COVID-19 / Influenza A&B Home Test

HEALTHCARE PROVIDER
INSTRUCTIONS FOR USE

REF WV01P0001

IVD

For use under Emergency Use Authorization (EUA) only
For *in Vitro* Diagnostic Use
For use with anterior nasal swab specimens

INTENDED USE

The WELLlife™ COVID-19 / Influenza A&B Home Test is a lateral flow immunoassay intended for the qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B protein antigens.

This test is authorized for non-prescription home use with self-collected anterior nasal swab specimens from individuals aged 14 years or older, or with adult-collected anterior nasal swab specimens from individuals aged two (2) years or older. This test is only authorized for individuals with signs and symptoms of respiratory infection consistent with COVID-19 within the first five (5) days of symptom onset when tested at least twice over three days with at least 48 hours between tests.

Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

Results are for the simultaneous identification of SARS-CoV-2, influenza A virus, and influenza B virus proteins antigens, but do not differentiate between SARS-CoV and SARS-CoV-2 viruses and are not intended to detect influenza C antigens.

The viral antigens targeted by this test are generally detectable from specimens collected using nasal swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status.

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definitive cause of disease. Individuals who test positive with the WELLlife™ COVID-19 / Influenza A&B Home Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out SARS-CoV-2, influenza A, and influenza B infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions such as isolating from others and wearing masks. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with SARS-CoV-2, influenza A, and influenza B infection.

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

The WELLlife™ COVID-19 / Influenza A&B Home Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION

Along with the common cold, influenza is one of the most common acute respiratory infections, producing symptoms such as headache, chills, dry cough, body aches, and fever. It affects 5%-20% of the United States population annually, resulting in more than 200,000 hospitalizations and 36,000 deaths.[1] The influenza A virus is typically more prevalent and

is associated with the most serious influenza epidemics, while influenza B infections usually present with milder symptoms. Diagnosis is difficult because the initial symptoms can be similar to those caused by other infectious agents. Considering that the influenza virus is highly contagious, accurate diagnosis and prompt treatment of patients can have a positive effect on public health. Accurate diagnosis and the ability to distinguish between A or B antigens can also help reduce the inappropriate use of antibiotics and gives the physician the opportunity to prescribe an antiviral therapy. Initiation of antiviral therapy should begin as soon as possible after onset, ideally within 48 hours of the appearance of symptoms, as treatment may reduce the duration of symptoms.[2]

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.[3] 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. Most epidemiological studies suggest a 1–14-day incubation period. The median incubation period is estimated at 5.1 days, with most developing symptoms before 11.5 days.[4] Infected but asymptomatic people can also be an infectious source. The WELLlife™ COVID-19 / Influenza A&B Home Test can provide rapid detection of influenza A, influenza B, and/or SARS-CoV-2 viral antigens from symptomatic patients.

PRINCIPLE OF PROCEDURE

The WELLlife™ COVID-19 / Influenza A&B Home Test consists of a test cassette that separately detects influenza A, influenza B, and SARS-CoV-2 antigens. The test procedure requires the anterior nasal swab specimen to be inserted into the prefilled extraction buffer tube to be solubilized, and then the specimen is eluted. The virus particles in the specimen are disrupted by the chemicals in the extraction buffer, exposing internal viral nucleoproteins. After the release of specimen, the swab is discarded. The extracted specimen is then dropped into the sample well of the test cassette.

If SARS-CoV-2, influenza A and/or influenza B antigens are present in the specimen, they will react with SARS-CoV-2 antibody coupled to dye particles and/or influenza antibody coupled to dye particles, migrate through the membrane as antigen-antibody-dye complexes, bind to the immobilized capture antibody line(s) on the membrane, and generate a colored pink to red line in the specific test line position. The rest of the sample and rabbit IgG dye particle complexes continue to migrate to the Control line position (C), where immobilized goat anti-rabbit IgG will capture the rabbit IgG dye particle complexes and form the Control line. Formation of the pink to red Control line serves as an internal control to demonstrate that test reagents are functional, antibody-dye conjugates in the dye pad have been hydrated and released and that sufficient sample has been applied to allow for migration through the Test and Control lines. If the Control line does not appear within the designated incubation time, the result is invalid, and the test should be repeated using a new test device and specimen.

If the antigen level is equal to or above the detection limit, a visible colored band appears at the test region. Absence of this pink to red colored band in the test region of test strip and only a visible control line will appear, suggests a negative result.

WELLlife™ COVID-19 / Influenza A&B Home Test has three Test lines, one for COVID-19, one for influenza A and one for influenza B. The three Test lines allow for the separate and differential identification of COVID-19, influenza A and/or B from a single specimen. If any Test line appears in the test result window, together with the Control line, the test result is

positive for COVID-19 and/or influenza.

