COVID-19 / Influenza A&B Test

INSTRUCTIONS FOR USE

REF WV01P0002

IVD Rx ONLY

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 Test is a lateral flow immunochromatographic assay intended for *in vitro* rapid, simultaneous qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly from anterior nasal swab specimens of 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. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet the requirements to perform moderate, high or waived complexity tests.

This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the simultaneous *in vitro* detection and differentiation of SARS-CoV-2, influenza A virus, and influenza B virus protein antigen, but do not differentiate between SARS-CoV and SARS-CoV-2 viruses and are not intended to detect influenza C antigens.

These viral antigens are generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but the 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 the disease.

All negative results should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out influenza or SARS-CoV-2 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 each respiratory infection.

The WELLlife™ COVID-19 / Influenza A&B Test is only for *in vitro* diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

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 Speedy Swab Rapid COVID-19 + Flu A&B Antigen 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 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 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.

KIT CONTENTS

Each WELLlife™ COVID-19 / Influenza A&B Test kit contains enough reagents and materials for 25 tests. The following components are included in a kit:

- 25 WELLlife™ COVID-19 / Influenza A&B test cassettes containing CHO monoclonal antibodies to nucleocapsid protein of influenza A, influenza B and SARS-CoV-2 and containing 0.05% Proclin 300 as preservative
- 25 Prefilled extraction buffer tubes containing 400µL of Tris-HCl buffer with detergents and preservative (containing 0.05% Proclin 300 as preservative)
- 25 Sterile swabs
- 1 Positive control swab coated with non-infective influenza A, B and SARS-CoV-2 antigen (non-infectious recombinant nucleocapsid protein) and containing 0.05% Proclin 300 as preservative
- 1 Negative control swab coated with non-infectious inactivated Streptococcus Group A and containing 0.05% Proclin 300 as preservative
- 1 Tube holder (1)
- 1 Instructions for Use (IFU)
- 1 Quick Reference Instructions (QRI)

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or watch
- WELLlife™ COVID-19 / Influenza A&B Test Control Kit for additional quality control (Catalog Number WV01P0003)

WARNINGS AND PRECAUTIONS

- Carefully read all instructions before performing the test. Failure to follow the instructions may result in inaccurate test results.
- For *in vitro* diagnostic use
- 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.
- The test has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories certified under the CLIA that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- **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.**
- This test may only be used in symptomatic individuals.
- Do not use after the expiration date printed on the outside of the box.
- Ensure that there is sufficient lighting for testing and interpretation.
- The WELLlife™ COVID-19 / Influenza A&B Test is only intended for use with direct anterior nasal swab specimens and is not validated or authorized for use with viral transport media.
- Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
- Follow your clinical and/or laboratory safety guidelines and use appropriate precautions in the collection, handling, storage, and disposal of patient samples, all used kit contents, and all items exposed to patient samples.
- Use only the swabs provided in the kit for collecting specimens. Other swabs have not been validated for use with this test.

- Do not touch the swab head when handling the swab.
- Wear disposable gloves while handling kit reagents or patient specimens and thoroughly wash hands afterwards.
- 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 reuse the used test cassettes, swabs, prefilled extraction tubes, or control swabs.
- Do not open the pouch until ready for use. If the test cassette is open for an hour or longer, false test results may occur.
- Do not use the test if the seal is broken or the pouch is damaged.
- If any liquid spills from the prefilled extraction tube, discard test components and re-start test using new test components.
- The Prefilled Extraction Buffer tube contains only enough liquid for one test. Do not attempt to test a second Test cassette with the same Prefilled Extraction Buffer tube as invalid or incorrect results may occur.
- Do not interchange or mix components from different kit lots.
- Follow your clinical and/or laboratory safety guidelines and use appropriate precautions in the collection, handling, storage, and disposal of patient samples, all used kit contents, and all items exposed to patient samples.
- Use of nitrile or latex (or other equivalent) gloves and other personal protective equipment are recommended when handling patient samples.
- **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.**
- Dispose of containers and unused contents in accordance with Federal, State, and Local regulatory requirements.
- All specimens should be handled as if they can transmit disease. Follow established precautions against microbiological hazards at all times and adhere to standard procedures for the proper disposal of specimens and test devices.
- **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

