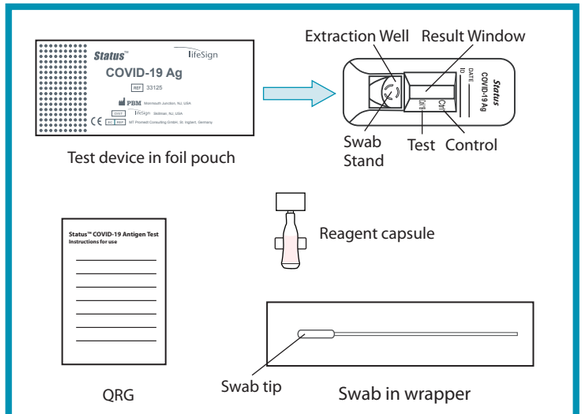
Status™ COVID-19 Antigen Rapid Test for Home Use

Quick Reference Guide

For use with anterior nasal swab specimens
In vitro diagnostic use
For Emergency Use Authorization (EUA) only

Carefully read the complete instructions before starting the test. Failure to follow the instructions may result in inaccurate test results. Wash your hands with soap and water or use hand sanitizer and dry thoroughly.

The test kit contains these items:



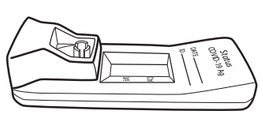
You will also need a clock or timer which is not included.

Storage and Stability

- **Store at 2–30°C/36–86°F, away from direct sunlight.**
- **Do not freeze.**
- **Do not use past the expiration date indicated on the external packaging.**

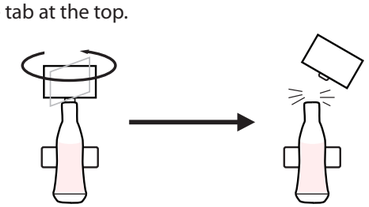
1 PREPARE TEST

Open the foil pouch and remove the test device and lay it on a flat surface.



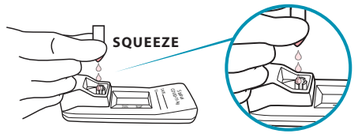
2 OPEN REAGENT CAPSULE

Twist the tab at the top.



3 ADD REAGENT

Hold the capsule directly over the Extraction Well and squeeze **all of the reagent** into the well. Discard the empty capsule in the trash.



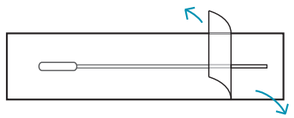
WARNING! False negative results may occur if all sample extraction reagent is not added to the Extraction Well or spilled during the addition to the Extraction Well.

Do not touch the result window or the Extraction Well of the test device.

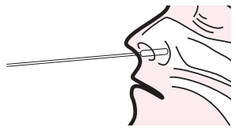
Do not add sample to the rectangular result window.

4 OPEN SWAB

Open the swab wrapper at the stick end. **Be careful not to touch the swab tip.**

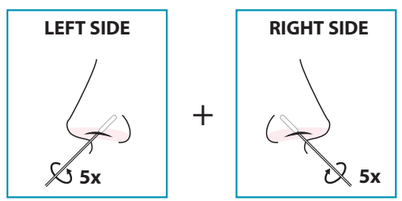


5 SWAB NOSTRILS



Holding the stick end of the swab, gently insert the swab tip into the nostril no more than 1/2–3/4 in.

Slowly rotate the swab in a circular motion 5 times by firmly pressing against the inside walls of the nostril.
Do not just spin the swab. Gently remove the swab and repeat in the second nostril using the same swab.



WARNING! Inaccurate test results may occur if the nasal swab specimen is not properly collected.

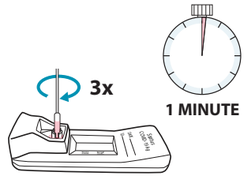
For test accuracy, make sure to collect sample from both nostrils.

NOTE: A nasal swab sample can be self-collected by persons aged 14 and older. Children aged 2-13 should be tested by an adult. 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. Please wear a face mask when swabbing others.

6 INSERT SWAB TIP

Insert the swab tip into the Swab Stand in the Extraction Well where you previously added the reagent.