REAGENTS AND MATERIALS

The WELLlife™ COVID-19 / Influenza A&B Home Test kit configurations are indicated below:

Components	1 Test/kit	2 Tests/kit	5 Tests/kit	10 Tests/kit	25 Tests/kit
Sealed Test Cassettes	1	2	5	10	25
Buffer Tubes	1	2	5	10	25
Swabs	1	2	5	10	25
Tube holder(Top right corner on Box)	1	1	1	1	1
Quick Reference Instructions(QRI)	1	1	1	1	1

Materials Required but Not Provided

- Timer or watch

WARNINGS AND PRECAUTIONS

- Read the instructions fully and carefully before performing the procedure. Failure to follow the instructions may result in inaccurate test results.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, influenza A, and influenza B, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/ or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- **Serial testing should be performed in individuals with SARS-CoV-2 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.**
- **Consistent with serial testing recommendations for SARS-CoV-2, for multi-analyte tests, symptomatic individuals who test positive for influenza A or B on the initial test but test negative for SARS-CoV-2 should be tested again in 48 hours to evaluate for co-infection with SARS-CoV-2 infection.**
- An anterior nasal swab sample can be self-collected by individuals aged 14 years and older. Children aged 2 to 13 years should be tested by an adult.
- Do not use on anyone under 2 years of age.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- This test may only be used in symptomatic individuals.
- Do not use if any of the test kit contents or packaging is damaged or open.
- Test components are single-use. Do not re-use the test strip, buffer liquid, or swab.
- If any liquid spills from the buffer tube, discard test components and re-start test using new test components.
- **Do not read test results before 10 minutes or after 20 minutes. Results read before 10 minutes or after 20 minutes may lead to a false positive, false negative, or invalid result.**
- If uncertain how to proceed, contact Technical Assistance at 1-888-444-3657.
- Do not touch swab tip when handling the swab.
- To ensure accurate test results, avoid contamination with liquid gel hand soap, hand sanitizer cream lotion, and fast-drying 80% ethanol hand sanitizer.
- Do not open the test contents until ready for use, if the test cassette is open for an hour or longer, false test results may occur.
- Testing should be performed in an area with good lighting.
- Do not use the test kit after its expiration date.

- **Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your skin, eyes, nose, or mouth. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your 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 skin irritation (H315) Causes eye irritation (H320)	0.05%

- For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
- For the most up-to-date information on COVID-19, please visit: www.cdc.gov/COVID19.

STORAGE AND STABILITY

- Store the test kit between 36-86°F (2-30°C) in a place out of direct sunlight
- Reagents and devices must be used at room temperature (59-86°F/15-30°C)
- The unsealed cassette is valid for 1 hour. It is recommended to use the test kit immediately after opening. The expiration date is on the package.

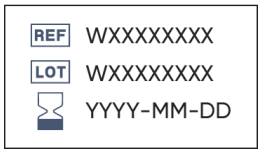
QUALITY CONTROL

Each WELLlife™ COVID-19 / Influenza A&B Home Test has a built-in internal procedural control. The red line appearing at the "C" position verifies proper assembly and capillary flow of the test strip. A distinct 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 using a new swab and new test kit.

PREPARING FOR THE TEST

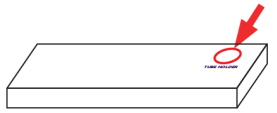
NOTE: Do not open the test materials until ready for use. If the test cassette is open for an hour or longer, invalid test results may occur.

1. **Check the expiration date of the test printed on the outer box.** For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit http://www.fda.gov/covid-tests.



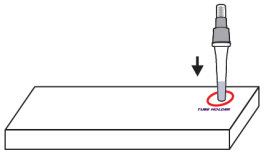
2. Wash your hands with soap and water for 20 seconds and dry them thoroughly, or use hand sanitizer.

3. Locate the tube holder on the box (look for the red circle on the kit's box).



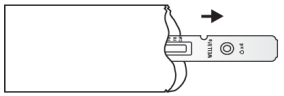
4.

a) Insert the buffer tube into the tube holder. Ensure that the buffer tube is stable and upright.



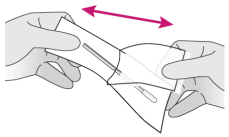
b) Remove the large cap from the buffer tube and set it aside for later use.

5. Remove test cassette from sealed pouch and lay it on a flat surface.



SAMPLE COLLECTION

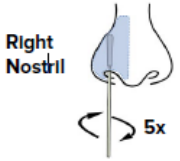
6. Remove the swab from the pouch.



Be careful not to touch the swab tip (soft end) with hand.

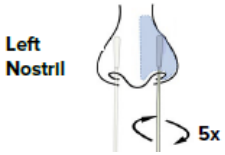
7.

a) Carefully insert the swab no more than 3/4 inch (1.5 cm) into the nostril. Slowly rotate the swab at least 5 times against the nostril wall.



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

b) Remove the swab and repeat in the other nostril using the same swab.

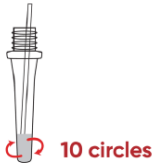


Check: Did you swab BOTH nostrils?

Note: If you are swabbing others, please wear a face mask. With children, the maximum depth of insertion into the nostril may be less than ½ to ¾ of an inch, and you may require another adult to hold the child's head while swabbing.

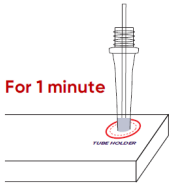
RUNNING THE TEST

8. Immerse the swab into the buffer tube and swirl the swab in the buffer. Ensure the sample is mixed thoroughly by making **at least 10 circles**.

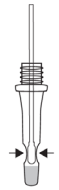


Sample must be adequately mixed into the buffer, otherwise, incorrect results may occur.

