USER INSTRUCTIONS

Carefully read the instructions below before performing the test. Failure to follow the instructions may result in inaccurate test results.

STORAGE AND STABILITY
Stone kit between 36-86°F (2-30°C). Ensure all test components are at room temperature before use. The Speedy Swab Rapid Covid-19 Antigen Self-Test is stable until the expiration date marked on the outer packaging and containers. Do not use beyond the expiration date.

BEFORE GETTING STARTED

1. Wash or sanitize your hands. Make sure they are dry before proceeding.

2. Check the expiration date on the back of the box. DO NOT use if expired.

PREPARE THE MATERIALS

3. Bring test to room temperature. On a flat level surface, retrieve all the materials from the box and place the empty box in front of you for further use.

4. Arrange the materials on a clean, dry, flat surface. Your box may contain more than one test kit. Use only 1 of each of the materials provided for each test.

5. Open large test card pouch and place the test card on flat surface. DO NOT touch any parts on the insides of the test card.

PERFORMING THE TEST

6. Remove test tube from its pouch. Press the test tube into the marked hole on the front of the box.

7. Twist the top off of the buffer solution and pour all of it into the test tube. If any liquid spills and does not enter into the tube, discard test kit, and re-start test using a new test kit.

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

9. Swab both nostrils carefully with the soft tip as shown.

Step A) Insert 1/2 to 3/4 of an inch the swab any farther if you feel any resistance.

Step B) Using medium pressure, rub and rotate the swab against the inside of the first nostril, making at least 5 circles (taking about 15 seconds).

Step C) Repeat in the other nostril. NOTE: If you are swabbing others, please wear a face mask. With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another person to steady the child’s head while swabbing.

10. Completely immerse the swab tip in the solution in the tube and mix well by rotating at least 10 times with one hand while holding the box with the other. Be sure to mix thoroughly.

11. While holding the swab stable in the liquid, take the test tube out of the box. Raise the swab tip out of the buffer, holding it in place within the side walls of the tube, and squeeze the tube 5 times to remove as much of the liquid from the swab as possible. Failure to squeeze the tube can lead to incorrect results due to excess buffer in the swab.

12. Remove dropper tip from it’s pouch. Push the dropper tip securely into the tube and swirl 5 times. Turn test tube over, hold it straight up and down, and gently squeeze 3 drops into the sample well on the test card.

13. Set the timer and read the test result at 15 minutes. (Timer Not Included)

DO NOT disturb the card during this time. Inaccurate test results can occur if the card is disturbed/turned or test results are read before 15 minutes.

DO NOT interpret test results after 30 minutes.

NOTE: Inaccurate test interpretations may occur if results are read before 15 minutes or after 30 minutes.

STOP Check: Did you swab BOTH nostrils?

14. If a Control (C) line is visible (regardless of how faint it is), and a Test (T) line is not visible, this means that the test is negative. A negative test result indicates that antigens from the virus that causes COVID-19 were not detected from the specimen.

A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19. If you test negative and continue to experience COVID-19 like symptoms of fever, cough, and/or shortness of breath you should seek follow up care with your healthcare provider. You should test again in 24 hours (but no more than 48 hours), regardless of whether or not you have symptoms.

RESULTS

If a Control (C) line and the Test (T) line are visible, this means that the test is positive. Any faint visible reddish/pink test (T) line with the control line (C) should be read as positive.

A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely you have COVID-19 and are contagious. Please contact your doctor/primary care physician or your local health authority immediately and 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). Your healthcare provider will work with you to determine how best to care for you based on your test results along with medical history and your symptoms.

AFTER TEST IS COMPLETED, DISPOSE OF USED MATERIALS IN HOUSEHOLD TRASH.
The Speedy Swab Rapid COVID-19 Antigen Self-Test is intended for non-prescription use by a person who is at least 18 years old and living in the United States. It is intended for use only under the Food and Drug Administration’s Emergency Use Authorization.

