Distributed by:
WATMIND USA

SpeedySwab™

Rapid **COVID-19** + **FLU A&B** Antigen Test

QUICK REFERENCE INSTRUCTIONS

For use under Emergency Use Authorization (EUA) only.
For *in vitro* diagnostic use.
For use with anterior nasal swab specimens.
Store the kit between (60~86°F/15~30°C). Bring the kit to room temperature before the test.
Carefully read the Instructions below before performing the test. Failure to follow the instructions may result in inaccurate results.
Please refer to the Instructions for Use (IFU) for more information and External Controls information.

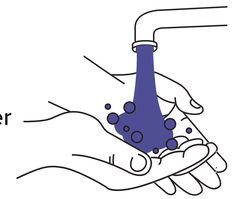
BEFORE GETTING STARTED

1.

Check expiration date on the outside of the box, Do not use beyond the expiration date. For the most current expiration dates of this test, please refer to: https://www.fda.gov/covid-tests.

2.

Wash hands thoroughly for at least 20 seconds before and after handling nasal swab samples.



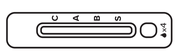
3.

Clean the tabletop on which the test will be performed. Before testing, read the User Instructions carefully.

PREPARE THE MATERIALS

MATERIALS PROVIDED:

25x Swabs



25x Test Devices in Pouches

25x Test Tubes with Buffer Solution

Materials required but not provided:
A clock or timer

4.

Arrange the materials on a clean, dry, flat surface.

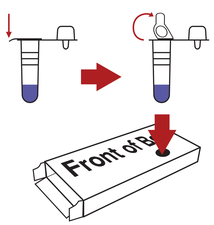
Use only one of each of the materials provided.

5.

Pick up the Test Tube and remove the sealing foil of the tube.

6.

Locate the tube holder on the front of the box labeled "Push Tube Here" and insert the buffer tube into the tube holder.



7.

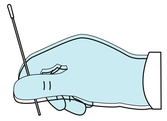
Remove the Test Device from its foil pouch.

NOTE: Use the Test Device within one hour of opening the test pouch.

PERFORMING THE TEST

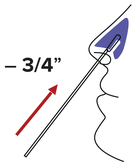
8.

Open swab package from its stick end and remove the swab from this end.
DO NOT touch the swab head or lay the swab on any surface.



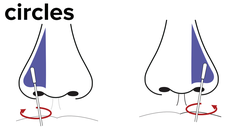
9.

Gently insert the swab 1/2 to 3/4 inch into a nostril.
DO NOT insert the swab any farther if you feel any resistance.



Using medium pressure, rub and rotate the swab against the inside walls of the nostril, making **at least 5 circles** for **at least 15 seconds**.

REPEAT IN THE OTHER NOSTRIL USING THE SAME SWAB.



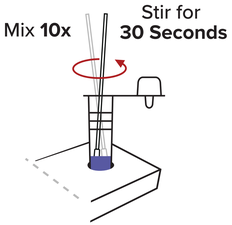
5x for 15 seconds, each nostril

STOP: Did you swab BOTH nostrils? Inaccurate test results may occur if the nasal sample is not properly collected.

10.

Place the swab into the buffer solution as soon as possible after collection and completely immerse the swab head in the sample.

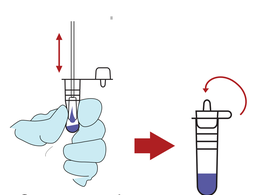
Swirl the swab in the solution by rotating the swab forcefully against the side of the tube **at least 10 times** for **30 seconds**, keeping the swab tip submerged in the buffer solution the entire time.



11.

Squeeze the tube **5 times** with your fingers to ensure that the sample on the swab is fully mixed into the buffer solution.

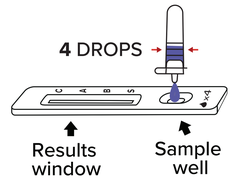
Attach the dropper cap to the test tube.



Squeeze and massage swab **5x**

12.

Squeeze only **4 DROPS** of the Buffer Solution into the sample well.



DO NOT squeeze more than 4 drops from the tube. Additional sample volume may yield inaccurate results.

13.

Set a timer and read the test result at 15 minutes.

DO NOT disturb the device during this time. Inaccurate results can occur if the device is disturbed.

TEST RESULT INTERPRETATION

Test results are read and interpreted visually. Read result at 15 minutes with good lighting.

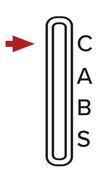
WARNING: Do not read the result before 15 minutes or after 20 minutes. Inaccurate test interpretations may occur.

= Control Line
= Influenza A Line
= Influenza B Line
= COVID-19 (SARS-CoV 2)

Look for lines next to 'C' (Control), 'A', 'B' and 'S'.

INVALID RESULTS

If a pink to red control line is not visible at "C" after 15 minutes, even if any other line is visible in the results window, THE TEST HAS FAILED and is considered **invalid.**



Invalid

STOP: If the control (C) line is not visible, the test is invalid. Do not continue reading the results. Re-test with a new swab and new test device.

NEGATIVE RESULTS

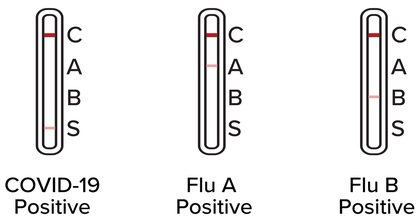
At 15 minutes, the appearance of ONLY the Control Line indicates that influenza A, influenza B, or SARS-CoV-2 has NOT been detected. A negative result should be reported as a presumptive negative for the presence of influenza and/or SARS-CoV-2 antigen.

Negative

POSITIVE RESULTS

If the control line at "C" is visible and any other line or multiple lines on 'A', 'B" and/or 'S' appear, the test is **positive for that or those viruses.** 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. If more than one positive Test Line is observed, retest with a new patient sample, Extraction Buffer vial, and Test Device to confirm dual positive results. A differing result should be followed by confirmatory testing with another test method, such as PCR.

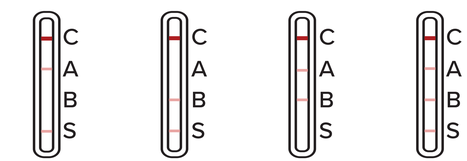
NOTE: Any pink to red line, no matter how faint, should be considered an indication of a positive result.



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

AFTER TEST IS COMPLETED, DISPOSE OF USED MATERIALS IN HOUSEHOLD TRASH.

SpeedySwab™

Rapid **COVID-19 + FLU A&B** Antigen Test

INTENDED USE

Please see the Instructions for Use for the full intended use.

The Speedy Swab Rapid COVID-19 + Flu A&B Antigen Test is a lateral flow immunochromatographic assay intended for *in vitro* rapid, simultaneous qualitative detection and differentiation of influenza A and 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.

WARNINGS AND PRECAUTIONS

- Read all instructions carefully before performing the test. 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.
- Do not read test results before 15 minutes or after 20 minutes. Results read before 15 minutes or after 20 minutes may lead to inaccurate results.
- Do not touch swab tip when handling the swab.
- Exposure to hand sanitizer may cause false positive results with this test.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- **This test may only be used in symptomatic individuals.**

EXTERNAL CONTROLS

To perform a positive or negative control test, complete the steps in the TEST PROCEDURES section, treating the control swab in the same manner as a patient swab.