9. Leave the swab in the buffer tube for 1 minute. A timer is recommended for this step.



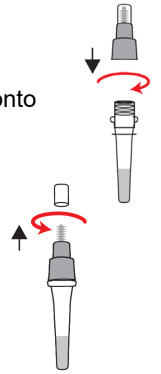
10. After 1 minute, pinch the tip of the swab from the outside of the tube to remove any excess liquid from the swab.



Remove and discard the swab.

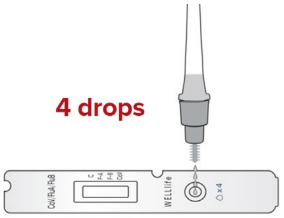
11.

a) Hold the buffer tube upright and screw the large cap back onto the tube. Ensure a tight fit to prevent leaking.



b) Twist to open the small cap at the top of the tube.

12. Invert the buffer tube and squeeze **4** drops of test sample into the sample well on the test cassette. Then discard the buffer tube.



Note: Incorrect results may be observed if <4 drops of sample are added.

Sample must be applied to the test cassette within one hour of completing step 8.

13. Start timer. Read results at 10 minutes.

Do not interpret results before 10 minutes or after 20 minutes. Inaccurate test interpretations may occur.

INTERPRETATION OF RESULTS

Look for lines next to 'C'(Control), 'F-A', 'F-B' and 'CoV'.

C = Control Line

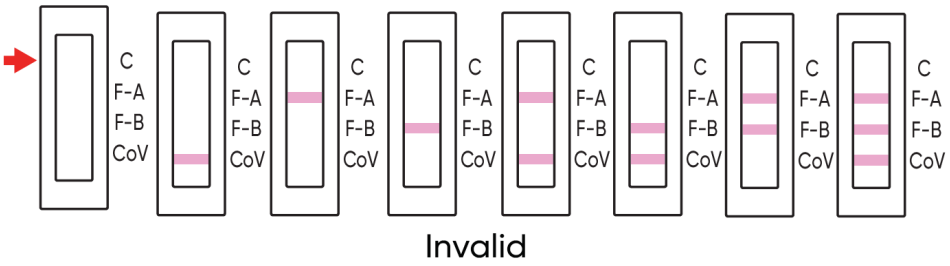
F-A = Flu A Test Line

F-B = Flu B Test Line

CoV = COVID-19 Test Line

A red line should always appear at the '**C**' position; this is a control line and singals that the test is working properly.

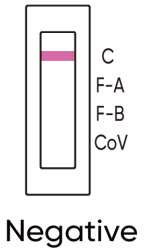
INVALID RESULT



Check to see if a pink to red line is visible at the control line '**C**' in the results window. If a line is not visible at "**C**", even if any other line is visible in the results window, the result is considered **invalid**.

If you do not see a C line, DO NOT CONTINUE reading the results. It means your test is invalid. Repeat the test with a new sample and new test kit materials.

NEGATIVE RESULT

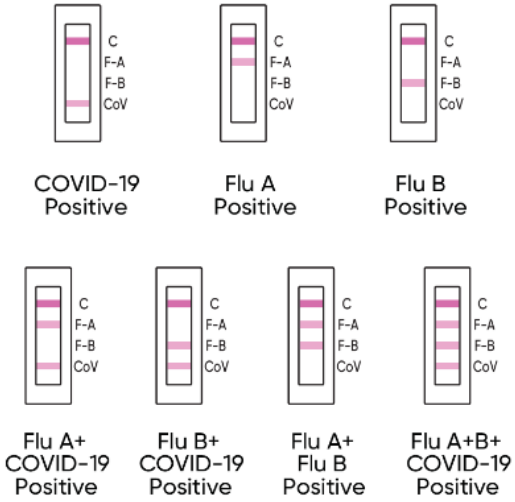


If a control 'C' line is visible and you do not see a line at 'F-A' , 'F-B' or 'CoV', it means the test is negative. The Flu A, Flu B or COVID-19 virus have not been detected.

To increase the chance that the negative result for COVID-19 in accurate, you should test again in 48 hours after the first day of testing.

If respiratory symptoms persist, you seek follow-up care with healthcare provider.

POSITIVE RESULT



If the control line at "**C**" is visible and any other line or multiple lines on '**F-A**', '**F-B**' and/or '**CoV**' are visible, the test is positive for that virus.

NOTE: Any pink to red test line, no matter how faint, should be considered a positive result when the control line is also present.

SERIAL TESTING

Repeat Testing is needed for all samples that are negative for SARS-CoV- 2 on the first day of testing, even if they are positive for influenza A and/or B. Repeat testing is needed to improve test accuracy for SARS-CoV-2. Please follow the table below when interpreting test results. Serial (repeat) testing does not need to be performed if patients have a positive SARS-CoV-2 result on the first day of testing.

