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

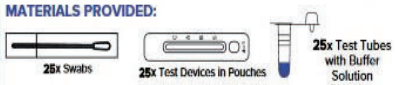
1.
Check expiration date on the outside of the box, Do not use beyond the expiration date. For the most current expiration dates of this test, please refer to: https://www.fda.gov/covid-tests.

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:

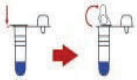


Materials required but not provided:
A clock or timer

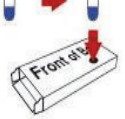
4.
Arrange the materials on a clean, dry, flat surface.

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.

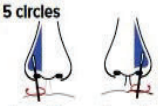
PERFORMING THE TEST

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.

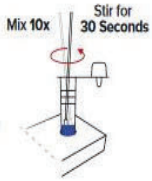
Using medium pressure, rub and rotate the swab against the inside walls of the nostril, making **at least 5 circles** for **at least 15 seconds.**

REPEAT IN THE OTHER NOSTRIL USING THE SAME SWAB.



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

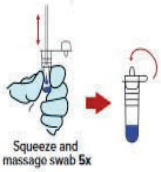
10.
Place the swab into the buffer solution as soon as possible after collection and completely immerse the swab head in the sample.



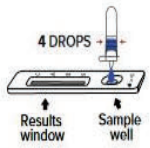
Swirl the swab in the solution by rotating the swab forcefully against the side of the tube **at least 10 times** for **30 seconds,** keeping the swab tip submerged in the buffer solution the entire time.

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.



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.

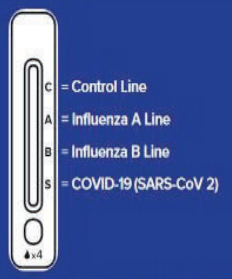
13.
Set a timer and read the test result at 15 minutes.

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.

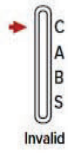
WARNING: Do not read the result before 15 minutes or after 20 minutes. Inaccurate test interpretations may occur.



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.**



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.

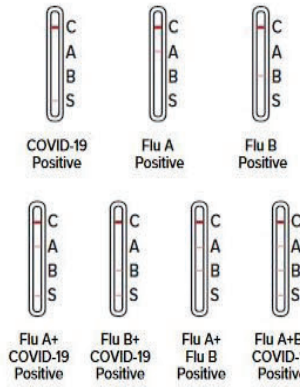
NEGATIVE RESULTS

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.

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.



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 negativeresults at least twice over three days (with 48 hours betweentests) 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.**

SERIAL TESTING

Repeat testing is needed for **all samples that are negativefor 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