PERFORMING THE TEST

8. Open swab package from its stick end and remove the swab from this end. DO NOT touch the swab head.

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 and completely immerse the swab head in the sample. Vigorously mix 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. Mix 10x for 30 Seconds.

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

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.

NOTE: Use the Test Card within one hour of opening.

STOP: If the test procedure using a new test kit and sample.

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.

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

NEGATIVE RESULTS

The COVID-19, Flu A and/or Flu B virus(es) were not detected in your sample. It is very likely that you have the respective infection(s) and are contagious. Please contact your healthcare provider or your local health authorities and follow local guidelines for self-isolation. There is a small chance that this test can give you a positive result that is incorrect (a false positive). Report your test result(s) at MakeMyTestCount.Org – this voluntary and anonymous reporting helps public health teams understand COVID-19 spread in your area and across the country and informs public health decisions.

INVALID RESULTS

If a 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 test is invalid, repeat the test procedure using a new test kit and sample.

UNDERSTANDING YOUR RESULTS

This test did not work. The result should not be used. The test cannot determine if you have COVID-19, influenza A (Flu A), or influenza B (Flu B). The test needs to be repeated with a new kit and sample.

POSITIVE RESULTS

If you still have COVID-19, Flu A, or Flu B symptoms, you should seek follow up care with your healthcare provider.

INVALID RESULT:

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.

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

NEGATIVE RESULT:

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

POSITIVE RESULT:

The virus from COVID-19, Flu A and/or Flu B virus(es) were detected in your sample. It is very likely that you have the respective infection(s) and are contagious. Please contact your healthcare provider or your local health authorities and follow local guidelines for self-isolation. There is a small chance that this test can give you a positive result that is incorrect (a false positive). Report your test result(s) at MakeMyTestCount.Org – this voluntary and anonymous reporting helps public health teams understand COVID-19 spread in your area and across the country and informs public health decisions.
The ongoing COVID-19 pandemic, along with other seasonally prevalent illnesses such as influenza (Flu), continue to be among the world’s most pressing healthcare issues. While contagious respiratory illnesses such as COVID-19 and influenza share some symptoms and means of transmission, they are caused by different viruses. The Centers for Disease Control and Prevention (CDC) has also raised concerns about the potential co-infection with two or more of the respiratory viruses. There is an urgent need for rapid COVID-19 and Influenza A/B diagnostic over-the-counter diagnostic tests so that patients can seek appropriate treatment with their healthcare provider before their symptoms worsen. These rapid COVID-19 and Influenza A/B diagnostic over-the-counter diagnostic tests can be used by untrained healthcare professionals operating under CLIA Waiver license.

**How to use this test**

**PLEASE FOLLOW THE INSTRUCTIONS IN THIS QUICK REFERENCE GUIDE.**

**Cross-attention to the test results interpretation section for ease of interpretation tests can be held next to each result.**

Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and influenza, and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19 and influenza, and with initial negative results, should be tested again after 48 hours and if the 2nd test is also negative, a 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.

If you test negative but continue to have symptoms of COVID-19 and influenza, and both tests are negative, you may not have COVID-19 or influenza, however you should follow-up with your healthcare provider.

If your test is positive, then proteins from the virus that causes COVID-19 and/or influenza have been found in your sample and you likely have COVID-19 and/or influenza.

**Warnings, precautions and safety information**

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- Serial testing may be performed in individuals with negative results at least twice over three days (with 48 hours between tests) or asymptomatic individuals and twice over five days (at least 48 hours between tests) for asymptomatic individuals who need to purchase additional tests to perform this serial testing.
- Test components are single-use. Do not re-use.
- Do not use kit past its expiration date.
- Do not touch the swab tip.
- Once opened, the test card should be used within 60 minutes.
- Do not read test results before 15 minutes or after 20 minutes. Results are invalid if read outside of this timeframe.
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- 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 touch the sample probe.
- The antigen solution contains harmful chemicals (see table in the next column) if the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water. If irritation persists, seek medical advice: https://www.poison-help.org or 1-800-222-1222.

**Chemical Name** | **GHS Code for each ingredient** | **Concentrations**
--- | --- | ---
Protein 300 | H37, allergic skin irritation | 0.0% 0.03%
Timothy grass | H315, skin irritation | 0.03%

- For the most up to date information on COVID-19, please visit: www.cdc.gov/covid19

**Frequently asked questions**

**Q: What are the known and potential risks and benefits of this test?**

A. Potential risks include:

- Possible incorrect test result (see Warnings and Interpretation sections for more information).

Potential benefits include:

- The test results can help you and your healthcare provider make informed recommendations about your care.

**Q: The results of this test may help limit the potential spread of COVID-19 and influenza in your community. For more information on EUAs go here: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

**Q: What is the difference between an antigen and molecular test?**

A. There are different kinds of tests for the COVID-19 and influenza that can be used to detect viral genetic material from the virus. Antigen tests, such as the SpeedySwab Rapid COVID-19 + Flu A&B Antigen Self-Test, detect proteins from the virus. Due to the lower sensory detection threshold, this test may have a higher chance this test may give a false negative result when you have COVID-19 and influenza, however you should follow-up with a healthcare provider.

**Q: How accurate is this test?**

A. Clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causes COVID-19 and influenza when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach provides a multi-test strategy for improving test accuracy.

For more information on the performance of the test and how the performance may apply to you, please refer to the performance data file (PBF) provided by the FDA at www.SpeedySwab.com.

**Q: What if I have a positive test result?**

A. A positive result mean that it is very likely you have COVID-19 or influenza because proteins from the virus that causes COVID-19 or influenza were found in your sample. You should self-isolate from your family and others in your community. For more information on EUAs go here: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorizations.

**Q: What if I have a negative test result?**

A. A negative test result indicates that no COVID-19 or influenza were detected in your sample. However, if you have symptoms of COVID-19 or influenza, and your healthcare provider makes an informed decision that another test is needed, you should follow-up with your healthcare professional and seek medical advice.

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Do not use if you have had symptoms longer than 5 days or no symptoms at all.

For information about current expiration dates for at-home COVID-19/Influenza diagnostic tests, please visit: www.gov/covid-tests/fda.
C) use T For Over the Counter (OTC) rapid specimen. For use with self-collected anterior nasal swab.

• For ages 2-14, an adult must collect and conduct the test.

• Keep testing kit and kit components out of the reach of children.

• This test is only authorized for individuals with signs and symptoms of 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.

• You may need to purchase additional tests to perform serial (repeat) testing. This is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

• To determine if you had COVID-19 or influenza, or if you have immunity to these viruses, you would need to purchase additional tests.

• Persons with risk factors for severe disease from respiratory pathogens should consult and follow-up with a healthcare provider.

• Do not use if you have had symptoms longer than 5 days or no symptoms at all.

For information about current expiration dates for at-home COVID-19/Influenza diagnostic tests, please visit: www.cdc.gov/covid-testing/flu-current-expiration-dates.html.