Status on First Day of Testing	Day 0 (First Test)	Serial Testing?	Day 2 (Second Test)	Interpretation
With Symptoms	SARS-CoV-2 (+) Influenza A and B (-)	NO	Not needed	Positive for COVID-19 Presumptive negative for Influenza
	SARS-CoV-2 (+) Influenza A and/or B (+)	NO	Not needed	Positive for COVID-19 Positive for Influenza A and/or B
	SARS-CoV-2 (-) Influenza A and/or B(-)	YES	SARS-CoV-2 (+) Influenza A and/ or B (-)	Positive for COVID-19 Presumptive Negative for Influenza
	SARS-CoV-2 (-) Influenza A and/or B (+)	YES	SARS-CoV-2 (+) Influenza A and/ or B (+)	Positive for COVID-19 Positive for Influenza A and/or B
	SARS-CoV-2 (-) Influenza A and/or B (-)	YES	SARS-CoV-2 (-) Influenza A and/ or B (+)	Presumptive Negative for COVID-19 Positive for Influenza A and/or B
	SARS-CoV-2 (-) Influenza A and/or B (-)	YES	SARS-CoV-2 (-) Influenza A and/ or B (-)	Presumptive Negative for COVID-19 Presumptive Negative for Influenza
	SARS-CoV-2 (-) Influenza A and/or B (-)	YES	SARS-CoV-2 (+) Influenza A and/ or B (+)	Positive for COVID-19 Positive for Influenza A and/or B
	SARS-CoV-2 (-) Influenza A and/or B (+)	YES	SARS-CoV-2 (-) Influenza A and/ or B (-)	Presumptive Negative for COVID-19 Positive for Influenza A and/or B
	SARS-CoV-2 (-) Influenza A and/or B (+)	YES	SARS-CoV-2 (-) Influenza A and/ or B (+)	Presumptive Negative for COVID-19 Positive for Influenza A and/or B
	SARS-CoV-2 (-) Influenza A and/or B (+)	YES	SARS-CoV-2 (+) Influenza A and/ or B (+)	Positive for COVID-19 Positive for Influenza A and/or B

UNDERSTANDING YOUR RESULTS

Invalid Result: The test could not tell whether or not you have COVID-19, influenza A (Flu A), or influenza B (Flu B). The test needs to be repeated with a new kit and sample.

Negative Result: The virus from COVID-19, Flu A, and/or Flu B were not detected in the sample. A negative result does not mean it is certain that you do not have COVID-19, Flu A and/or Flu B infection. There is a higher chance of false negative results with antigen tests compared to laboratory-based molecular tests. If you tested negative and continue to experience COVID-19, Flu A and/or Flu B-like symptoms, you should seek follow-up care with your healthcare provider.

All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

Positive Result: The SARS-CoV-2, Flu A and/or Flu B virus(es) were detected in your sample. It is very likely that you have the respective infection(s) and are contagious. Please contact your healthcare provider or your local health authorities and follow local guidelines for self-isolation. There is a small chance that this test can give you a positive result that is incorrect (a false positive).

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the WELLlife™ COVID-19 / Influenza A&B Home Test should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

RESULTS REPORTING

Report your test result(s) at MakeMyTestCount.Org–this voluntary and anonymous reporting helps public health teams understand COVID-19 spread in your area and across the country and informs public health decisions.

LIMITATIONS

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between December 2023 and March 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.
- 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 negative results SARS-CoV-2 or influenza are presumptive and confirmation with a molecular assay may be necessary.
- If you continue to have symptoms of COVID-19 or influenza and both your first and second tests are negative, you may not have COVID-19 or influenza, however, you should follow up with a healthcare provider.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you likely have COVID-19 and the individual likely has respiratory infection with COVID-19 or influenza.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Individuals who recently received nasally administered influenza A or influenza B vaccine may have false positive test results after vaccination.
- Based on sequence and epitope analyses, a potential for cross-reactivity between the SARS-CoV-2 test and HKU1 exist. Wet testing with HKU1 coronavirus was not conducted and therefore, cross-reactivity between SARS-CoV-2 and HKU1 coronavirus cannot be ruled out.

PERFORMANCE CHARACTERISTICS

ANALYTICAL PERFORMANCE

Limit of Detection (Analytical Sensitivity)

Limit of detection (LoD) for SARS-CoV-2 and influenza A and B in WELLlife™ COVID-19 / Influenza A&B Home Test was determined by evaluating different concentrations of UV-inactivated SARS-CoV- and live influenza A and B viruses. The viruses were diluted in pooled negative swab matrix (PNSM) to generate virus dilutions for testing. Anterior nasal swab samples were prepared by adding 50µL of each virus dilution onto the sterile swab. The swab samples were tested according to the test procedure in package insert. Range-finding testing was conducted with three replicates at various dilutions and confirmatory testing was conducted with 20 replicates. The lowest concentration that generated ≥95% positive detection rate was set as the LoD concentration.

Virus Strains	Stock Concentration ($TCID_{50}$/mL)	LoD ($TCID_{50}$/mL)	LoD ($TCID_{50}$/ Swab)	#Positive/ #Total	Percent Detected (%)
SARS-CoV-2 UV inactivated, USA-WA1/2020	3.16×10^{6}	$7.90\ x10^{2}$	39.5	20/20	100%
Influenza A A/Victoria/4897/2022(H1N1)	2.02×10^{5}	$1.01\ x10^{2}$	5.05	20/20	100%
Influenza A A/Darwin/6/2021(H3N2)	4.17×10^{5}	$2.09\ x10^{2}$	10.45	20/20	100%
Influenza B B/Washington/02/2019(Victoria)	3.16×10^{6}	$3.16\ x10^{3}$	158	20/20	100%

Analytical Reactivity

The analytical reactivity of the antibodies targeting Influenza A, influenza B, and SARS-CoV-2 in WELLlife™ COVID-19 / Influenza A&B Home Test was evaluated with the currently available strains.

