COVID-19 Antigen Home Test

INSTRUCTIONS FOR USE

For *in vitro* diagnostic use.
For Over the Counter (OTC) Use
For use with anterior nasal swab specimens.

INTENDED USE

The WELLlife™ COVID-19 Antigen Home Test 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 COVID-19.

This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using either an antigen test or a molecular test for SARS-CoV-2. Negative results do not rule out SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment.

Positive results do not rule out co-infection with other respiratory pathogens.

This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider.

The performance characteristics for SARS-CoV-2 were established from April, 2023 to February, 2024 when SARS-CoV-2 Omicron was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.

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 Home Test can provide rapid detection of SARS-CoV-2 viral antigens from symptomatic patients.

PRINCIPLE OF PROCEDURE

The WELLlife™ COVID-19 Antigen Home Test 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 by the lay user 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 annti-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 Home Test contains enough reagents and materials for different configurations. The following components are included in a kit:

Components	1 Test/kit	2 Tests/kit	5 Tests/kit	10 Tests/kit	25 Tests/kit
Test Cassette	1	2	5	10	25
Tube	1	2	5	10	25
Swab	1	2	5	10	25
Quick Reference Instructions (QRI)	1	1	1	1	1

Should users need a hard copy of Instructions for Use, it is offered free of charge.

MATERIALS PROVIDED BUT NOT REQUIRED

Timer or clock

WARNINGS AND PRECAUTIONS

- **Do not use this test when you have symptoms for more than 5 days or if you have no symptoms.**
- **Do not use on individuals under 2 years of age.**
- **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.
- 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)	0.02%

	Cause mild skin irritation (H316)	
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 2-30°C (36-86°F). The test kit is stable until the expiration date on kit box and pouch. Do not use beyond the expiration date.

STEP BY STEP INSTRUCTIONS

BEFORE STARTING

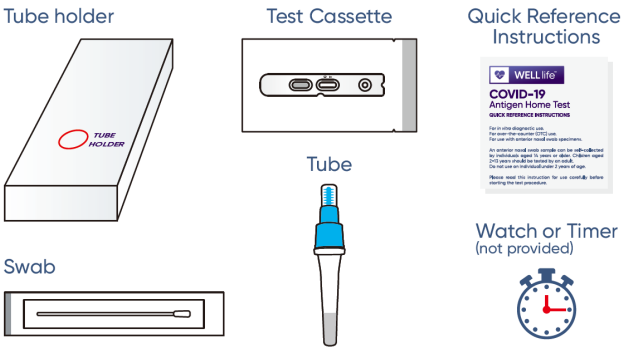
1 Wash and dry hands before you begin to perform the test.

PREPARE MATERIALS

2 Ensure you have all required testing components. Place the kit components on a flat surface.

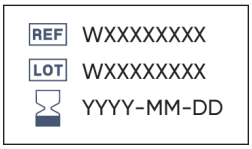
NOTE:

Ensure all test components are at room temperature (15-30℃/59-86°F) before use.



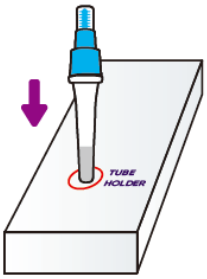
3 **Check the expiration date of the test kit before use.**

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



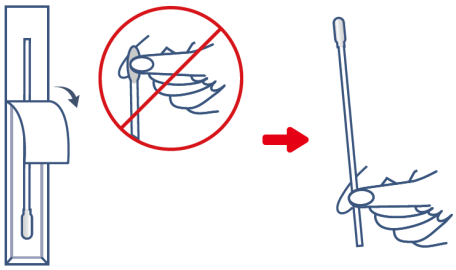
4 Remove the large blue cap from the **TUBE**.

5 Place **TUBE** in the **Tube Holder** (round opening in kit box).



COLLECT SAMPLE

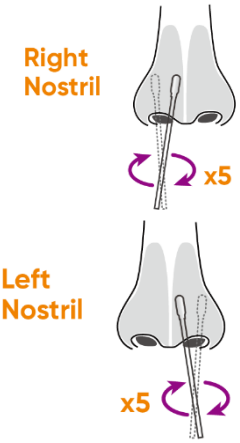
6 Remove the **SWAB** from its wrapper.
Do not touch the tip of the swab.