**WARNING:**

- **For Emergency Use Authorization (EUA) only.**
- **In Vitro Diagnostic (IVD) use only.**
- **Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.**
- **The results of this test may help limit the spread of COVID-19 to your family and others in your community, especially if you have the virus and are not showing any COVID-like symptoms.**
- **Possible discomfort during sample collection. The swab should be mixed into the buffer immediately, but no more than 1 hour after collection.**
- **Do not use on anyone under two years of age.**
- **To ensure correct results, you must follow the instructions for use.**
- **Do not touch the swab tip.**
- **The test should be performed at ambient temperature (i.e., 15-30°C).**
- **An invalid result means that the test was not able to tell if you have COVID-19 or not. If the test is invalid, a new swab should be used to collect a new nasal specimen and the test should be repeated using a new test kit.**
- **Testing for all individuals should be performed at least twice over three days, with at least 24 hours and no more than 48 hours between tests. You may need to purchase additional test kits to perform this serial [testing)](https://www.speedyswab.com).**
- **Serial testing ([i.e., testing every day or every other day](https://www.speedyswab.com)) is more likely to detect COVID-19.**
- **If your first and second test is negative, then please check with your healthcare provider if there are any high-risk COVID-19**

**FREQUENTLY ASKED QUESTIONS**

**Q. WHAT IS COVID-19?**

- **A.** COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can prevent with mild to severe illness, although some individuals can have severe illness with COVID-19 and can have symptoms at or above the age of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 test provides results to aid in the identification of those who are infected and for those to be treated or isolated, e.g., cough, difficulty breathing, etc. A full list of symptoms of COVID-19 can be found at (https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html).

**Q. WHAT IS SERIOUS TESTING?**

- **A.** Serial testing is when one person tests themselves multiple times for COVID-19 on a routine basis, such as every day or after every day. By testing more frequently, you may detect COVID-19 more quickly and reduce your risk of spreading the virus. Serial testing may be beneficial at any time of day, and you can detect COVID-19 by testing several days in a row, with at least 24 hours and no more than 48 hours between tests. You may need to purchase additional test kits to perform this serial [testing).**

**Q. WHAT TEST WILL THIS be?**

- **A.** The test is not sensitive, and it should not hurt. Sometimes the swab can feel uncomfortable. If you feel pain, please stop the test and see advice from a healthcare provider.

**Q. WHAT ARE THE KNOWN POTENTIAL RISKS AND BENEFITS OF THIS TEST?**

- **A.** Possible risks include:
  - Possible incorrect test results (see Warning and Risk Interpretation sections for more information).
  - Possible discomfort during sample collection.
  - Potential benefits include:
    - The results, along with other information, help you and your healthcare provider make decisions about your further care.
    - The results of this test help you limit the spread of COVID-19 to your family and others in your community.

**Q. WHAT IS THE INFLUENCE OF THE HEPATITIS A AND MOLLUSCUM CONTAGIOSUM?**

- **A.** There are differences of tests for the virus that causes Hepatitis A. Molluscum Contagiosum test detect genetic markers for the virus. Antigen tests, such as the Speedy Swab Rapid COVID-19 Antigen Self-Test, screen for the presence of a viable or inactivated virus within the sample. The test may not detect SARS-CoV-2 virus but is generally not sensitive as a molecular test. This means that a positive result is less accurate, but a negative result does not rule out infection. There is a higher chance of false-negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19. As a result, you should discuss with your healthcare provider whether an additional test is necessary and you should continue isolating at home.

**Q. HOW ACCURATE IS THIS TEST?**

- **A.** The performance of the Speedy Swab Rapid COVID-19 Antigen Self-Test was established in a study in a limited number of individuals using standard laboratory testing methods. There is a chance that this test may not detect COVID-19. Serial testing may be beneficial at any time of day, and you can detect COVID-19 by testing several days in a row, with at least 24 hours and no more than 48 hours between tests.

**Q. WHAT HAS THE PERFORMANCE OF THE SPEEDY SWAB RAPID COVID-19 ANTIGEN SELF-TEST BEEN?**

- **A.** The performance of the Speedy Swab Rapid COVID-19 Antigen Self-Test was evaluated in a limited number of individuals using standard laboratory testing methods. There is a chance that this test may not detect COVID-19. Serial testing may be beneficial at any time of day, and you can detect COVID-19 by testing several days in a row, with at least 24 hours and no more than 48 hours between tests.

**Q. WHAT IF I HAVE A POSITIVE TEST RESULT?**

- **A.** A positive result means that it is very likely you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. You should self-isolate from others and contact your healthcare provider to determine if additional testing is needed. Your healthcare provider will work with you to determine how best to care for you based on your result, medical history, and symptoms.