Minimally, Watmind recommends that positive and negative external controls be run with each new lot, shipment received, and with each new untrained operator.

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: With Symptoms			
Day 0 (First Test)	**Serial Testing?**	**Day 2 (Second Test)**	**Interpretation**
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

SUPPORT

If you have questions regarding the use of this product, or if you want to report a problem with the test, please contact Watmind USA at +1 866-928-6463 or technicalsupport@watmindusa.com

Distribution by :
Watmind USA, Inc.
4780 I 55 N Ste 450
– Jackson, MS 39211 USA
Tel: 1-866-928-6463 (1-866-Watmind)
Email: sales@watmindusa.com
Website: watmindusa.com

LBL-013 Ver. 11

Speedy Swab Rapid COVID-19 + FLU A&B Antigen Test

Instructions for Use

For use under an Emergency Use Authorization (EUA) Only
Rx only
For *in vitro* diagnostic use
For use with anterior nasal swab specimens

1. Intended Use

The Speedy Swab Rapid COVID-19 + Flu A&B Antigen Test is a lateral flow immunochromatographic assay intended for *in vitro* rapid, simultaneous qualitative detection and differentiation of influenza A and 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 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 are presumptive, and should be 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 measures 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 Speedy Swab Rapid COVID-19 + Flu A&B Antigen 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.

2. 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.

---

[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.

3. Principle of the Procedure

The Speedy Swab Rapid COVID-19 + FLU A&B Antigen Test is a rapid, qualitative immunochromatographic assay for the determination of the presence of SARS-CoV-2 and influenza A&B antigens in anterior nasal swab specimens. The test strip in each device contains mouse monoclonal capture antibodies to the nucleocapsid protein (NP) of SARS-CoV-2, Influenza A and Influenza B and goat anti-Mouse IgG control antibody immobilized in the test and control regions on the nitrocellulose membrane, respectively. The conjugate pad is coated with colloidal gold conjugated SARS-CoV-2, Influenza A and Influenza B antibody and colloidal gold conjugated IgY. Once the extracted specimen is added in the sample well of the test device, it migrates chromatographically on the membrane by capillary action. The formation of the specific antibody-antigen conjugate complex Au-IgY is visualized by the presence of a colored band in the control region, which validates the test results. If SARS-CoV-2 nucleocapsid antigen and influenza A and influenza B nucleoprotein antigens are present in a specimen, the specific antibody antigen colored conjugate complex is formed and a distinct color band in the labeled region (S, B, A) is observed. Absence of this colored band in any of the test regions (S, B, A) indicates a negative result (when the control band is present).

4. Materials Provided

Test components provided within the test kit:

25 – Test Devices
25 – Sterile Nasal Swabs
25 – Test Tube with Buffer Solution vials containing 500uL of buffer
5 – Tube Holders in Box Top
1 – Positive Control Swab
1 – Negative Control Swab
1 – Quick Reference Instruction

5. Materials Required but not Provided

- A timer: required to determine the time to read the test results after addition of the extracted specimen to the test device
- Personal protective equipment: mask (if swabbing others) and gloves.

6. Warnings and Precautions

1 For *in vitro* diagnostic use.

2 Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.

3 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.

4 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.

5 **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.**

6 **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.**

7 Do not use kit past its expiration date.

8 Test components are for single use. Do not re-use.

9 If any liquid spills from the buffer tube, discard test components and re-start test using new test components.

10 The Buffer vial contains only enough liquid for one test. Do not use the same Buffer vial with an additional test as invalid or incorrect results may occur.

11 Do not interchange or mix components from different kit lots.

12 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.[5]

13 Use of nitrile or latex (or other equivalent) gloves and other personal protective equipment are recommended when handling patient samples.

[5] CLSI. Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline – Fourth Edition. CLSI document M29-A4. Wayne, PA: Clinical and Laboratory Standards.

14 Inadequate or inappropriate sample collection, storage, and transport may yield false test results.

15 This test is only intended for use with direct anterior nasal swab specimens and is not validated for use with viral transport media.

16 Only use the nasal swabs provided in the kit. Do not touch the swab head prior to testing. Exposure to hand sanitizer may cause false positive results with this test.

17 Once opened, the test device should be used within 60 minutes.

18 **Do not read test results before 15 minutes or after 20 minutes. Results read before 15 minutes or after 20 minutes may lead to a false positive, false negative, or invalid result.**

19 Dispose of unused contents and containers in accordance with federal, state, and local regulations.

20 Wear a safety mask or other face-covering when collecting a specimen.

21 Do not use if any of the test kit contents or packaging opened or is damaged.

22 This test may only be used in symptomatic individuals.

23 Ensure that there is sufficient lighting for testing and interpretation.

24 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.

25 **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.**

26 **If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.**

Chemical Name	GHS Code for each Ingredient	Concentrations
Proclin 300	H317, allergic skin reaction	0.1%
Trimethylsilyl acetamide	H316, mild skin irritation	0.03%

27 For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-response/mcmlegal-regulatory-and-policy-framework/emergency-use-authorization

28 For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

7. Kit Storage and Stability

Store the Speedy Swab Rapid COVID-19 + FLU A&B Antigen Test at room temperature (15 to 30^0C / 60 to 86^0F) in the original packaging, away from direct sunlight. Kit contents are stable in the unopened box until the expiration date printed on the kit box.

- Do not freeze any of the test kit components.
- Ensure all test components are at room temperature before use (15 – 30 ^{0}C / 60 – 86 ^{0}F).
- Do not use test kit after expiration date.
- The Test Device must remain in the sealed foil pouch until use. Once the pouch has been opened, the test device should be used within 60 minutes. Use beyond one hour may not produce accurate results.

8. Sample Handling, Transport, and Storage

- The test performance depends on the quality of the sample obtained as well as the handling and transport of the sample. 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.
- To obtain accurate results, do not use visually bloody or overly viscous samples.
- Test components should not be used for any other purpose other than performing this test.
- Test samples immediately after collection. Swabs should be placed into buffer within 60 minutes of collection. Inoculated buffer should be added to the device within 30 minutes of swab addition and mixing.
- 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.
- When collecting anterior nasal swab specimens, make sure to use only the swab included in the test kit.
- Transport media should not be used. This test has not been validated or authorized for use with viral transport media.

9. Quality Control

The Speedy Swab Rapid COVID-19 + Flu A&B Antigen Test provides two types of controls: internal controls to aid in determining test validity, and two external controls, a positive and negative control swab.

Internal Procedural Control

Each **Speedy Swab Rapid COVID-19 + FLU A&B Antigen Test** has a built-in internal procedural control. The reddish/pink line appearing at the "C" position is an internal procedural control. This procedural control line indicates that sufficient flow has occurred. A distinct reddish/pink 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.

Contact Watmind USA at +1 866-928-6463 or technicalsupport@watmindusa.com if you experience a problem.

External Quality Control

The Speedy Swab Rapid COVID-19 + Flu A&B Antigen Test includes one combined positive control swab that contains recombinant antigen for influenza A, influenza B, and SARS-CoV-2 and one blank negative control swab.