Influenza Virus (Type/Subtype)	Virus Strain Name	Analytical Reactivity	Positive/ Replicates
SARS-CoV-2(XBB.1.5)	hCoV-19/USA/MD-HP40900/2022	7.8E+01 $TCID_{50}$/mL	10/10
A(H1N1)pdm09	A/California/04/2009	2.80E+03 $TCID_{50}$/mL	3/3
	A/Brisbane/02/18	1.51E+02 $TCID_{50}$/mL	3/3
	A/Michigan/45/15	1.86E+01 $TCID_{50}$/mL	3/3
	A/Guangdong- Maonan/SWL1536/19	2.09E+02 $TCID_{50}$/mL	3/3
	A/NY/03/09	2.29E+04 $TCID_{50}$/mL	3/3
	A/Indiana/02/2020	9.70E+06 $CEID_{50}$/mL	3/3
	A/Wisconsin/588/2019	7.00E+03 FFU/mL	3/3
	A/Sydney/5/2021	4.80E+03 $TCID_{50}$/mL	3/3
	A/Hawaii/66/2019	1.85E+07 $CEID_{50}$/mL	3/3
	A/Wisconsin/67/22	4.21E+02 $TCID_{50}$/mL	3/3
A(H3N2)	A/Tasmania/503/2020	1.30E+05 FFU/mL	3/3
	A/New York/21/2020	2.60E+05 FFU/mL	3/3
	A/Alaska/01/2021	3.75E+04 FFU/mL	3/3
	A/Hong Kong/45/2019	1.50E+04 FFU/mL	3/3
	A/Hong Kong/2671/19	1.05E+03 $TCID_{50}$/mL	3/3
A(H3N2)v	A/Indiana/08/2011	8.10E+02 $TCID_{50}$/mL	3/3
A(H1N1)v	A/Ohio/09/2015	7.00E+05 $CEID_{50}$/mL	3/3
A(H1N2)v	A/Minnesota/19/2011	4.00E+06 $CEID_{50}$/mL	3/3
A(H5N1)	A/mallard/Wisconsin/2576/2009	4.00E+05 $CEID_{50}$/mL	3/3
A(H7N3)	A/northern pintail/Illinois/10OS3959/201	7.00E+05 $CEID_{50}$/mL	3/3

Influenza Virus (Type/Subtype)	Virus Strain Name	Analytical Reactivity	Positive/ Replicates
	0		
B(Non Victoria and Non Yamagata)	B/Maryland/1/59	3.38E+03 $CEID_{50}$/mL	3/3
B(Victoria lineage)	B/Brisbane/60/2008	1.29E+00 $TCID_{50}$/mL	3/3
	B/Colorado/06/17	5.85E+01 $TCID_{50}$/mL	3/3
	B/Texas/02/2013	2.45E+01 $TCID_{50}$/mL	3/3
	B/Michigan/01/2021	1.43E+04 $TCID_{50}$/mL	3/3
B(Yamagata lineage)	Yamagata - B/Texas/06/2011	7.55E+02 $TCID_{50}$/mL	3/3
	Yamagata - B/Utah/09/2014	1.26E+03 $TCID_{50}$/mL	3/3
	B/Wisconsin/01/2010	1.78E+02 $TCID_{50}$/mL	3/3

Analytical Specificity: Cross-Reactivity and Microbial Interference

Cross-reactivity of the WELLlife™ COVID-19 / Influenza A&B Home Test was evaluated by testing a panel of related pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in clinical specimens and could potentially cross-react with the WELLlife™ COVID-19 / Influenza A&B Home Test including twenty (20) bacteria, twenty (20) viruses and one (1) negative matrix. Each organism and virus were tested in triplicate the absence (cross-reactivity) or presence (interference) of co-spiked UV-inactivated SARS-CoV-2, influenza A, and B at 3 x LoD. No cross-reactivity was observed with the listed microorganisms when tested at the concentration presented in the table below. No interference was observed with the listed microorganisms when tested at the concentration presented in the table below in the presence of the target analytes.