7 ROTATE SWAB



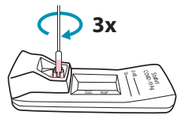
Rotate the swab 3 times to mix the sample.

Leave the swab in place.

Set a timer for **1 minute**.

WARNING! Results may be inaccurate if the swab is not rotated and left in place for 1 minute.

8 ROTATE SWAB AGAIN

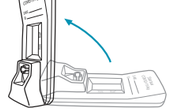


After 1 minute, rotate the swab 3 times again.

Discard the swab in the trash.

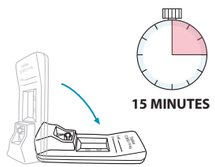
9 RAISE DEVICE TO STAND

Slowly raise the device to stand upright and **let stand for 3 seconds**. The reagent will flow into the hole in the Test Well. Failure to let the device stand upright for 3 seconds may result in an invalid test result.



WARNING! If any reagent spills out of the test device, the test will be invalid and you will need to perform another test.

10 LAY DEVICE DOWN

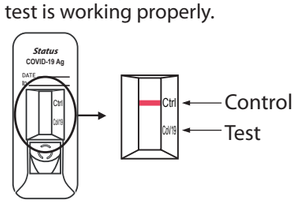


Slowly lay the device back down on the flat surface and set a timer for 15 minutes. Do not move the device during this time.

11 READ TEST RESULTS AT 15 MINUTES

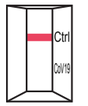
WARNING! Results may be inaccurate if read before 15 minutes or after 20 minutes.

Look at the Result Window and locate the Ctrl and the CoV19 on the side of the window. A pink/purple color line should always appear at the Ctrl position. This is a control line and shows that the test is working properly.



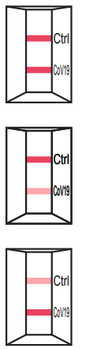
Read test results at 15 minutes.

NEGATIVE RESULT



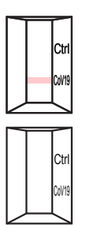
If the Control (Ctrl) line is visible, but the Test (CoV19) line is not visible, the test is negative.
To increase the chance that the negative result for COVID-19 is accurate, you should:
Test again in 48 hours if you have symptoms on the first day of testing.
Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.
A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If you test negative and continue to experience COVID-19-like symptoms, (e.g., fever, cough, and/or shortness of breath) you should seek follow up care with your health care provider.

POSITIVE RESULT



If a pink/purple test line (CoV19) is visible together with a control line (Ctrl), this means that the result is positive. Any faint visible pink/purple test line (CoV19) with a control line (Ctrl) should be read as positive. **You do not need to perform repeat testing if you have a positive result at any time.** A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely that 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).

INVALID RESULT



If the control (Ctrl) line is not visible at 15 minutes, the test is invalid. Re-test with a new swab and new test device.

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.

Serial Test Results Interpretation

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

Status on first day of testing	First Result Day 1	First Result Day 1	First Result Day 1	Interpretations
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

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.

Intended Use

The **Status™ COVID-19 Antigen Rapid Test for Home Use** is a lateral flow immunoassay device intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2.

This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older or adult-collected anterior nasal (nares) swab samples from individuals aged two years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 5 days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests.

The **Status™ COVID-19 Antigen Rapid Test for Home Use** does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which 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 past medical 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 disease. Individuals who test positive with the **Status™ COVID-19 Antigen Rapid Test for Home Use** should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. 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 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 COVID-19.

Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough, and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow-up care with their physician or healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting and to receive appropriate medical care. 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 **Status™ COVID-19 Antigen Rapid Test for Home Use** is intended for non-prescription self-use and/or, as applicable, an adult lay user testing another person aged 2 years or older in a non-laboratory setting. The **Status™ COVID-19 Antigen Rapid Test for Home Use** 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.