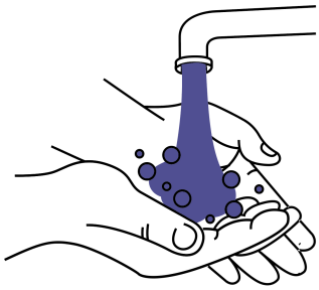
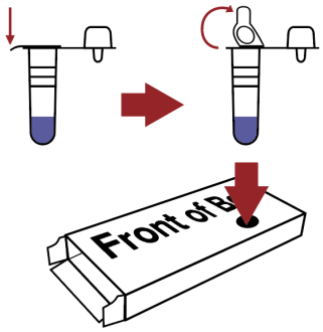
Use the controls to help ensure that the test is functioning properly and to demonstrate proper performance by the test operator. It is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure was run correctly and to verify the test is working properly.

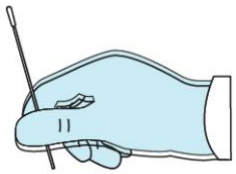
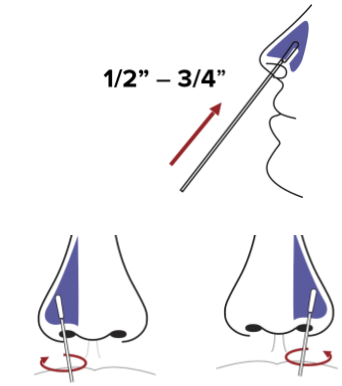
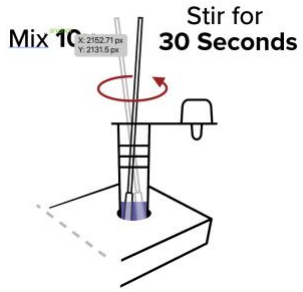
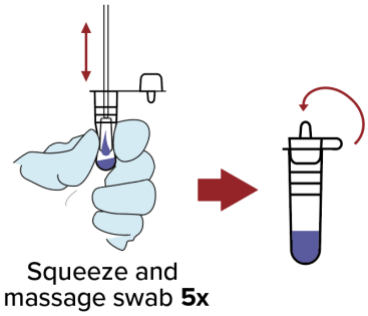
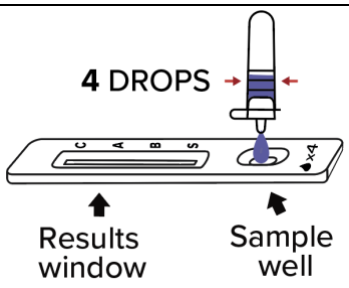
External quality control requirements should be established in accordance with your local, state, and federal regulations or accreditation requirements. To perform a positive or negative control test, complete the steps in the Test Procedure section, treating the control swab in the same manner as a patient swab. Minimally, WATMIND USA recommends that Positive and Negative external controls be run with each new lot, shipment received, and with each new untrained operator. When the positive control is tested, reddish lines appear at the C as well as S, B, A positions. When the negative control is tested, a reddish line appears at the C position only.

If the controls do not perform as expected, do not use the kit and contact Watmind USA for assistance.

10. Test Procedure

Steps outlining the test are as follows:

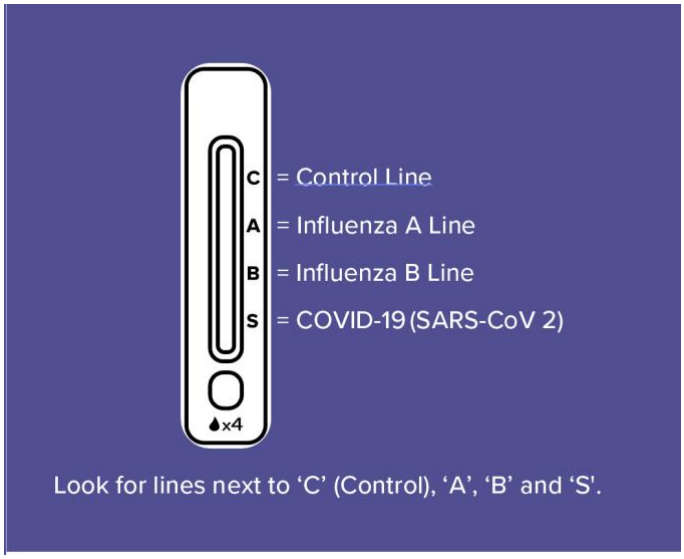
<table>
<tr><th colspan="3">Speedy Swab Rapid COVID-19 + FLU A&B Antigen Test Steps</th></tr>
<tr><td rowspan="3">Before Getting Started</td><td rowspan="3">  </td><td>Step 1: Check expiration date on the outside of the box, Do not use beyond the expiration date. For the most current expiration dates of this test, please refer to: https://www.fda.gov/covid-tests.</td></tr>
<tr><td>Step 2: Wash hands thoroughly for at least 20 seconds before and after handling nasal swab samples.</td></tr>
<tr><td>Step 3: Clean the tabletop on which the test will be performed. Before testing, read the User Instructions carefully.</td></tr>
<tr><td rowspan="3">Prepare the Materials</td><td rowspan="3"> 
</td><td>Step 4: Arrange the materials on a clean, dry, flat surface. Use only one of each of the materials provided for each test.</td></tr>
<tr><td>Step 5: Pick up the Test Tube and remove the sealing foil of the tube.</td></tr>
<tr><td>Step 6: Locate the tube holder on the front of the box labeled "Push Tube Here" and insert the buffer tube into the tube holder.</td></tr>
<tr><td colspan="2"></td><td>Step 7: Remove the Test Device from its foil pouch.
NOTE: Use the Test Device within one hour of opening the test pouch.</td></tr>
</table>

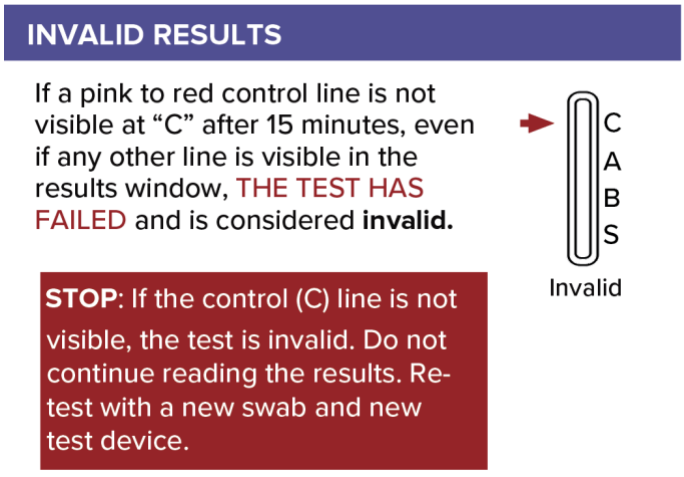
Speedy Swab Rapid COVID-19 + FLU A&B Antigen Test Steps		
Performing the Test		**Step 8:** Open swab package from its stick end and remove the swab from this end. **NOTE: DO NOT** touch the swab head or lay the swab on any surface.
		**Step 9:** Gently insert the swab ½ to ¾ inch into a nostril. **NOTE: DO NOT** insert the swab any farther if you feel any resistance. Using medium pressure, rub and rotate the swab against the inside walls of the nostril, making at least 5 circles for at least 15 seconds. REPEAT IN THE OTHER NOSTRIL USING THE SAME SWAB.
		**Step 10:** Place the swab into the buffer solution as soon as possible after collection and completely immerse the swab head in the sample. Swirl the swab in the solution by rotating the swab forcefully against the side of the tube **at least 10 times for 30 seconds**, keeping the swab tip submerged in the buffer solution the entire time.
		**Step 11:** Squeeze the tube **5 times** with your fingers to ensure that the sample on the swab is fully mixed into the buffer solution. Attach the dropper cap to the test tube.
		**Step 12:** Squeeze only **4 DROPS** of the Buffer Solution into the sample well. **NOTE:** DO NOT squeeze more than 4 drops from the tube. Additional sample volume may yield inaccurate results.