Potential Cross-Reactant	Concentration Tested
SARS-CoV-1	$1.25X10^5$ PFU/ml
MERS-coronavirus	$1.47X10^5$ $TCID_{50}$/mL
Human coronavirus OC43	$7.00X10^5$ $TCID_{50}$/mL
Human coronavirus 229E	$1.58X10^5$ $TCID_{50}$/mL
Human coronavirus NL63	$7.05X10^4$ $TCID_{50}$/mL*
Adenovirus Type 1	$2.23X10^5$ $TCID_{50}$/mL
Adenovirus Type 7	$1.58X10^5$ $TCID_{50}$/mL
Cytomegalovirus	$7.05X10^4$ $TCID_{50}$/mL*
Epstein Barr Virus	$1.83X10^6$ CP/mL
Human Metapneumovirus	$3.50X10^5$ $TCID_{50}$/mL
Parainfluenza virus 1	$2.00X10^5$ $TCID_{50}$/mL
Parainfluenza virus 2	$1.75X10^5$ $TCID_{50}$/mL
Parainfluenza virus 3	$7.00X10^5$ $TCID_{50}$/mL
Parainfluenza virus 4	$2.39X10^5$ $TCID_{50}$/mL
Enterovirus Type 68	$2.23X10^5$ $TCID_{50}$/mL
Respiratory syncytial virus A	$3.50X10^5$ $TCID_{50}$/mL
Respiratory syncytial virus B	$2.29X10^5$ $TCID_{50}$/mL
Rhinovirus 1A	$7.05X10^4$ $TCID_{50}$/mL
Bordetella pertussis	$2.90X10^8$ CFU/mL
Candida albicans	$1.21X10^7$ CFU/mL
Chlamydia pneumoniae	$4.33X10^6$ IFU/mL
Corynebacterium xerosis	$2.30X10^7$ CFU/mL
Escherichia coli	$1.79X10^8$ CFU/mL
Hemophilus influenzae	$9.68X10^6$ CFU/mL
Lactobacillus Acidophilus	$1.21X10^7$ CFU/mL
Legionella spp pneumophila	$6.50X10^6$ CFU/mL
Moraxella catarrhalis	$2.50X10^8$ CFU/mL
Mycoplasma pneumoniae	$2.50X10^7$ CFU/mL
Mycobacterium tuberculosis avirulent	$3.03X10^6$ CFU/mL
Neisseria meningitidis	$3.43X10^6$ CFU/mL
Neisseria sp. Elongata	$2.68X10^8$ CFU/mL
Pneumocystis jirovecii	$1.30X10^7$ CFU/mL
Pseudomonas aeruginosa	$3.45X10^8$ CFU/mL

Potential Cross-Reactant	Concentration Tested
Staphylococcus aureus subsp. aureus	$2.60X10^8$ CFU/mL
Staphylococcus epidermidis	$9.00X10^7$ CFU/mL
Streptococcus salivarius	$1.01X10^6$ CFU/mL
Streptococcus pneumoniae	$1.81X10^7$ CFU/mL
Streptococcus pyogenes	$7.50X10^7$ CFU/mL
Measles	$8.48X10^5$ $TCID_{50}$/mL
Mumps	$8.48X10^5$ $TCID_{50}$/mL
Pooled Negative Nasal Wash	NA

Endogenous Interfering Substances

The potential interference of endogenous substances with the antibodies used for the detection of SARS-CoV-2, influenza A and B was examined by testing nineteen (19) substances in a negative clinical matrix in triplicate, in the absence or presence of each virus at 3 x LOD concentrations for SARS-CoV-2, influenza A(H1N1), and influenza B(Yamagata). The interference study was conducted using medically relevant concentrations of the potentially interfering substances listed below to assess the potential interference of the substances on the performance of the WELLlife™ COVID-19 / Influenza A&B Home Test.

At 15% (v/v) and when diluted down to 0.75% (v/v), FluMist Quadrivalent Live Intranasal Influenza Virus Vaccine yielded false positive results for Influenza A and Influenza B. At a dilution of 0.375% (v/v), the results were negative (0/3 positive results). Hand sanitizer containing 80% ethanol yielded false positive results for SARS-CoV-2 and Influenza B at a dilution of 15% (v/v) and when diluted down to 3.75% (v/v). At a dilution of 1.875% (v/v), the results were negative. Two interferents produced false-negative results for Influenza B: hand sanitizer cream lotion (15% v/v) and hand soap liquid gel (10% w/v). All Influenza B results were positive when tested with 7.5% (v/v) hand sanitizer cream lotion and 0.05% (w/v) hand soap liquid gel.

No interference was observed with the other listed substances when tested at the concentration presented in the table below in the presence or absence of the target analytes.

Results of Endogenous Interfering Substances

Potential Interferent	Concentration	Cross-reactivity (no analyte) (# pos reps / total reps)			Interference (3x co-spike analyte LoD) (# pos reps / total reps)		
		SARS-CoV-2	Flu A	Flu B	SARS-CoV-2	Flu A	Flu B
Human Whole Blood (EDTA tube)	4% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Mucin	0.50%	0/3	0/3	0/3	3/3	3/3	3/3
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Naso GEL (NeilMed)	5% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal Drops (Phenylephrine)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal Spray (Oxymetazoline)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal Spray (Cromolyn)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Zicam	5% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Homeopathic (Alkalol)	10% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Sore Throat Phenol Spray	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Tobramycin	4 µg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Mupirocin	10 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Fluticasone Propionate	5% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
FluMist/ FluMist Quadrivalent Live intranasal influenza virus vaccine	15% v/v	0/3	3/3	3/3	3/3	3/3	3/3
	0.375% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Zanamivir	282 ng/mL	0/3	0/3	0/3	3/3	3/3	3/3
Biotin	3,500 ng/mL	0/3	0/3	0/3	3/3	3/3	3/3
Body & Hand Lotion	0.5% w/v	0/3	0/3	0/3	3/3	3/3	3/3
Body Lotion, with 1.2% dimethicone	0.5% w/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand Lotion	5% w/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand Sanitizer with Aloe, 62% ethyl alcohol	5% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand Sanitizer cream lotion	15% v/v	0/3	0/3	0/3	3/3	3/3	0/3
	7.5% v/v	-	-	-	3/3	3/3	3/3
Hand Sanitizer, 80% ethanol, fast drying	15% v/v	3/3	0/3	2/3	3/3	3/3	3/3
	1.875% v/v	0/3	0/3	0/3	-	-	-
Hand soap liquid gel	10% w/v	0/3	0/3	0/3	3/3	3/3	0/3
	0.05% w/v	-	-	-	3/3	3/3	3/3

High Dose Hook Effect

A high-dose hook effect was not observed in WELLlife™ COVID-19 / Influenza A&B Home Test for the SARS-CoV-2, influenza A and B viral strains at the concentration listed below.

