Distributed by:
WATMIND USA

SpeedySwab™
Rapid **COVID-19** Antigen Self-Test

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
Store kit between36-86°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.

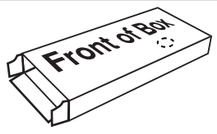
Check the expiration date on the back of the box.

DO NOT use if expired.

PREPARE THE MATERIALS

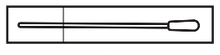
3.

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.

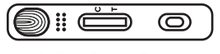


Tests are available in 1, 2, 4, and 25 pack boxes.

MATERIALS PROVIDED:



1x Swab



1x Test Card in Pouch

1x Dropper Top

1x Test Tube

1x Buffer Solution

Timer Not Included
It is recommended that gloves are used during testing. A face mask should be worn if swabbing others. Gloves and face mask are not provided.

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.

DO NOT open the individual pouches until instructed to do so.

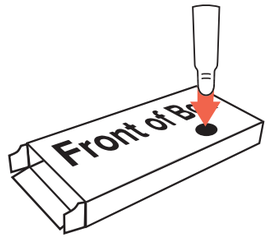
5.

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.

6.

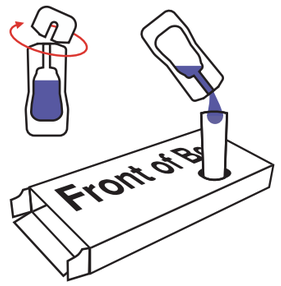
Remove test tube from it's pouch. Press the test tube into the marked hole on the front of the box.



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.

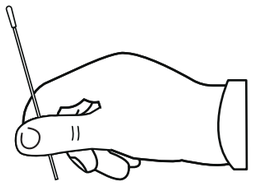


PERFORMING THE TEST

8.

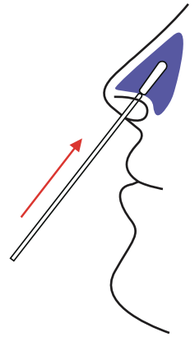
Open swab package from its stick end and remove the swab from this end.

DO NOT touch the swab head.



9.

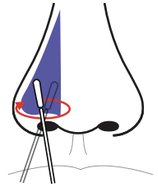
Swab both nostrils carefully with the soft tip as shown.



Step A) Insert **1/2** to **3/4** of an inch

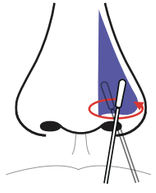
DO NOT insert the swab any farther if you feel any resistance.

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).



Make at least **5** big circles

15 seconds per nostril



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.

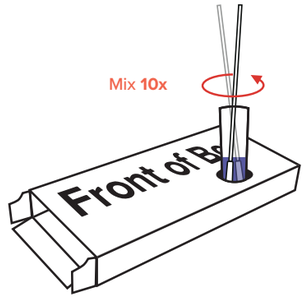
STOP Check: Did you swab BOTH nostrils?

NOTE: inaccurate test results may occur if the nasal sample is not properly collected.

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.

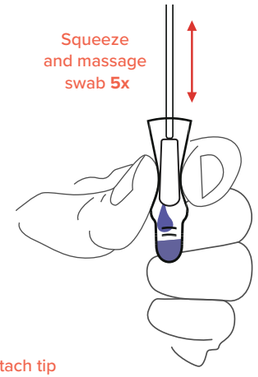


11.

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.

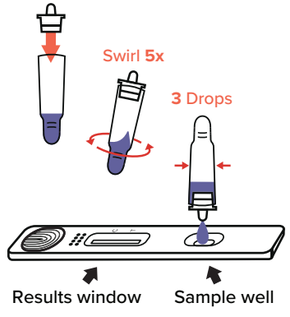
Discard the swab.



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.

DO NOT apply the liquid in the rectangular results window.

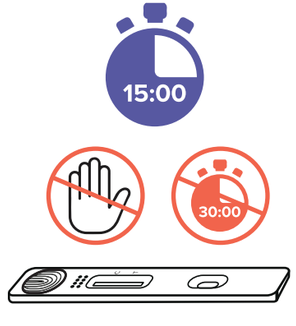


13.