7 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.

8 Firmly and slowly brush against the nasal wall in a circular motion **at least 5 times**. Take **at least 15 seconds** to collect the specimen and be sure to collect any nasal drainage on the swab.

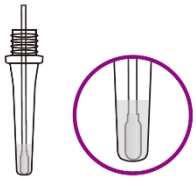


WARNING: Be sure to rub BOTH nostrils with the same SWAB.

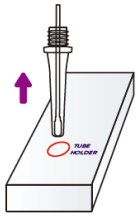
NOTE: With children, you may not need to insert the swab as far into the nostril and you may need another person to steady the child's head while swabbing. Wear safety mask or other face covering when collecting swabs from children or others.
NOTE: Failure to swab properly may cause false negative results.

PROCESS THE SAMPLE

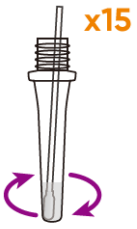
9 Immediately place the **SWAB** into the liquid inside the **TUBE**, and ensure it is touching the bottom of the **TUBE.**



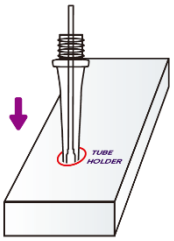
10 Remove the **TUBE** from the tube holder.



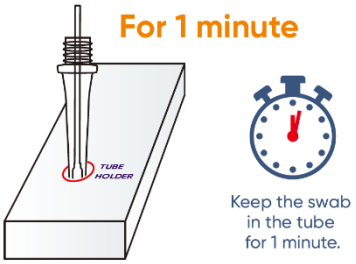
11 Stir the swab vigorously **at least 15 times**.



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

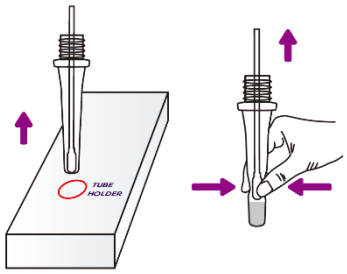


13 **Start timer for 1 minute.**

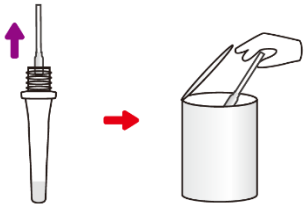


14 After 1 minute, take the tube out of the tube holder. **Remove the swab while squeezing the sides of the tube** to express as much liquid as possible from the swab.

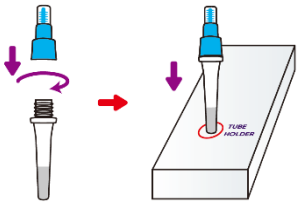
WARNING: Be sure to squeeze the tube while removing the swab.



15 Dispose the SWAB in the trash.

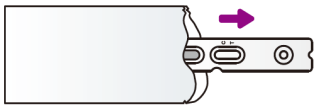


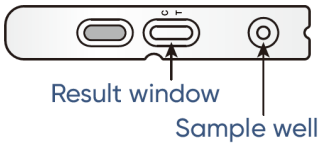
16 Screw the large blue cap back onto the TUBE. Place TUBE in the Tube Holder.



ADD SAMPLE TO THE TEST CASSETTE

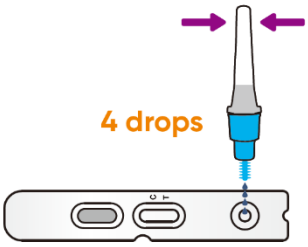
17 Remove the TEST CASSETTE from the sealed pouch and lay it flat.





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

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



WAIT AND READ TEST RESULTS

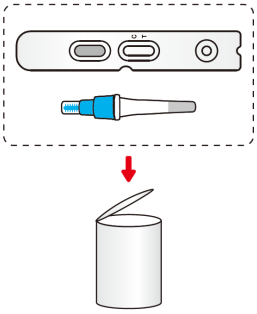
20 Wait **10 minutes**. And then read the result at **10 minutes as described in the section READ AND INTERPRET RESULT below.**

WARNING: Do not read the result before 10 minutes or after 20 minutes.