Virus Type	Virus Strain	Concentration Tested
SARS-CoV-2	UV inactivated, USA-WA1/2020	3.16×10^6 $TCID_{50}$/mL
Influenza A (H1N1)	A/Victoria/4897/2022	2.02×10^5 $TCID_{50}$/mL
Influenza A(H3N2)	A/Darwin/6/2021	4.17×10^5 $TCID_{50}$/mL
Influenza B (Victoria lineage)	B/Washington/02/2019	3.16×10^6 $TCID_{50}$/mL
Influenza B (Yamagata lineage)	B/Florida/4/2006	1.17×10^5 $TCID_{50}$/mL

Competitive Interference

For co-infection, SARS-CoV-2 at levels near LoD was tested in the presence of high levels of influenza A or influenza B and influenza A and influenza B at levels near LOD were tested in the presence of high levels of SARS-CoV-2. No competitive interference was seen between high levels of SARS-CoV-2 and low levels of Influenza A and B and between high levels of Influenza A and low levels of SARS-CoV-2 and influenza B in this testing at the concentration listed in the tables below. Competitive inhibition were observed between high levels of influenza B(Yamagata Lineage) and low levels of Influenza A in this testing at the concentration listed in the tables below.

SARS-CoV-2&Influenza A &Influenza B Virus(Yamagata Lineage)

SARS-CoV-2 USA-WA1/2020		Influenza A Virus(H1N1pdm09) A/Victoria/4897/2022		Influenza B Virus(Yamagata Lineage) B/Florida/4/2006	
Concentration ($TCID_{50}$/mL)	Percent Agreement	Concentration ($TCID_{50}$/mL)	Percent Agreement	Concentration ($TCID_{50}$/mL)	Percent Agreement
Negative	100%	$6.73x10^4$	100%	$1.76\ x10^2$	100%
$2.37x10^3$	100%	$6.73x10^4$	100%	Negative	100%
$2.37x10^3$	100%	$6.73x10^4$	100%	$1.76\ x10^2$	100%
Negative	100%	$3.03x10^2$	0	$3.90\ x10^4$	100%
Negative	100%	$3.03x10^2$	0	$1.95\ x10^4$	100%
Negative	100%	$3.03x10^2$	100%	$7.80\ x10^3$	100%
$2.37x10^3$	100%	$3.03x10^2$	100%	$3.90\ x10^3$	100%
$2.37x10^3$	100%	Negative	100%	$3.90\ x10^4$	100%
$2.37x10^3$	100%	$3.03x10^2$	0	$3.90\ x10^4$	100%
$2.37x10^3$	100%	$3.03x10^2$	0	1.95E+04	100%
$2.37x10^3$	100%	$3.03x10^2$	100%	$7.80\ x10^3$	100%
$2.37x10^3$	100%	$3.03x10^2$	100%	$3.90\ x10^3$	100%
$1.05x10^6$	100%	$3.03x10^2$	100%	Negative	100%
$1.05x10^6$	100%	Negative	100%	$1.76\ x10^2$	100%
$1.05x10^6$	100%	$3.03x10^2$	100%	$1.76\ x10^2$	100%

SARS-CoV-2&Influenza A &Influenza B Virus(Victoria Lineage)

SARS-CoV-2 USA-WA1/2020		Influenza A Virus(H1N1pdm09) A/Victoria/4897/2022		Influenza B Virus(Victoria Lineage) B/Washington/02/19	
Concentration ($TCID_{50}$/mL)	Percent Agreement	Concentration ($TCID_{50}$/mL)	Percent Agreement	Concentration ($TCID_{50}$/mL)	Percent Agreement
Negative	100%	$6.73\ x10^4$	100%	$3.51\ x10^2$	100%
$2.37\ x10^3$	100%	$6.73\ x10^4$	100%	Negative	100%
$2.37\ x10^3$	100%	$6.73\ x10^4$	100%	$3.51\ x10^2$	100%
Negative	100%	$3.03\ x10^2$	100%	$1.05\ x10^6$	100%
$2.37\ x10^3$	100%	Negative	100%	$1.05\ x10^6$	100%
$2.37\ x10^3$	100%	$3.03\ x10^2$	100%	$1.05\ x10^6$	100%
$1.05\ x10^6$	100%	$3.03\ x10^2$	100%	Negative	100%
$1.05\ x10^6$	100%	Negative	100%	$3.51\ x10^2$	100%
$1.05\ x10^6$	100%	$3.03\ x10^2$	100%	$3.51\ x10^2$	100%

CLINICAL PERFORMANCE

A prospective study was performed in which seven hundred eighty-seven (787) direct anterior nasal swab specimens were sequentially enrolled (between December 2023 and March 2024) and tested fresh. 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 within five (5) days of symptom onset with signs and symptoms of respiratory infection generally observed from SARS-CoV-2, influenza A and/or influenza B, 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 a FDA-cleared molecular comparator method, and the other swab was self-collected and tested immediately with the WELLlife™ COVID-19 / Influenza A&B Home Test per the test procedure. Out of 787 enrolled subjects, there were 769 evaluable subjects.