Speedy Swab Rapid COVID-19 + FLU A&B Antigen Test Steps		
Performing the Test		**Step 13:** Set a timer and read the test result at 15 minutes. **NOTE:** **DO NOT** disturb the card during this time. Inaccurate results can occur if the card is disturbed.

11. Interpretation of Results

Test results are read and interpreted visually. Read results at 15 minutes with good lighting. WARNING: Do not read the result before 15 minutes or after 20 minutes. Inaccurate test interpretations may occur.





NEGATIVE RESULTS

At 15 minutes, the appearance of ONLY the Control Line indicates that influenza A, influenza B, or SARS-CoV-2 has NOT been detected. A negative result should be reported as a presumptive negative for the presence of influenza and/or SARS-CoV-2 antigen.

Negative

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.**

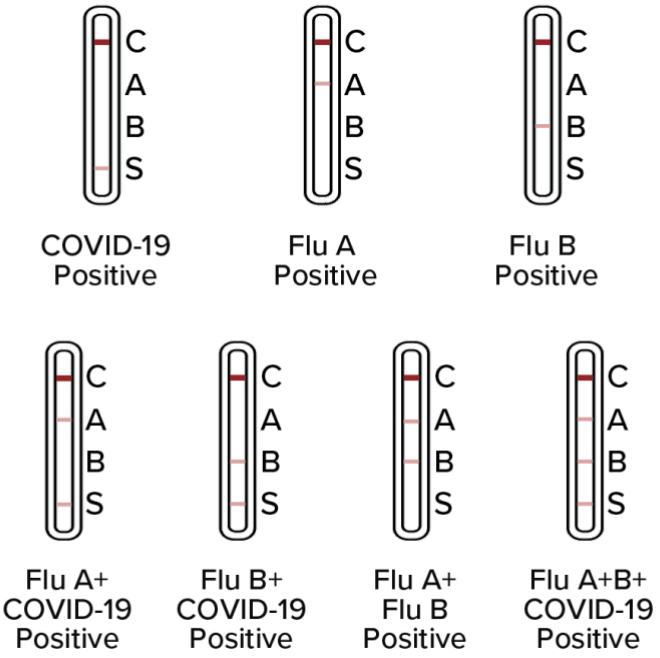
A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like 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 RESULTS

If the control line at "C" is visible and any other line or multiple lines on 'A', 'B" and/or 'S' appear, the test is **positive for that or those viruses.** 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. If more than one positive Test Line is observed, retest with a new patient sample, Extraction Buffer vial, and Test Device to confirm dual positive results. A differing result should be followed by confirmatory testing with another test method, such as PCR.

NOTE: Any pink to red line, no matter how faint, should be considered an indication of a positive result.



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

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 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 (-)	YES	SARS-CoV-2 (-)	Presumptive Negative for COVID-19

Status on First Day of Testing	Day 0 (First Test)	Serial Testing?	Day 2 (Second Test)	Final Interpretation
	Influenza A and/or B (+)		Influenza A and/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 (+)	Positive for COVID-19 Positive for Influenza A and/or B

12. Limitations

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between June 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 COVID-19 and influenza A&B antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.
- If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19 infection, however additional follow-up may be needed.
- If the test is positive, then proteins from the virus that causes 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.
- Based on sequence analysis, a potential for cross-reactivity between the SARS-CoV-2 test and HKU1 exists. Wet testing for HKU1 coronavirus was not conducted and therefore, cross-reactivity between SARS-CoV-2 and HKU1 coronavirus cannot be ruled out.
- Use of Speedy Swab Rapid COVID-19 + Flu A&B Antigen Test is limited to laboratory personnel and CLIA waived users. Not for home use.

- The contents of this kit are to be used for the qualitative detection of influenza type A and B antigens as well as SARS-CoV-2 antigen from direct anterior nasal swab samples only.
- This test detects both viable (live) and non-viable influenza A, influenza B, and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture or molecular results performed on the same sample.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
- Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
- Results from the Speedy Swab Rapid COVID-19 + Flu A&B Antigen Test should be correlated with the clinical history, epidemiological data and other data available to the clinician evaluating the patient.
- Positive test results do not rule out co-infections with other pathogens.
- Positive test results do not identify 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.
- Negative test results cannot rule out diseases caused by other bacterial or viral 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.
- Individuals who recently received nasally administered influenza A or influenza B vaccine may have false positive test results after vaccination.
- 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.
- The performance of the Speedy Swab Rapid COVID-19 + Flu A&B Antigen Test has not been evaluated for use in patients who do not show signs and symptoms of respiratory infection.

13. Conditions of Authorization for the Laboratory and Patient Care Settings

The Speedy Swab Rapid COVID-19 + Flu A&B Antigen 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 Speedy Swab Rapid COVID-19 + Flu A&B Antigen 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 Speedy Swab Rapid COVID-19 + Flu A&B Antigen 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 any significant deviations from the established performance characteristics of your product of which they become aware to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Watmind USA by contacting Technical Services (via email at technicalsupport@watmindusa.com or via phone at +1 866-928-6463).
- 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.
- Watmind USA, 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"

14. Analytical Performance

14.1 Analytical Sensitivity: Limit of Detection (LoD) - Analytical Sensitivity

The limit of detection (LoD) for the Speedy Swab Rapid COVID-19 + FLU A&B Antigen Test was established using dilutions of one SARS Coronavirus 2 (SARS-CoV-2) Isolate USA-WA1/2020 strain (BEI Resources Catalog number NR-52287), two influenza A strains (Influenza A H1N1: Influenza A/Indiana/02/2020, Influenza A H3N2: Influenza A/Alaska/232/2015) and two influenza B strains (Influenza B/Washington/02/2019, Influenza B/Florida/4/2006) in negative clinical matrix. The isolate dilutions were tested by adding fifty (50) µL to the head of the nasal swab and extracting the swab per the Speedy Swab Rapid COVID-19 + FLU A&B Antigen Test Instructions for Use.

In this study, range finding testing was followed by final dilution testing to determine the LoD of the assay. Range finding involved testing a series of 10-fold dilutions in replicates of three (3) to determine the starting point for the dilution series to determine LoD. The dilution of each virus which resulted in the lowest concentration that generated 100% positive detection rate was set as the target for the next dilution series, which involved testing three (3) replicates of two (2)-fold dilutions. In the final dilution testing, the lowest concentration that generated ≥95% positive detection rate was set as the LoD concentration. Confirmatory testing was performed by testing twenty (20) replicates at the preliminary (1X) LoD concentrations.