KIT STORAGE AND STABILITY

- Store the WELLlife™ COVID-19 / Influenza A&B Test in a dry place between 2°C-30°C (35.6°F-86°F) in the sealed pouch up to the expiration date printed on the outside of the kit box.
- Ensure all kit components are at room temperature before use.
- Keep away from direct sunlight, moisture and heat.
- Do not freeze any of the test kit components.
- Do not use Test cassettes or Prefilled Extraction Buffer after expiration date.
- Test cassettes that have been outside of sealed pouch for more than 1 hour should be discarded.

QUALITY CONTROL

The WELLlife™ COVID-19 / Influenza A&B Test provided two (2) types of controls; an internal procedural control to aid in determining test validity and two External Controls (one negative swab and one positive swab) to monitor the performance of the test.

INTERNAL QUALITY CONTROL

Each WELLlife™ COVID-19 / Influenza A&B Test 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 TESTING

External quality control swabs (containing one (1) positive control swab and one (1) negative control swab) are provided with the WELLlife™ COVID-19 / Influenza A&B Test kit. If an additional external quality control kit is needed, the WELLlife™ COVID-19 / Influenza A&B Test Control Kit (Catalog number WV01P0003) can be separately sold for use with the WELLlife™ COVID-19 / Influenza A&B Test. 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 may not produce the expected results, and therefore, will not meet the requirements for an adequate quality assurance program for the WELLlife™ COVID-19 / Influenza A&B Test. 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.

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.

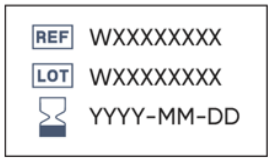
SPECIMEN COLLECTION AND PREPARATION

- Only nasal swabs can be used with this test. Use of nasal washes, nasal aspirates, or nasopharyngeal swabs has not been validated for use with this test.
- Proper specimen collection, storage, and transport are critical to the performance of this test. Negative results can occur from inadequate sample collection and/or handling. Training in specimen collection is highly recommended because of the importance of specimen quality.
- When collecting anterior nasal swab specimens, make sure to use only the swab included in the WELLlife™ COVID-19 / Flu A&B Test kit.
- To obtain accurate results, do not use visually bloody or overly viscous samples.
- If a culture result is desired for influenza, a separate swab must be collected for the culture.
- Use fresh samples for best performance. Freshly collected specimens should be tested immediately. If a testing delay is unavoidable, swab samples can be stored for up to 1 hour at room temperature.
- Once the swab has been mixed in the Extraction Buffer tube, the extracted sample must be used within 1 hour when stored at room temperature (15-30ºC/59-86ºF).
- Transport media should not be used. This test has not been validated or authorized for use with viral transport media.

PREPARING FOR TESTING

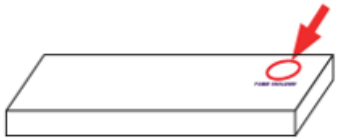
NOTE: Do not open the test contents until ready for use. If the test cassette is open for an hour or longer, invalid test results may occur.

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



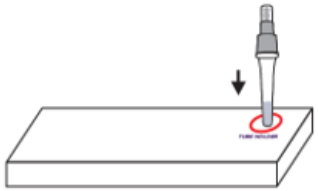
2. Wash your hands with soap and water for 20 seconds and dry them thoroughly, or use hand sanitizer.

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

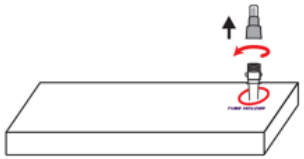


4.

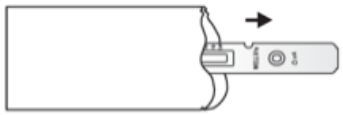
a) Insert the buffer tube into the tube holder. Ensure that the buffer tube is stable and upright.