SUBJECTS DEMOGRAPHICS

Subjects Demographics.

Characteristic	Lay-user/ Tester Collection N=174	Self-Collecting N=595	Overall N=769
Age			
Mean (SD)	8.7 (4.5)	46.3 (18.8)	37.8 (22.9)
Median[Min, Max]	8[2, 32]	43[14, 94]	35[2, 94]
Age Group			
<14	149 (85.6%)	0	149 (19.4%)
14-24	24 (13.8%)	85 (14.3%)	109 (14.2%)
25-64	1 (0.6%)	380 (63.9%)	381 (49.5%)
>64	0	130 (21.8%)	130 (16.9%)
Six at Birth			
Female	98 (56.3%)	370 (62.2%)	468 (60.9%)
Male	76 (43.7%)	225 (37.8%)	301 (39.1%)
Ethnicity			
Hispanic/Latino	91 (52.3%)	250 (42.0%)	341 (44.3%)
Not Hispanic/Latino	83 (47.7%)	330 (55.5%)	413 (53.7%)
Unknown/Prefer not to answer	0	15 (2.5%)	15 (2.0%)
Race			
American Indian or Alaskan Native	1 (0.6%)	2 (0.3%)	3 (0.4%)
Asian	19 (10.9%)	162 (27.2%)	181 (23.5%)
Black or African American	44 (25.3%)	95 (16.0%)	139 (18.1%)
White	106 (60.9%)	294 (49.4%)	400 (52.0%)
Native Hawaiian or Other Pacific Islander	0	0	0
More than one race	1 (0.6%)	6 (1.0%)	7 (0.9%)
Unknown/Prefer not to answer	2 (1.1%)	30 (5.0%)	32 (4.2%)
Other	1 (0.6%)	6 (1.0%)	7 (0.9%)

SARS-COV-2 PERFORMANCE

WELLlife™ COVID-19 / Influenza A&B Home Test performance compared to reference PCR: SARS-CoV-2

SARS-CoV-2	Comparator Positives	Comparator Negatives	*Total*
Candidate Positives	112	2	114
Candidate Negatives	16	639	655
Total	**128**	**641**	**769**
Positive Percent Agreement (PPA) = 87.5% (112/128)		95% CI: 80.7 – 92.2%	
Negative Percent Agreement (NPA) = 99.7% (639/641)		95% CI: 98.9 – 99.9%	

SARS-CoV-2 Clinical Performance in Subjects on Days Post Symptoms Onset

Days of COVID-19 Symptoms	Number of Subject samples tested	WELLlife™ COVID-19 / Influenza A&B Test Positives	Comparator Positives	% Positive Rate (by Comparator)	PPA (95%CI)
Day 0	39	3	5	12.80%	60.0% (23.1%, 88.2%)
Day 1	168	26	28	16.70%	92.9% (77.4%, 98.0%)
Day 2	236	30	36	15.25%	83.3% (68.1%, 92.1%)
Day 3	156	27	27	17.30%	96.3%

Days of COVID-19 Symptoms	Number of Subject samples tested	WELLlife™ COVID-19 / Influenza A&B Test Positives	Comparator Positives	% Positive Rate (by Comparator)	PPA (95%CI)
					(81.7%, 99.3%)
Day 4	106	16	19	17.90%	84.2% (62.4%, 94.5%)
Day 5	64	12	13	20.30%	84.6% (57.8%, 95.7%)
Total	769	114	128	16.64%	87.5% (80.7%, 92.2%)

INFLUENZA A PERFORMANCE
WELLlife™ COVID-19 / Influenza A&B Home Test performance compared to reference PCR: Influenza A

Influenza A	Comparator Positives	Comparator Negatives	Total
Candidate Positives	79	2	81
Candidate Negatives	13	675	688
Total	**92**	**677**	**769**
Positive Percent Agreement (PPA) = 85.9% (79/92)		95% CI: 77.3 – 91.6%	
Negative Percent Agreement (NPA) = 99.7% (675/677)		95% CI: 98.9 – 99.9%	

INFLUENZA B PERFORMANCE
WELLlife™ COVID-19 / Influenza A&B Home Test performance compared to reference PCR: Influenza B

Influenza B	Comparator Positives	Comparator Negatives	Total
Candidate Positives	33	2	35
Candidate Negatives	5	729	734
Total	**38**	**731**	**769**
Positive Percent Agreement (PPA) = 86.8% (33/38)		95% CI: 72.7 – 94.2%	
Negative Percent Agreement (NPA) = 99.7% (729/731)		95% CI: 99.0 – 99.9%	

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 RTPCR, 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.

ASSISTANCE

If the test does not perform as expected, please email at wondfo@wondfousa.com or call 1-888-444-3657.

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INDEX OF SYMBOLS

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

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