Virus Strains	Stock Concentration	LoD Concentration	LOD per Swab	# Positive / # Total Tested	Percent Detected
SARS-CoV-2 USA-WA1/2020	7.9×10^5 $TCID_{50}$/mL	7.9×10^2 $TCID_{50}$/mL	4.0×10^1 $TCID_{50}$	20/20	100%
Influenza A A/Indiana/02/2020 (H1N1)	9.7×10^8 $CEID_{50}$/mL	9.7×10^6 $CEID_{50}$/mL	4.9×10^5 $CEID_{50}$	20/20	100%
Influenza A A/Alaska/232/2015 (H3N2)	2.6×10^8 $CEID_{50}$/mL	2.6×10^4 $CEID_{50}$/mL	1.3×10^3 $CEID_{50}$	20/20	100%
Influenza B B/Washington/02/2019 (Victoria)	2.1×10^9 $CEID_{50}$/mL	2.1×10^6 $CEID_{50}$/mL	1.1×10^5 $CEID_{50}$	19/20	95%
Influenza B B/Florida/4/2006 (Yamagata)	7.3×10^7 $CEID_{50}$/mL	1.8×10^4 $CEID_{50}$/mL	9.2×10^2 $CEID_{50}$	20/20	100%

14.2 Inclusivity (Analytical Reactivity)

The analytical reactivity of the Speedy Swab Rapid COVID-19 + FLU A&B Antigen Test was evaluated with currently available influenza strains and SARS-CoV-2 strains using a dilution series. Concentrations listed in the table below indicate the lowest detectable concentrations in pooled nasal wash (PNW) and/or pooled nasal swab matrix (PNSM) for which all replicates were positive.

Virus	Strain	Concentration in PNW	Concentration in PNSM	Concentration Units
Influenza A, H1N1	A/Michigan/45/2015	1.0×10^7	3.9×10^2	$CEID_{50}$/mL
	A/St. Petersburg/61/2015	1.2×10^6	4.7×10^5	$CEID_{50}$/mL
	A/Hawaii/66/2019	1.9×10^7	1.9×10^7	$CEID_{50}$/mL
	A/Wisconsin/588/2019	2.8×10^3	2.8×10^3	FFU/mL
	A/Idaho/07/2018	8.0×10^1	1.6×10^2	$TCID_{50}$/mL
	A/Brownsville/39H/2009	N/A	8.0×10^1	$TCID_{50}$/mL
	A/Massachusetts/15/2013	N/A	1.6×10^6	$CEID_{50}$/mL
	A/Bangladesh/3002/2015	N/A	6.5×10^4	$CEID_{50}$/mL
	A/Dominican/Republic/7293/2013	N/A	1.3×10^3	$TCID_{50}$/mL
	A/Iowa/53/2015	N/A	2.9×10^6	$CEID_{50}$/mL
Influenza A, H3N2	A/New York/21/2020	6.5×10^4	6.5×10^4	FFU/mL
	A/Tasmania/503/2020	3.3×10^4	3.3×10^4	FFU/mL
	A/Hong Kong/2671/2019	1.6×10^6	6.2×10^5	$CEID_{50}$/mL
	A/Hong Kong/45/2019	3.8×10^3	3.8×10^3	FFU/mL
	A/Singapore/INFIMH-16-0019/2016	1.1×10^5	5.5×10^4	$CEID_{50}$/mL
Influenza A, H1N1v	A/Ohio/09/2015	N/A	7.0×10^5	$CEID_{50}$/mL
Influenza A, H1N2	A/Minnesota/19/2011	N/A	4.00×10^6	$CEID_{50}$/mL
Influenza A, H3N2v	A/Indiana/08/2011	N/A	2.0×10^2	$TCID_{50}$/mL
Influenza A, H7N3	A/northern pintail/Illinois/10OS3959/2010	N/A	2.8×10^5	$CEID_{50}$/mL
Influenza A, H5N1	A/mallard/Wisconsin/2576/2009	N/A	1.6×10^5	$CEID_{50}$/mL
Influenza B, Non-Victoria, Non-Yamagata	B/Maryland/1/1959	4.5×10^2	4.5×10^2	$CEID_{50}$/mL
Influenza B, Victoria	B/Colorado/6/2017	1.6×10^5	1.6×10^5	$CEID_{50}$/mL
	B/Florida/78/2015	1.7×10^6	1.7×10^6	$CEID_{50}$/mL

Virus	Strain	Concentration in PNW	Concentration in PNSM	Concentration Units
Influenza B, Yamagata	B/Texas/06/2011	8.0×10^6	4.0×10^6	$CEID_{50}$/mL
	B/Wisconsin/1/10	7.05×10^1	3.53×10^1	$TCID_{50}$/mL
SARS-CoV-2	hCoV-19/USA/MD-HP40900/2022 (Lineage XBB.1.5; Omicron Variant)	N/A	8.0×10^1	$TCID_{50}$/mL

14.3 Analytical Specificity: Cross-reactivity and Microbial interference

Cross-Reactivity

Cross-reactivity and microbial interference with related pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in the clinical specimen were evaluated with the Speedy Swab Rapid COVID-19 + FLU A&B Antigen Test. Each organism was tested in replicates of three (3) at the concentration listed in the following table of test results.

For cross reactivity, the organisms listed below were tested in negative samples. No cross-reactivity was observed for any of the organisms tested, except for SARS-coronavirus which exhibited cross-reactivity when tested neat (7.9×10^3 $TCID_{50}$/mL). A titration of SARS-CoV was performed and it was shown that cross reactivity was no longer observed for SARS-CoV at 7.9×10^0 $TCID_{50}$/mL. These results are not unexpected in that the Speedy Swab Rapid COVID-19 + FLU A&B Antigen Test targets the SARS-CoV-2 nucleocapsid protein which is present on both the SARS-CoV and SARS-CoV-2 viruses.

No cross reactivity was observed for any organism.

Microorganism Introduced	Concentration Tested for Cross Reactivity	Influenza A Test Results (Positive/Total)	Influenza B Test Results (Positive/Total)	SARS-CoV-2 Test Results (Positive/Total)
Human coronavirus 229E	1.5×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Human coronavirus OC43	1.5×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Human coronavirus NL63	1.5×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
SARS-coronavirus Urbani	7.9×10^3 $TCID_{50}$/mL	0/3	0/3	3/3
MERS-coronavirus	1.5×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Adenovirus Goman	1.5×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Adenovirus Adenoid 71	1.5×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Human metapneumovirus 4	1.5×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Parainfluenza virus 1	1.5×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Parainfluenza virus 2	1.5×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Parainfluenza virus 3	1.5×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Parainfluenza virus 4b	1.5×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Enterovirus	1.5×10^5 $TCID_{50}$/mL	0/3	0/3	0/3