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

DO NOT disturb the card during this time. Inaccurate results can occur if the card is disturbed/moved 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.

READING THE RESULTS

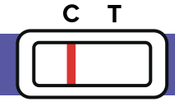
Results should be considered in the context of an individuals recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Find result window and look carefully for one or two reddish/pink lines.

C = Control line
T = Test line

Results window

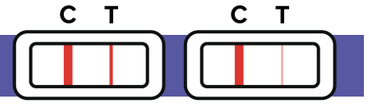
NEGATIVE



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.

POSITIVE



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.

INVALID

If a control (C) line is not visible, even if a test line (T) is visible, the test is invalid. Re-test with a new swab and new test device.

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

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Rapid **COVID-19** Antigen Self-Test

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, 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.

- In Vitro Diagnostic (IVD) use only.
- For Emergency Use Authorization (EUA) only.
- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- An anterior nasal swab sample can be self-collected by an individual age 14 years and older. Children age 2 to 13 years should be tested by an adult.
- For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-andresponse/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- For the most up to date information on COVID-19, please visit: www.cdc.gov/-COVID19

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INTENDED USE

The **Speedy Swab Rapid COVID-19 Antigen Self-Test** is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. The test is authorized for non-prescription home use with self-collected anterior nasal (nares) swabs from individuals aged 14 years and older when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests. This test is also authorized for non-prescription home use with adult-collected anterior nasal (nares) swab specimens from individuals aged 2 years and older when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

The test is authorized for individuals aged 2 years and older with symptoms of COVID-19 within the first 6 days of symptom onset, or individuals without symptoms or other epidemiological reasons to suspect COVID-19. The **Speedy Swab Rapid COVID-19 Antigen Self-Test** does not differentiate between SARS-CoV or SARS-CoV-2 viruses.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal (nares) 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 definite cause of disease. Individuals who test positive with the **Speedy Swab Rapid COVID-19 Antigen Self-Test** should self-isolate and seek follow up care with their 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.

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. 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 COVID-19.

Individuals who test negative and continue to experience COVID-like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from their healthcare provider. Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements, using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The **Speedy Swab Rapid COVID-19 Antigen Self-Test** is intended for non-prescription self-use and/or as applicable, for an adult lay user testing another aged 2 years or older. The **Speedy Swab Rapid COVID-19 Antigen Self-Test** is only for use under the Food and Drug Administration's Emergency Use Authorization.

WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

Read instructions carefully before performing a test. Failure to follow directions may produce inaccurate test results.
- Leave the test card sealed in its pouch until just before use. Once opened, the test card should be used within 60 minutes.
- The test should be performed at ambient temperature (i.e., 15-30°C).
- Ensure Test Card remains flat and is not disturbed throughout the duration of the test.
- This test is read visually. Individuals with impaired vision or color-impaired vision may not be able to adequately interpret these results.
- False negative test results may occur if a specimen is incorrectly collected or handled.
- Do not touch the swab tip.
- To ensure correct results, you must follow the instructions for use.
- Test components are single-use. Do not re-use.
- Children 2 to 13 years of age should not swab themselves and should instead be swabbed by an adult.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Do not use on anyone under two years of age.
- The swab should be mixed into the buffer immediately, but no more than 1 hour after collection. The buffer should be added to the device within 30 minutes of mixing the swab into the buffer.
- Do not use kit past its expiration date.
- Do not use if any of the test kit contents or packaging is damaged or open.
- Adding fewer or greater than 3 drops to the test may lead to false results
- If the test is read before 15 minutes or after 30 minutes, false negative or false positive results may occur, and the test should be repeated with a new test device.
- False negative test results may occur if the specimen swab is not mixed well in the tube (step 10 and 11 in the test procedure section).
- Use of personal protection materials such as gloves is recommended.
- 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 a harmful chemical (see table below). If contact the body occurs, flush with copious amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.

