir*	5 mg/mL	0/3	3/3
Leukocytes	≥1 x10^6 cells/mL	0/3	3/3
Sulfur*	1.25%	0/3	3/3
Zinc*	15% v/v	0/3	3/3
Luffa opperculata*	1.25%	0/3	3/3
Galphimia glauca*	15% v/v	0/3	3/3
Histaminum hydrochloricum*	15% v/v	0/3	3/3
Zanamivir*	10mg/mL	0/3	3/3

** Tested with 2xLoD of SARS-CoV-2 Omicron Variant lineage BA.5 while the other potential interferents were tested at 3xLoD.*

High Dose Hook Effect
No high-dose hook effect was observed when WELLlife™ COVID-19 Antigen Test Rx was used to test specimens containing SARS-CoV-2 Omicron Lineage BA.5 (hCoV19/USA/COR-22-063113/2022) viral concentration as high as 1.98 x 10^6 $TCID_{50}$/mL.

Flex Studies
To assess the robustness and risk for false results of the test when deviating from the IFU/QRI test steps, flex studies were conducted that assessed all major aspects of the test procedure (sample volume, reading time, swab extraction time, swab rotation, and tube squeezing) and variability of environmental test conditions that the test may be subjected to when in use (lighting, disturbance during use, temperature, and humidity stress conditions). Testing was performed with contrived positive nasal swabs generated by diluting SARS-CoV-2 virus into negative NCM at 2xLoD. False results are observed with too little sample volume and insufficient incubation time, specifically with less than two drops of sample and with less than five minutes incubation. However, these failures are mitigated in the labeling with warning statements in the procedural steps. The studies support that the test is robust in the intended use condition with an insignificant risk of erroneous result.

CLINICAL PERFORMANCE

A prospective study was performed in which one thousand and fifty-three (1053) direct anterior nasal swab specimens were sequentially enrolled (between April 2023 and February 2024) and tested fresh with the WELLlife™ COVID-19 Antigen Test Rx. The samples were collected from symptomatic patients suspected of infection with respiratory symptoms, at nine (9) clinical sites. Subjects performed testing on self-collected swab samples in age groups 14 and older, and adult collected samples for age groups 2–13, in a simulated at-home environment. To be enrolled in the study, patients had to present at the participating study site with signs and symptoms of respiratory infection generally observed from SARS-CoV-2 during the study period. Two anterior nasal swab specimens were collected from each patient: one swab was collected by a healthcare professional and sent for testing using an FDA-cleared highly sensitive molecular comparator method, and the other swab was self-collected and tested immediately with the WELLlife™ COVID-19 Antigen Test Rx per the test procedure. Out of 1053 enrolled subjects, there were 1032 evaluable subjects within 5 days of symptom onset (DPSO).

Subjects Demographics

Characteristic	# Evaluable Subjects	% of Total
2–13 years of age	117	11.34%
14–21 years of age	86	8.33%
22–64 years of age	698	67.64%
≥ 65 years of age	131	12.69%
Total	**1032**	**100%**
Male	414	40.12%
Female	618	59.88%
Total	**1032**	**100%**
Self-collected sample	900	87.21%
Sample collected by other	132	12.79%
Total	**1032**	**100%**

Performance of the WELLlife™ COVID-19 Antigen Test Rx in Symptomatic subjects

		FDA-Cleared Comparator Method		
		Positive	Negative	Total
The proposed device	Positive	108	3	111
	Negative	20	901	921
	Total	128	904	1032
Positive Percent Agreement (PPA)		84.38% (108/128) (95% CI:77.10% - 89.65%)		
Negative Percent Agreement (NPA)		99.67% (901/904) (95% CI:99.03% - 99.89%)		

Clinical Performance in Subjects on Days Post Symptoms Onset

Days Since Symptom Onset	PPA	NPA
0	100.00% (5/5)	100.00% (19/19)
1	90.91% (20/22)	100.00% (153/153)
2	82.35% (28/34)	99.69% (318/319)
3	83.33% (25/30)	99.13% (228/230)
4	86.36% (19/22)	100.00% (116/116)
5	73.33% (11/15)	100.00% (67/67)
Total	84.38% (108/128)	99.67% (901/904)

SERIAL TESTING
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 tests 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.

Performance of the antigen test with serial testing in symptomatic individuals is described in the table below. 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.
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	SYMPTOMATIC ON FIRST DAY OF TESTING		
	Ag Positive / PCR Positive (Antigen Test Performance % PPA)		
	1 Test	2 Test	3 Test
0	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	58/62 (93.5%)	59/60 (98.3%)	43/43 (100.0%)
4	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	4/9 (44.4%)	3/7 (42.9%)	NA

1 Test = one (1) test performance 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 performance 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.

ASSISTANCE

If the test does not perform as expected, please call 1-888-444-3657.

REFERENCES

1. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17: 181–192.

INDEX OF SYMBOLS

Keep away from sunlight	Store between 2°C–30°C (36°F–86°F)	Keep dry	Do not re-use
Catalogue number	Batch code	Use-by date	In Vitro diagnostic medical device
Consult instructions for use	Do not use if package is damaged	Contains sufficient for <n> tests	Manufacturer
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物料编码：13031587	项目名称： 新冠510K专业版说明书(660x210mm)WELLlife A1.1			
尺寸(长*宽*高)： 660x210mm	颜色： C83M100K44 C62Y35 C76M56Y20K29		材质：70g双胶纸	工艺：
折页方式：长边风琴5折6页+上下对折	修改内容：■文字 □颜色 □尺寸 □工艺 □材质 □其他 □无			
改稿前编码：13028409	申请人： 刘思莹	设计师：申芳		设计时间： 2026.06.15

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