Microorganism Introduced	Concentration Tested for Cross Reactivity	Influenza A Test Results (Positive/Total)	Influenza B Test Results (Positive/Total)	SARS-CoV-2 Test Results (Positive/Total)
Respiratory syncytial virus A 3/2015	1.5×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Respiratory syncytial virus B	1.5×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Rhinovirus	1.0×10^5 pfu/mL	0/3	0/3	0/3
Haemophilus influenzae	1.1×10^6 cfu/mL	0/3	0/3	0/3
Streptococcus pneumonia	1.1×10^6 cfu/mL	0/3	0/3	0/3
Streptococcus pyogenes	1.1×10^6 cfu/mL	0/3	0/3	0/3
Candida albicans	1.1×10^6 cfu/mL	0/3	0/3	0/3
Bordetella pertussis	$>1.0 \times 10^4$ cfu/mL	0/3	0/3	0/3
Mycoplasma pneumonia	1.1×10^6 cfu/mL	0/3	0/3	0/3
Chlamydia pneumoniae	1.1×10^6 ifu/mL	0/3	0/3	0/3
Legionella pneumophila Philadelphia	1.1×10^6 cfu/mL	0/3	0/3	0/3
Mycobacterium tuberculosis	1.1×10^6 cfu/mL	0/3	0/3	0/3
P. jiroveci-S. cerevisiae	1.1×10^6 cfu/mL	0/3	0/3	0/3
Staphylococcus aureus subsp. aureus	1.1×10^6 cfu/mL	0/3	0/3	0/3
Staphylococcus epidermidis	3.3×10^7 cfu/mL	0/3	0/3	0/3
Corynebacterium sp.	$>1.0 \times 10^4$ cfu/mL	0/3	0/3	0/3
Escherichia coli Crooks	$>2.5 \times 10^4$ cfu/mL	0/3	0/3	0/3
Lactobacillus sp. Gere A	$>1.0 \times 10^4$ cfu/mL	0/3	0/3	0/3
Moraxella catarrhalis	1.1×10^6 cfu/mL	0/3	0/3	0/3
Neisseria meningitidis	1.05×10^5 cfu/mL	0/3	0/3	0/3
Neisseria sp.	$>1.0 \times 10^4$ cfu/mL	0/3	0/3	0/3
Pseudomonas aeruginosa	1.1×10^6 cfu/mL	0/3	0/3	0/3
Streptococcus salivarius	$>1.0 \times 10^4$ cfu/mL	0/3	0/3	0/3
Measles Edmonston	1.5×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Mumps Isolate 1	1.5×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Epstein Barr Virus	$>2.5 \times 10^3$ $CEID_{50}$/mL	0/3	0/3	0/3
Cytomegalovirus	1.5×10^5 $TCID_{50}$/mL	0/3	0/3	0/3

Microbial Interference

For evaluating microbial interference against the SARS-CoV-2, Influenza A (H1N1), Influenza B (Victoria) test lines, the organisms were tested with co-spiked SARS-CoV-2 Isolate USA-WA1/2020 strain (BEI Resources Catalog number NR-52287), Influenza A/Alaska/232/2015 (International Reagent Resource Catalog number FR-1540) or Influenza B/Florida/04/2006

(BEI Resources Catalog number NR-41795) diluted to 3x LoD concentration in negative clinical matrix. SARS-CoV-2, Influenza A and Influenza B were detected in all samples tested in the presence of potentially interfering organisms demonstrating no interference.

Microorganism Introduced	Microorganism Concentration	Influenza A Test Results (Positive/Total)	Influenza B Test Results (Positive/Total)	SARS-CoV-2 Test Results (Positive/Total)
Human coronavirus 229E	1.5×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Human coronavirus OC43	1.5×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Human coronavirus NL63	1.5×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
SARS-coronavirus Urbani	7.9×10^0 $TCID_{50}$/mL	3/3	3/3	3/3
MERS-coronavirus	1.5×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Adenovirus Goman	1.5×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Adenovirus Adenoid 71	1.5×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Human metapneumovirus 4	1.5×10^5 TCID50/mL	3/3	3/3	3/3
Parainfluenza virus 1	1.5×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Parainfluenza virus 2	1.5×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Parainfluenza virus 3	1.5×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Parainfluenza virus 4b	1.5×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Enterovirus	1.5×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Respiratory syncytial virus A 3/2015	1.5×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Respiratory syncytial virus B	1.5×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Rhinovirus	1.0×10^5 pfu/mL	3/3	3/3	3/3
Haemophilus influenzae	1.1×10^6 cfu/mL	3/3	3/3	3/3
Streptococcus pneumonia	1.1×10^6 cfu/mL	3/3	3/3	3/3
Streptococcus pyogenes	1.1×10^6 cfu/mL	3/3	3/3	3/3
Candida albicans	1.1×10^6 cfu/mL	3/3	3/3	3/3
Bordetella pertussis	$>1.0 \times 10^4$ cfu/mL	3/3	3/3	3/3
Mycoplasma pneumonia	1.1×10^6 cfu/mL	3/3	3/3	3/3
Chlamydia pneumoniae	1.1×10^6 ifu/mL	3/3	3/3	3/3
Legionella pneumophila Philadelphia	1.1×10^6 cfu/mL	3/3	3/3	3/3
Mycobacterium tuberculosis	1.1×10^6 cfu/mL	3/3	3/3	3/3

Microorganism Introduced	Microorganism Concentration	Influenza A Test Results (Positive/Total)	Influenza B Test Results (Positive/Total)	SARS-CoV-2 Test Results (Positive/Total)
P. jiroveci-S. cerevisiae	1.1×10^6 cfu/mL	3/3	3/3	3/3
Staphylococcus aureus subsp. aureus	1.1×10^6 cfu/mL	3/3	3/3	3/3
Staphylococcus epidermidis	3.3×10^7 cfu/mL	3/3	3/3	3/3
Corynebacterium sp.	$>1.0 \times 10^4$ cfu/mL	3/3	3/3	3/3
Escherichia coli Crooks	$>2.5 \times 10^4$ cfu/mL	3/3	3/3	3/3
Lactobacillus sp. Gere A	$>1.0 \times 10^4$ cfu/mL	3/3	3/3	3/3
Moraxella catarrhalis	1.1×10^6 cfu/mL	3/3	3/3	3/3
Neisseria meningitidis	1.05×10^5 cfu/mL	3/3	3/3	3/3
Neisseria sp.	$>1.0 \times 10^4$ cfu/mL	3/3	3/3	3/3
Pseudomonas aeruginosa	1.1×10^6 cfu/mL	3/3	3/3	3/3
Streptococcus salivarius	$>1.0 \times 10^4$ cfu/mL	3/3	3/3	3/3
Measles Edmonston	1.5×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Mumps Isolate 1	1.5×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Epstein Barr Virus	$>2.5 \times 10^3$ $CEID_{50}$/mL	3/3	3/3	3/3
Cytomegalovirus	1.5×10^5 $TCID_{50}$/mL	3/3	3/3	3/3

14.4 Endogenous Interfering Substances

A total of twenty nine (29) potentially interfering substances, either naturally present in respiratory specimens or artificially introduced into the nasal cavity or nasopharynx, were tested to evaluate the performance of the Speedy Swab Rapid COVID-19 + FLU A&B Antigen Test when these substances were added to the nasal swab head in the absence (negative) and presence (positive) of co-spiked SARS-CoV-2 Isolate USA-WA1/2020 strain (BEI Resources Catalog number NR-52287), influenza A (Influenza A/Alaska/232/2015, International Reagent Resource Catalog number FR-1540), or two different strains of influenza B (Influenza B/Florida/04/2006, BEI Resources Catalog number NR-41795) diluted to 3x LoD concentration. Each substance was tested in replicates of three (3). For testing Zanamivir, pooled nasal swab matrix (PNSM) was used instead of pooled nasal wash (PNW).

At 15% v/v, hand sanitizer cream lotion produced a false positive and false negative result in three of three (3/3) replicates for all three target analytes. When diluted to 5% v/v, SARS-CoV-2 only false positive results were observed in all three (3) test replicates.

False positive results were also detected for Influenza A and Influenza B analytes in the presence of FluMist Quadrivalent Live Intranasal Influenza Virus Vaccine at 15% v/v and 1.5% v/v. One out of three (1/3) replicates tested positive for SARS-CoV-2 at 1.5% v/v.