**Q. WHAT IF I HAVE A NEGATIVE TEST RESULT?**

- **A.** A negative result means that you do not have COVID-19 because proteins from the virus that causes COVID-19 were not found in your sample. You should test again 24 to 48 hours later. If you receive a second negative result 24 to 48 hours after your first negative result, then you are likely not infected with COVID-19. However, negative results do not rule out SARS-CoV-2 infection. It is possible that the tests give a negative result that is incorrect (false-negative) in some people with COVID-19. This means that you could still have COVID-19 even when the test result is negative. For example, you may get a false negative result if you did not perform the test correctly or if the level of antigen from the virus causing COVID-19 was below the test limit. The amount of antigen in a sample may decrease the longer you have symptoms of infection. If you test negative and continue to experience symptoms of fever, cough, and/ or shortness of breath you should seek follow-up care with your healthcare provider. Your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled), in deciding how to care for you. Your healthcare provider may suggest you undergo another test to determine if you have the virus causing COVID-19. It is important that you work with your healthcare provider to help understand the next steps you should take.

**Q. DOES THIS TEST INFLUENCE THE HEPATITIS A AND MOLLUSCUM CONTAGIOSUM?**

- **A.** Yes. Please see the healthcare provider instructions for fully available at www.speedyswab.com.

**Q. IS THERE OTHER INFORMATION AVAILABLE DESCRIBING THE PERFORMANCE OF THIS TEST?**

- **A.** Yes. Please see the healthcare provider instructions for fully available at www.speedyswab.com. Additional information. The performance of this test is still being assessed in patients with acute and subacute respiratory symptoms and for serial screening. Performance may occur in these populations.

**INDEX OF SYMBOLS**

- **Contains sufficient for**
- **Use-by date**
- **Batch code**

**SERIAL TESTING INFORMATION AND LIMITATIONS**

- **Testing for all individuals should be performed at least twice over three days, with at least 24 hours and no more than 48 hours between tests. You may need to purchase additional test kits to perform this serial [testing).**

**IMPORTANT**

This text is intended to be used as an aid in the clinical diagnosis of infection with COVID-19. It is not intended to replace the need for medical advice or management of your illness. Please consult your healthcare provider if your symptoms persist or become more severe, or if you are concerned at any time. Individuals should provide all results obtained with this product to their healthcare provider for public health reporting.
Colors

EXP YYYYMMDD LOT xxxxxxxxxx

Manufactured for Watmind USA
4780 I 55 N Ste 450 – Jackson, MS 39211 USA
1-866-928-6463 (1-866-Watmind)
Email: sales@watmindusa.com
www.watmindusa.com
Made in China

SIZE: 70mm(L) x 40mm(W)
You will need at least two tests per person to complete testing.

You may need to purchase additional tests to perform serial (repeat) testing.

This test does NOT determine if you had COVID-19 in the past or if you have immunity.

This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

If you test positive for COVID-19 please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation.

1 Test/Box

SIZE:

140mm(L)

x65mm(W)

x18mm(H)
You will need at least two tests per person to complete testing. You may need to purchase additional tests to perform serial (repeat) testing. This test does NOT determine if you had COVID-19 in the past or if you have immunity. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test. If you test positive for COVID-19 please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation.

2 Test/Box
SIZE: 140mm(L) x70mm(W) x23mm(H)
You will need at least two tests per person to complete testing. You may need to purchase additional tests to perform serial (repeat) testing. This test does NOT determine if you had COVID-19 in the past or if you have immunity. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test. If you test positive for COVID-19 please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation.
You will need at least two tests per person to complete testing. You may need to purchase additional tests to perform serial (repeat) testing.

This test does NOT determine if you had COVID-19 in the past or if you have immunity. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

If you test positive for COVID-19 please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation.
1 Test/Box – Outer box

SIZE: 47cm(L)x34cm(W)x58cm(H)

2 Test/Box – Outer box

SIZE: 50.7cm(L)x36.5cm(W)x60cm(H)

4 Test/Box – Outer box

SIZE: 42cm(L)*40cm(W)*31.5cm(H)

25 Test/Box – Outer box

SIZE: 61cm(L)*47cm(W)*38cm(H)