How to Use This Test

- Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19, 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 both your first and second tests are negative, you may not have COVID-19, however you should follow-up with your healthcare provider.
- If your test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

Warnings, Precautions, and Safety Information

- Read the Package Insert carefully before performing a test. Failure to follow directions may produce 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, 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.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing. If you have had symptoms longer than 5 days you should consider testing at least three times over five days with at least 48 hours between tests.**
- If you skip a step or perform a step incorrectly, discard the test device, start over with a new test and make sure to perform all steps correctly.
- 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.
- Do not use on anyone under 2 years of age.
- Wear a safety mask or other face-coverings when collecting a specimen from a child or another individual.
- Do not use if any of the test kit contents or packaging is damaged or open.
- Test components are single-use. Do not reuse.
- Do not touch the swab tip.
- Leave the test device sealed in its pouch until just before use. Once opened, the test device should be used within 60 minutes.
- Do not use the test after the expiration date shown on the external packaging.
- Ensure that there is sufficient lighting for testing and interpretation.
- This test may give false negative results when tested in conditions of <15% humidity.
- Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.
- The use of some hand sanitizer lotions may affect the results of the test. Please ensure your hands are dry before performing the test.
- Remove any piercings from the nose before starting the test.
- Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.
- 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.
- 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 component. The Reagent solution contains a harmful chemical (see table below). **If contact with the body occurs, flush with a copious amount of water. If irritation persists, seek medical advice. https://www.poisonhelp.org or 1-800-222-1222.**

Chemical Name CAS	GHS Code for Each Ingredient	Concentration (%)
Sodium Azide 26628-22-8	H300, Harmful if swallowed H310, Skin irritation	0.09%
Triton X-100 9036-19-5	H302, Harmful if swallowed H315, Causes skin irritation H318, Causes serious eye damage H410, Very toxic to aquatic life with long-lasting effects	0.2%

- For more information on EUAs please visit: "https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization"
- For the most up to date information on COVID-19, please visit: "http://www.cdc.gov/COVID19"

Limitations

- 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.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between January 2023 - February 2023. 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.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you likely have COVID-19.
- These test results are shown as lines of color. Because these lines can be very faint, users with conditions affecting their vision - such as far-sightedness, glaucoma, or color blindness - are encouraged to seek assistance to interpret results accurately (e.g., reading glasses, additional light source, or another person).
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- This test detects both viable (live) and nonviable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.

Frequently Asked Questions

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

A: Potential risks include:

- Possible discomfort during sample collection.
- Possible incorrect test results (see Warnings and Result Interpretation sections for more information).

Potential benefits include:

- The results, along with other information, can help you and your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the potential spread of COVID-19 to 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-authorization

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 **Status™ COVID-19 Antigen Rapid Test for Home Use**, detect proteins from the virus. Due to the lower sensitivity of antigen tests, there is a higher chance this test will give you a false negative result when you have COVID-19 than a molecular test would.

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 when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach is recommended to minimize the risk of incorrect results. For more information on the performance of the test and how the performance may apply to you, please refer to the performance data in the Healthcare Provider Instructions for Use (IFU), available at www.lifesignmed.com.

Q: WHAT IF I HAVE A POSITIVE TEST RESULT?

A: A positive result means 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.

Q: WHAT IF I HAVE A NEGATIVE TEST RESULT?

A: A negative test result indicates that antigens from the virus that causes COVID-19 were not detected in your sample. However, if you have symptoms of COVID-19, and your first test is negative, you should test again in 48 hours since antigen tests are not as sensitive as molecular tests. If you do not have symptoms and received a negative result, you should test at least two more times with 48 hours in between tests for a total of three tests. If you have a negative result, it does not rule out SARS- CoV-2 infection; you may still be infected and you may still infect others. 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 all new test components.

IMPORTANT

Do not use this test as the only guide to managing your illness. Please consult your healthcare provider if your symptoms persist or become more severe. Individuals should provide all results obtained with this product to their healthcare provider.

Index of Symbols

Manufacturer	Catalogue number
Contains sufficient for <n> tests	Use-by date
Temperature limit	Batch code
Consult instructions for use	Do not reuse
Distributed by	For in vitro diagnostic use

DIST Distributed by

lifeSign
A PBM Group Company
85 Orchard Road
Skillman, NJ 08558
www.lifesignmed.com
Help line: 1-800-526-2125

Manufactured by PBM
Princeton BioMeditech Corp.
4242 U.S. Hwy 1
Monmouth Junction, NJ 08852

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