Substance	Concentration Tested	Virus Unspiked Test Results (Positive/Total)		
		SARS-CoV-2	Flu A	Flu B
Biotin	3,500 ng/mL	0/3	0/3	0/3
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	0/3	0/3	0/3
Fluticasone Propionate	5% v/v	0/3	0/3	0/3
Homeopathic (Alkalol)	10% v/v	0/3	0/3	0/3
Human Whole Blood (EDTA tube)	4% v/v	0/3	0/3	0/3
Mucin (porcine stomach, type II)	0.5%	0/3	0/3	0/3
Mupirocin	10 mg/mL	0/3	0/3	0/3
Nasal Drops (Phenylephrine)	15% v/v	0/3	0/3	0/3
Nasal Spray (Cromolyn)	15% v/v	0/3	0/3	0/3
Nasal Spray (Oxymetazoline)	15% v/v	0/3	0/3	0/3
Naso GEL (NeilMed)	5% v/v	0/3	0/3	0/3
Sore Throat Phenol Spray	15% v/v	0/3	0/3	0/3
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	0/3	0/3	0/3
Tobramycin	4 µg/mL	0/3	0/3	0/3
Zicam	5% v/v	0/3	0/3	0/3
FluMist Quadrivalent Live Intranasal Influenza Virus Vaccine	15% v/v	0/3	3/3	3/3
FluMist Quadrivalent Live Intranasal Influenza Virus Vaccine	1.5% v/v	1/3	3/3	3/3
FluMist Quadrivalent Live Intranasal Influenza Virus Vaccine	0.15% v/v	0/3	0/3	0/3
Body and Hand Lotion	0.5% w/v	0/3	0/3	0/3
Body Lotion with 1.2% Dimethicone	0.5% w/v	0/3	0/3	0/3
Hand Lotion	5% w/v	0/3	0/3	0/3
Hand Sanitizer with Aloe, 62% Ethyl Alcohol	5% v/v	0/3	0/3	0/3
Hand Sanitizer Cream Lotion	15% v/v	3/3	3/3	3/3
Hand Sanitizer Cream Lotion	5% v/v	3/3	0/3	0/3
Hand Sanitizer Cream Lotion	1.5% v/v	0/3	0/3	0/3
Hand Sanitizer, 80% Ethanol	15% v/v	0/3	0/3	0/3
Hand Soap Liquid Gel	10% w/v	0/3	0/3	0/3
Hand Soap Liquid Gel	5.0% w/v	0/3	0/3	0/3
Zanamivir	282 ng/mL	0/3	0/3	0/3

Substance	Concentration Tested	Virus Spiked Test Results (Positive/Total)		
		SARS-CoV-2	Flu A	Flu B
Biotin	3,500 ng/mL	3/3	3/3	3/3
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	3/3	3/3	3/3
Fluticasone Propionate	5% v/v	3/3	3/3	3/3
Homeopathic (Alkalol)	10% v/v	3/3	3/3	3/3
Human Whole Blood (EDTA tube)	4% v/v	3/3	3/3	3/3
Mucin (porcine stomach, type II)	0.5%	3/3	3/3	3/3
Mupirocin	10 mg/mL	3/3	3/3	3/3
Nasal Drops (Phenylephrine)	15% v/v	3/3	3/3	3/3
Nasal Spray (Cromolyn)	15% v/v	3/3	3/3	3/3
Nasal Spray (Oxymetazoline)	15% v/v	3/3	3/3	3/3

Substance	Concentration Tested	Virus Spiked Test Results (Positive/Total)		
		SARS-CoV-2	Flu A	Flu B
Naso GEL (NeilMed)	5% v/v	3/3	3/3	3/3
Sore Throat Phenol Spray	15% v/v	3/3	3/3	3/3
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	3/3	3/3	3/3
Tobramycin	4 µg/mL	3/3	3/3	3/3
Zicam	5% v/v	3/3	3/3	3/3
FluMist Quadrivalent Live Intranasal Influenza Virus Vaccine	15% v/v	3/3	3/3	3/3
FluMist Quadrivalent Live Intranasal Influenza Virus Vaccine	1.5% v/v	3/3	3/3	3/3
FluMist Quadrivalent Live Intranasal Influenza Virus Vaccine	0.15% v/v	3/3	3/3	3/3
Body and Hand Lotion	0.5% w/v	3/3	3/3	3/3
Body Lotion with 1.2% Dimethicone	0.5% w/v	3/3	3/3	3/3
Hand Lotion	5% w/v	3/3	3/3	3/3
Hand Sanitizer with Aloe, 62% Ethyl Alcohol	5% v/v	3/3	3/3	3/3
Hand Sanitizer Cream Lotion	15% v/v	3/3	3/3	3/3
Hand Sanitizer Cream Lotion	5% v/v	3/3	3/3	3/3
Hand Sanitizer Cream Lotion	1.5% v/v	3/3	3/3	3/3
Hand Sanitizer, 80% Ethanol	15% v/v	3/3	3/3	3/3
Hand Soap Liquid Gel	10% w/v	3/3	3/3	1/3
Hand Soap Liquid Gel	5.0% w/v	3/3	3/3	3/3
Zanamivir	282 ng/mL	3/3	3/3	3/3

14.5 High Dose Hook Effect

No high-dose hook effect was observed with the Speedy Swab Rapid COVID-19 + FLU A&B Antigen Test when testing high concentrations of SARS-CoV-2, Influenza A or Influenza B strains.

Virus Strain Tested	Concentration	Results (Positive/Total)
USA-WA1/2020	2.8×10^6 $TCID_{50}$/mL	3/3
Influenza A/Indiana/02/2020 (H1N1)	9.7×10^8 $CEID_{50}$/mL	3/3
Influenza A/Alaska/232/2015 (H3N2)	2.6×10^8 $CEID_{50}$/mL	3/3
Influenza B/Washington/02/2019 (Victoria)	2.1×10^9 $CEID_{50}$/mL	3/3
Influenza B/Texas/06/2011 (Yamagata)	1.6×10^9 $CEID_{50}$/mL	3/3

14.6 Competitive Interference

Competitive interference was evaluated to determine if high concentrations of one target virus interferes with the detection of low concentrations of another target virus. No competitive interference was observed between SARS-CoV-2 and influenza A and B as listed in the table below.