DISPOSE THE TEST KIT

21 Screw back the small white cap.

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



READ AND INTERPRET RESULT

UNDERSTANDING YOUR 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.

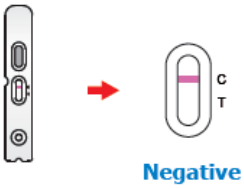
Look carefully for a C line for a valid test result. For positive result, look carefully for a T line.

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. **You do not need to perform repeat testing if you have a positive result at any time.**

A positive test result means that proteins from the virus that causes COVID-19 were found in your sample and it is very likely you have COVID-19 and are contagious. You should self-isolate following local guidelines. Please contact your healthcare provider to discuss your tests results and receive follow-up care. In rare instances, individuals may have co-infections with other bacteria or viruses that this test is not designed to detect. This means that the virus detected by this test may not be the definitive or the only cause of your disease. There is a very small chance that this test can give you a positive test result that is wrong (false positive).

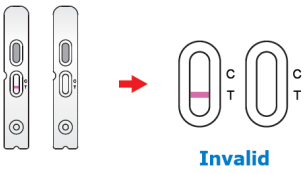
Negative Result



If the Control(C) line is visible, but the Test(T) line is not visible, the test is negative.
To increase the chance that the negative test result for COVID-19 is accurate, you should test again in 48 hours if you have symptoms on the first day of testing.

A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. A negative result is presumptive because despite a negative result you may still have COVID-19 and may be contagious. False negative results can occur if you read your test result before 10 minutes have passed or when your sample has only a low amount of virus in it. Low amount of virus can occur if you take your sample at a time when your symptoms just started appearing, or when you already started to feel better at the end of your infection. If you test negative and continue to experience COVID-19-like symptoms, (e.g., fever, cough, and/or shortness of breath) you should seek follow up care with your health care provider.

Invalid Result



If a Control (C) line is NOT visible, DO NOT CONTINUE reading the results. It means that your test result is INVALID. An invalid test result means that the test is unable to determine if you are infected with SARS-CoV-2 (COVID-19) or not. The test needs to be repeated with a new kit and sample.

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. There is a risk of false negative results due to the presence of novel, emerging respiratory virus variants. Test accuracy may change as new virus variants of COVID-19.
- 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 you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19 but you should follow-up with a healthcare provider.
- 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.
- Persons with risk factors for severe disease from respiratory pathogens (e.g., chronic lung or heart disease, compromised immune system, diabetes, and other conditions listed by the CDC) should consult and follow-up with a healthcare provider, who will advise if additional testing or treatment is necessary.
- It is important to discuss your test results with a healthcare provider if you or the person on whose behalf you perform the test have/has persisting or worsening symptoms, a high risk for severe illness based on age or a preexisting medical condition, or a condition that makes it difficult to use the test (e.g., problems with vision, handling the test components, or understanding test instructions or results).Your healthcare provider will consider additional information such as personal medical history and symptoms, current disease prevalence in the community, and additional test results if applicable, to help determine what steps are best for diagnosis and treatment if needed.

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.

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	% 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%)

Negative	24/24 (100%)	24/24 (100%)	24/24 (100%)	72/72 (100%)
0.9 x LoD SARS-CoV-2	20/24 (83.33%)	20/24 (83.33%)	24/24 (100%)	64/72 (88.89%)

Limit of Detection (Analytical Sensitivity)

The Limit of Detection (LoD) of the WELLlife™ COVID-19 Antigen Home Test 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	1.0×10^4	500
Omicron BA.5	USA/COR-22-063113/2022	3.33×10^3	166.7

WHO Standard Testing

The Limit of Detection (LoD) of the WELLlife™ COVID-19 Antigen Home Test was determined by using different dilutions of 1st WHO International Standard for SARS-CoV-2 antigen (NIBS 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	$2.00x10^2$	10

Inclusivity (Analytical Reactivity)

Analytical reactivity for WELLlife™ COVID-19 Antigen Home Test 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 Home Test with the variants is shown in table below:

Variant	**Virus Strain**	**Lowest Reactivity Concentration**
Alpha	England/204820464/2020	1.0×10^3 $TCID_{50}$/mL
Beta	South_Africa/KRISP-K005325/2020	$1.0x10^3$ $TCID_{50}$/mL
Gamma	Japan/TY7-503/2021	1.0×10^3 $TCID_{50}$/mL
Delta	USA/PHC658/2021	1.0×10^2 $TCID_{50}$/mL
Omicron B.1.1.529	USA/MD-HP20874/2021	1.0×10^2 $TCID_{50}$/mL
Omicron BA.2.3	USA/MD-HP24556/2022	3.33×10^2 $TCID_{50}$/mL
JN.1	Clinical specimen	Ct=27.9 (2.28×10^4 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 Home Test 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 2xLoD. 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** (2xLoD 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 (n=2)*	Ct = 20.5 - 22	0/6	6/6
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-5) 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$$TCID_{50}$/mL	0/3	3/3
Influenza A/Victoria/4897/22	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Influenza A/Darwin/6/21	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Influenza B/Washington/02/19	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Influenza B/Florida/04/06	1.17 x $10^5$$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

**Clinical specimens were evaluated.*

#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 Home Test. 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 2xLoD. 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** (2xLoD SARS-CoV-2) (# pos reps/total reps)
Whole Blood	2.5%	0/3	3/3
Mucin	2.5mg/mL	0/3	3/3
Chloraseptic sore throat lozenges (Benzocaine)	3mg/mL	0/3	3/3
Chloraseptic 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	0/3	3/3

Interfering Substances	Concentration	Cross-Reactivity (no analyte) (# pos reps/total reps)	Interference (2xLoD SARS-CoV-2) (# pos reps/total reps)
	cells/mL		
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

High Dose Hook Effect

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

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 Home Test. 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 Home Test 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 Home Test 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)		
	1Test	2 Test	3Test
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.

USABILITY AND USER COMPREHENSION STUDIES

Usability Study

A usability study was conducted to assess the lay user's ability to understand the instructions for use and to adequately execute the device accordingly. A total of 30 participants, aged 14 years and older and caregiver-child (ages 2-13 years) pairs and caregiver-adult pairs, were enrolled in the study and were observed during testing. A total of 30 participants completed testing monitored by investigators. Following the usability study, all subjects were assessed for their understanding and were issued a questionnaire to assess users' comprehension of the test. The questionnaire was completed by 30 subjects. The questionnaire assessed users' understanding of concepts such as the test purpose and interpretation of results. The results of each study were deemed acceptable and demonstrated that the instructions for use were easy to follow.

Readability Study

The purpose of this study was to evaluate whether lay users (patients or their caregivers) can interpret test results correctly with low positive samples from the WELLlife™ COVID-19 Antigen Home Test. The Readability Study was conducted in a simulated home environment. A total of 50 lay users with diverse gender, ages and educational background who met the study inclusion criteria, were enrolled for the Readability Study. Each lay user was asked to interpret two panels of 5 test devices with three different concentrations that were arranged in blinded test panels with the following sample results; the order of the results within the panel was randomized:

- Panel 1: Negative, 1.5xLoD, 1.5xLoD, 5xLoD, Invalid
- Panel 2: Negative, Negative, 1.5xLoD, 5xLoD, Invalid

42% (21/50) of the study participants were male and 58% (29/50) of the study participants were female. 64% (32/50) of individuals were vision impaired, and 18% (9/50) of individuals were either still at high school or had a high school degree as their highest level of education. Readability outcomes are shown in the table below.

Sample Level	Number of Test Results Across all Participants	Number of Correct Interpretation	Observed Performance (%)
Negative	150	146	97.33%
1.5xLoD	150	140	93.33%
5xLoD	100	100	100%
Invalid	100	100	100%

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

	Do not re-use		Use-by date (Expiration date)		Keep dry
	Batch code		Consult instructions for use		Keep away from sunlight
	Store at 36~86^{O}F/2~30^{O}C		*In Vitro* diagnostic medical device		Catalogue number
	Do not use if package is damaged				

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www.wondfousa.com
Made in China

Rev. A1 Rel.:2024/10/11