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



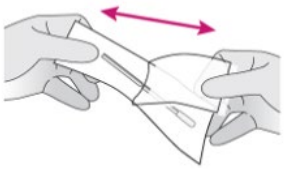
5. Remove test cassette from sealed pouch and lay it on a flat surface.



SAMPLE PREPARING FOR TESTING

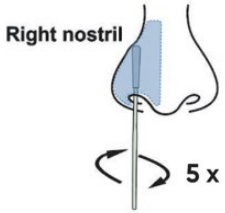
6. Remove the swab from the pouch.

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

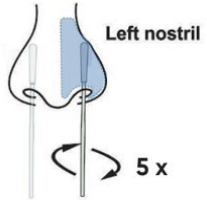


7.

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.



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

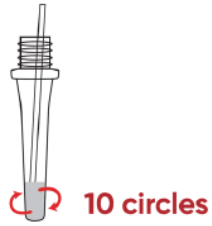


Check: Did you swab BOTH nostrils?

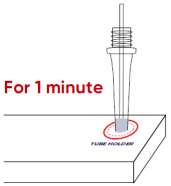
RUNNING THE TEST

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 or the test will not work properly.



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



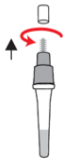
10. After 1 minute, pinch the tip of the swab from the outside of the tube to remove any excess liquid from the swab.

Remove and discard the swab.

11.

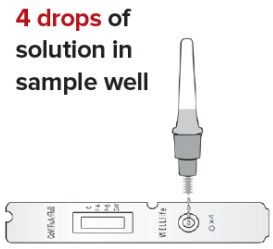
a) Hold the buffer tube upright and screw the large cap back onto the tube. Ensure a tight fit to prevent leaking.

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.

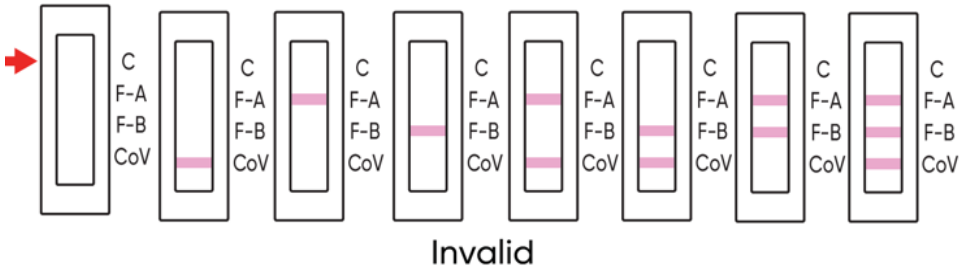
13. Start timer. Read results at 10 minutes.

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

INTERPRETATION OF RESULTS

INVALID RESULT

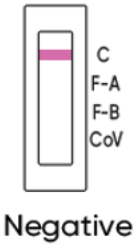
Check to see if a pink to red line is visible at the control line 'C' in the results window. If a line is not visible at 'C', even if any other line is visible in the results window, the result is considered invalid.



If you do not see a C line, DO NOT CONTINUE reading the results. It means the 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', the test is negative.



Negative

All negative results should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out influenza or SARS-CoV-2 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 a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with each respiratory infection.

COVID-19 Negative (-) Result

To increase the chance that the negative result for COVID-19 is accurate, you should:

• Test again in 48 hours if the individual has symptoms on the first day of testing.

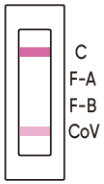
A negative test result indicates that the virus that causes COVID-19, Flu A, or Flu B was not detected in the sample. A negative result does not rule out COVID-19 or influenza infection. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care 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.

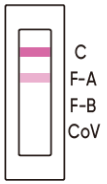
POSITIVE RESULT

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.

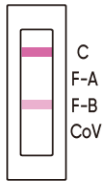
NOTE: Any pink to red test line, no matter how faint, should be considered a positive result when the control line is also present.