Combination Number	Concentration			Results (Positive/Total)		
	Influenza A	Influenza B	SARS-CoV-2	Influenza A	Influenza B	SARS-CoV-2
1	6.5×10^7 $CEID_{50}$/mL	2.2×10^5 $CEID_{50}$/mL	Negative	3/3	3/3	0/3
2	6.5×10^7 $CEID_{50}$/mL	Negative	2.4×10^3 $TCID_{50}$/mL	3/3	0/3	3/3
3	2.0×10^5 $CEID_{50}$/mL	3.7×10^7 $CEID_{50}$/mL	Negative	3/3	3/3	0/3
4	Negative	3.7×10^7 $CEID_{50}$/mL	2.4×10^3 $TCID_{50}$/mL	0/3	3/3	3/3
5	2.0×10^5 $CEID_{50}$/mL	Negative	4.0×10^5 $TCID_{50}$/mL	3/3	0/3	3/3
6	Negative	2.2×10^5 $CEID_{50}$/mL	4.0×10^5 $TCID_{50}$/mL	0/3	3/3	3/3

15. Clinical Evaluation

A prospective study was completed at seven sites in the United States between June 2023 and March 2024 for clinical validation of the detection of SARS-CoV-2, Influenza A, and Influenza B in subject-collected anterior nasal (AN) swab samples. The study evaluated the performance in symptomatic individuals (i.e., those with symptoms of upper respiratory infection). The testing of each enrolled subject included two AN swab samples: one was collected by a healthcare professional and sent for testing using an FDA-cleared molecular comparator method, and the other swab was either self-collected or collected from the study subject by another lay individual. Each subject then performed the test according to the Quick Reference Instructions (QRI) provided with the test kit in a simulated home-use environment. 1245 symptomatic subjects were enrolled with a total of 1171 subjects evaluable. Performance was determined by comparing Speedy Swab Rapid COVID-19 + Flu A&B Antigen Self-Test results to results from the highly sensitive RT-PCR molecular comparator. 1132 individuals met the eligibility criteria for SARS-CoV-2, in which 148 (13.1%) individuals tested positive for SARS-CoV-2 and 984 (86.9%) individuals tested negative for SARS-CoV-2. From the same study cohort, 1171 individuals met the eligibility criteria for Flu A and Flu B. 80 (6.8%) individuals tested positive and 1091 (93.2%) individuals tested negative for Flu A. The study also had 30 (2.6%) individuals who tested positive and 1141 (97.4%) individuals who tested negative for Flu B. At least 30 enrolled subjects were below the age of 14. The positive percent agreement (PPA) is 92.6% [87.2%, 95.8%] for SARS-CoV-2, 82. 5% [72.7%, 89.3%] for Influenza A, and 90.0% [74.4%, 96.5%] for Influenza B. The negative percent agreement (NPA) is 99.4% [98.7%, 99.7%] for SARS-CoV-2, 99.7% [99.2%, 99.9%] for Influenza A, and 99.9% [99.7%, 100.0%] for Influenza B.

Subject Demographics

	Subjects (by lay-user collection and testing (N=140)	Self-collecting and testing (N=1032)	Overall (N=1172)
Age			
Mean (SD)	8.5 (5.9)	42.1 (16.0)	38.1 (18.6)
Median [Min, Max]	8 [2, 63]	40 [14, 89]	37 [2, 89]
Age Group			
≥ 2 - <14 years of age	129 (92.1%)	0 (0.0%)	129 (11.0%)
14 - 24 years of age	10 (7.1%)	156 (15.1%)	166 (14.2%)
> 24 - 64 years of age	1 (0.7%)	784 (76.0%)	785 (67.0%)

	Subjects (by lay-user collection and testing (N=140)	Self-collecting and testing (N=1032)	Overall (N=1172)
≥ 65 years of age	0 (0.0%)	92 (8.9%)	92 (7.8%)
Sex at Birth			
Female	71 (50.7%)	647 (62.7%)	718 (61.3%)
Male	69 (49.3%)	385 (37.3%)	454 (38.7%)
Ethnicity			
Hispanic/Latino	82 (58.6%)	619 (60.0%)	701 (59.8%)
Not Hispanic/Latino	58 (41.4%)	402 (39.0%)	460 (39.2%)
Unknown/Prefer not to answer	0 (0.0%)	11 (1.1%)	11 (0.9%)
Race			
American Indian or Alaskan Native	1 (0.7%)	2 (0.2%)	3 (0.3%)
Asian	0 (0.0%)	7 (0.7%)	7 (0.6%)
Black or African American	35 (25.0%)	305 (29.6%)	340 (29.0%)
Native Hawaiian/Pacific Islander	1 (0.7%)	0 (0.0%)	1 (0.1%)
White	91 (65.0%)	672 (65.1%)	763 (65.1%)
Unknown/Prefer not to answer	3 (2.1%)	2 (0.2%)	5 (0.4%)
Other (Mixed race/biracial)	9 (6.4%)	44 (4.3%)	53 (4.5%)

SARS-CoV-2 Performance

SARS-CoV-2	Comparator Positives	Comparator Negatives	Total
Investigational Positives	137	6	**143**
Investigational Negatives	11	978	**989**
Total	**148**	**984**	**1132**

Positive Percent Agreement = (137/148) = 92.6% (95% CI: 87.2% - 95.8%)

Negative Percent Agreement = (978/984) = 99.4% (95% CI: 98.7% - 99.7%)

Days Post Symptom Onset	Number of Subject Samples Tested	Investigational Positives	Comparator Positives	% Positive Rate (by Comparator)	PPA (95% CI)
0	15	0	0	0.0%	**N/A**
1	155	12	13	8.4%	**92.3% (66.7% -99.6%)**
2	323	40	44	13.6%	**90.9% (78.8% - 96.4%)**
3	349	42	47	13.5%	**89.4% (77.4% - 95.4%)**
4	212	23	24	11.3%	**95.8% (79.8% - 99.8%)**
5	78	20	20	25.6%	**100.0% (83.9% -100.0%)**
Total	**1132**	**137***	**148**	**13.1%**	**92.6% (87.2% - 95.8%)**

* 6 subjects had a false positive result on the investigational test and were excluded.

Influenza A Performance

Influenza A	Comparator Positives	Comparator Negatives	Total
Investigational Positives	66	3	**69**
Investigational Negatives	14	1088	**1102**
Total	**80**	**1091**	**1171**

Positive Percent Agreement = (66/80) = 82.5% (95% CI: 72.7% - 89.3%)

Negative Percent Agreement = (1088/1091) = 99.7% (95% CI: 99.2% - 99.9%)

Influenza B Performance

Influenza B	Comparator Positives	Comparator Negatives	Total
Investigational Positives	27	0	**27**
Investigational Negatives	3	1141	**1144**
Total	**30**	**1141**	**1171**

Positive Percent Agreement = (27/30) = 90.0% (95% CI: 74.4% - 96.5%)

Negative Percent Agreement = (1141/1141) = 100.0% (95% CI: 99.7% - 100.0%)

16. 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.

DAYS AFTER FIRST PCR POSITIVE TEST RESULT	**SYMPTOMATIC ON FIRST DAY OF TESTING**		
	Ag Positive/PCR Positive (Antigen Test Performance % PPA)		
	1 Test	2 Tests	3 Tests
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%)
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%)	

1 Test= one (1) test performed 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 performed 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 performed 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.

17. Technical Support

If you have questions regarding the use of this product, or if you want to report a problem with the Speedy Swab Rapid COVID-19 + Flu A&B Antigen Test, please contact Watmind USA Technical Support at +1 866-928-6463

(Available Hours: Mon. to Fri. 8 am to 8 pm EST) or technicalsupport@watmindusa.com

18. 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.
5. CLSI. Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline – Fourth Edition. CLSI document M29-A4. Wayne, PA: Clinical and Laboratory Standards.

19. Reorder

Speedy Swab Rapid COVID-19 + Flu A&B Antigen Test (LFA0462-25N)

20. Symbols

	Manufacturer
	Contains sufficient for <n> tests
	*In vitro* diagnostic medical device
	Consult instructions for use
	Temperature limit
Rx	Prescription only

	Date of manufacture
	Catalogue number
	Use-by date
	Batch code
	Do not reuse

LBL-012 Ver. 13, 05/17/24