Hazardous Ingredients (%)	Hazard Category (mixture)	GHS Hazard Class for mixture	Labeling of Harm(s)	Recommended PPE
Proclin 300 (0.1%)	Category 1	Skin sensitization	May cause an allergic skin reaction (H317)	Gloves
BIS (trimethylsilyl) acetamide (0.03%) Proclin 300 (0.1%)	Category 3	Skin irritation	Causes mild skin irritation (H316)	NA

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 present with mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people 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 virus can be spread to others even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

Q: WHAT IS SERIAL TESTING?
A: Serial testing is when one person tests themselves multiple times for COVID-19 on a routine basis, such as every day or every other day. By testing more frequently, you may detect COVID-19 more quickly and reduce spread of infection. Serial testing (i.e. testing every day or every other day) is more likely to detect COVID-19. Testing 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 tests to perform this serial (repeat) testing.

Q: WILL THIS TEST HURT?
A: No, the swab is not sharp, and it should not hurt. Sometimes the swab can feel slightly uncomfortable. If you feel pain, please stop the test and seek advice from a healthcare provider.

Q: WHAT ARE THE KNOWN POTENTIAL RISKS AND BENEFITS OF THIS TEST?
A: Potential risks include:
- Possible incorrect test results (see Warnings and Result Interpretation sections for more information).
- Possible discomfort during sample collection.

Potential benefits include:
- The results, along with other information, can help you and your healthcare provider make informed decisions about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?
A: There are different kinds of tests for the virus that causes COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, such as the **Speedy Swab Rapid COVID-19 Antigen Self-Test**, detect proteins from the virus. Antigen tests are very specific for the SARS-CoV-2 virus but are not as sensitive as molecular tests. This means that a positive result is highly 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. If your test result is negative, you should discuss with your healthcare provider whether an additional test is necessary and if 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 prospective clinical study of symptomatic individuals using an EUA molecular test as a comparator method. The data from this study were analyzed using the minimum recommended number of low positives demonstrating that the test correctly identified 83.3% of positive samples and correctly identified 100% of negative samples. For more detailed information on test performance please see Section 2.12 of the Healthcare Provider Instructions for Use. A negative result in individuals with or without symptoms does not rule out COVID-19. You can still infect others if you have a negative result. COVID-19 antigen tests are less sensitive than molecular (PCR) tests. The performance of antigen tests can vary with the amount of virus in your sample. Therefore, you should contact your healthcare provider to determine if additional testing with a highly sensitive COVID-19 molecular test is needed. Additional information is available in the Healthcare Provider Instructions for Use at http://www.SpeedySwab.com.

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 a healthcare provider for medical advice about your positive result. Your healthcare provider will work with you to determine how best to care for you based on your test result, medical history, and symptoms.

Q: WHAT IF I HAVE A NEGATIVE TEST RESULT?
A: A negative test result indicates antigens from the virus that causes COVID-19 were not found in your sample. You should test again in 24 to 48 hours. 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 for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test 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 limits. 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 need another test to determine if you have contracted the virus causing COVID-19. It is important that you work with your healthcare provider to help you understand the next steps you should take.

Q. WHAT DOES AN INVALID TEST RESULT MEAN?
A: An invalid result means 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 run again, using a new test and tube.

Q: IS THERE OTHER INFORMATION AVAILABLE DESCRIBING THE PERFORMANCE OF THIS TEST?
A: Yes. Please see the Healthcare Provider Instructions for Use available at www.Speedy-Swab.com for additional information. The performance of this test is still being assessed in patients without signs and symptoms of respiratory infection and for serial screening. Performance may differ in these populations.

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 tests to perform this serial (repeat) testing.
- For serial testing, if your first test result is negative, you should test again with a new test in 24 to 48 hours.
- Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19.
- If your first or second test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.
- If both your first and second tests are negative, you may not have COVID-19, however you should follow-up with your healthcare provider if you are at high risk for COVID-19.

IMPORTANT

This test is intended to be used as an aid in the clinical diagnosis of infection with the virus that causes COVID-19. Do not use this test as the only guide to manage 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.

INDEX OF SYMBOLS

	Manufacturer		Date of manufacture
	Contains sufficient for <n> tests	REF	Catalogue number
	Temperature limit	EXP	Use-by date
	Do not reuse	LOT	Batch code

TURN OVER

DOCUMENT VERSION #29 - 07/22