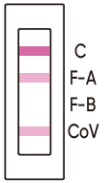
COVID-19 Positive



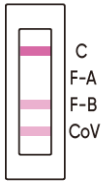
Flu A Positive



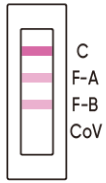
Flu B Positive



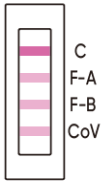
Flu A+ COVID-19 Positive



Flu B+ COVID-19 Positive



Flu A+ Flu B Positive



Flu A+B+ COVID-19 Positive

The SARS-CoV-2, Flu A and/or Flu B virus(es) were detected in the sample. A positive result does not rule out co-infections with other pathogens or identify any specific influenza A subtype, influenza B lineage, or SARS-CoV-2 variant.

Note: Look closely! The test line at 'CoV', 'F-A', and/or 'F-B' may be very faint. Any pink to red line visible is a Positive Result. It is possible to have more than one positive Test Line, which could indicate a co-infection with influenza A, B, and/or SARS-CoV-2, the virus that causes COVID-19. If more than one positive Test Line is observed, retest with a new patient sample and test kit. A differing result should be followed by confirmatory testing with another test method, such as PCR.

COVID-19 Positive (+) Result

Repeat testing does not need to be performed if patients have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self- isolation. There is a very small chance that this test can give 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 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.

SERIAL TESTING

Repeat Testing is needed to improve test accuracy for negative SARS-CoV-2 results. Please follow the table below when interpreting test results with symptoms. Serial (repeat) SARS-CoV-2 testing does not need to be performed if patients have a positive SARS-CoV-2 result.

Status on First Day of Testing	Day 0 (First Test)	Serial Testing?	Day 2 (Second Test)	Final 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	YES	SARS-CoV-2 (-) Influenza A and/	Presumptive Negative for COVID-19

Status on First Day of Testing	Day 0 (First Test)	Serial Testing?	Day 2 (Second Test)	Final Interpretation
	B (+)		or B (-)	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

LIMITATIONS OF PROCEDURE

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between December 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.
- 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 SARS- CoV-2 as compared to a molecular test, especially in samples with low viral load.
- All COVID-19 and influenza 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 SARS- CoV-2 infection, however additional follow-up may be needed.
- If the test is positive, then proteins from the viruses that cause COVID-19 or influenza infection have been found in the sample and the individual likely has a respiratory infection with SARS- CoV-2 or influenza.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- Negative results do not preclude influenza or SARS virus infection and should not be used as the sole basis for treatment or other patient management decisions.
- Results from the WELLlife™ COVID-19 / Influenza A&B Test should be correlated with the clinical history, epidemiological data and other data available to the clinician evaluating the patient.
- WELLlife™ COVID-19 / Influenza A&B Test has been evaluated for use with human direct anterior nasal swab specimens only.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
- Monoclonal antibodies may fail to detect, or detect with less sensitivity, influenza viruses that have undergone minor amino acid changes in the target epitope region.
- Positive test results can distinguish among influenza A, B and SARS-CoV-2 viruses but do not differentiate specific influenza A subtypes, influenza B lineages or SARS-CoV-2 variants. If the differentiation of specific influenza A, influenza B, or SARS subtypes or variants is needed, additional testing, in consultation with state or local public health departments, is required.
- WELLlife™ COVID-19 / Influenza A&B Test is a qualitative test and does not provide information on the viral load present in the specimen.
- The performance of the WELLlife™ COVID-19 / Influenza A&B Test has not been evaluated for use in patients who do not show signs and symptoms of respiratory infection.
- The performance of the WELLlife™ COVID-19 / Influenza A&B Test has not been evaluated for monitoring treatment of COVID-19 or influenza infection.
- The performance of the WELLlife™ COVID-19 / Influenza A&B Test has not been evaluated for the screening of blood or blood products for the presence of COVID-19 or influenza.
- The WELLlife™ COVID-19 / Influenza A&B Test cannot rule out diseases caused by other bacterial or viral pathogens. Positive test results do not rule out co-infections with other pathogens.

- Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods of low viral activity when prevalence is moderate to low.
- The use of the WELLlife™ COVID-19 / Influenza A&B Test is limited to laboratory personnel and CLIA waived users. Not for home use.
- Individuals who recently received nasally administered influenza A or influenza B vaccine may have false positive test results after vaccination.
- Liquid gel hand soap and hand sanitizer cream lotion may cause false negative results with this test. Fast-drying 80% ethanol hand sanitizer may cause false positive results with this test. Please ensure that hands are dry after washing prior to performing the test.
- A potential for cross-reactivity between the SARS-CoV-2 test and HKU1 exists. Wet testing for HKU1 coronavirus was not conducted and therefore, cross-reactivity between SARS-CoV-2 and HKU1 coronavirus cannot be ruled out.

CONDITIONS OF AUTHORIZATION FOR THE LABORATORY AND PATIENT CARE SETTINGS

The WELLlife™ COVID-19 / Influenza A&B Test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

However, to assist in using the WELLlife™ COVID-19 / Influenza A&B Test ("your product" in the conditions below) the relevant Conditions of Authorization are listed below:

- Authorized laboratories* using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating this labeling may be used, which may include mass media.
- Authorized laboratories using your product must use your product as outlined in WELLlife™ COVID-19 / Influenza A&B Test Instructions for Use and Quick Reference Instructions. Deviations from the authorized procedures, including authorized instruments, authorized clinical specimen types, authorized control materials, authorized ancillary reagents and authorized materials required to use your product are not permitted.
- Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Wondfo by contacting Technical Services (via email at wondfo@wondfousa.com via phone at 1-888-444-3657) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
- All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
- Wondfo USA Co., Ltd., authorized distributors, and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

* The Letter of Authorization refers to "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate complexity, high complexity, or waived tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation" as "Authorized Laboratories".

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 Test was determined by evaluating different concentrations of UV-inactivated SARS-CoV-2 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%
Influenza B B/Florida/4/2006(Yamagata)	1.17×10^{5}	$5.85\ x10^{1}$	2.925	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 Test was evaluated with 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/SWL 1536/19	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/10OS3959/2010	7.00E+05 $CEID_{50}$/mL	3/3
B(Non Victoria and Non Yamagata)	B/Maryland/1/59	3.38E+03 $CEID_{50}$/mL	3/3

Influenza Virus (Type/Subtype)	Virus Strain Name	Analytical Reactivity	Positive/ Replicates
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 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 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(H1N1), and influenza B(Yamagata) 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
Staphylococcus aureus subsp. aureus	$2.60X10^8$ CFU/mL
Staphylococcus epidermidis	$9.00X10^7$ CFU/mL
Streptococcus salivarius	$1.01X10^6$ CFU/mL

Potential Cross-Reactant	Concentration Tested
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

*Recommended testing concentrations were not achievable due to the low vial concentrations.

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 Test.

At 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 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.

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
	0.5% 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 Test for the SARS-CoV-2, influenza A and B viral strains at the concentrations 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 A 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%
Negative	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%

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
$2.37x10^3$	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 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 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% (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 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 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.

REFERENCES

1. US Department of Health and Human Services. National Institutes of Health. Influenza [Fact Sheet]. January 2011.
2. Montalto N, Byrd R. An Office-Based Approach to Influenza: Clinical Diagnosis and Laboratory Testing. American Family Physician. January 2003; 67:11-118.
3. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17: 181-192.
4. Lauer S, et al. The Incubation Period of Coronavirus Disease 2019 (COVID-19) From Publicly Reported Confirmed Cases: Estimation and Application. Ann Intern Med 2020 May 5;172(9):577-582.

INDEX OF SYMBOLS

	Consult instructions for use		Manufacturer		Use-by date
	Do not reuse		Store between 2-30°C (35.6°F-86°F)	LOT	Batch code
REF	Catalog number		Keep away from sunlight		Keep dry
CONTROL+	Positive control	CONTROL-	Negative control		Contains sufficient for <n> Tests
IVD	For in vitro diagnostic use	℞ONLY	Prescription Use Only		

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