In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA. 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.
25 COVID-19 Antigen
Rapid Test for Home Use

Simple & Easy Nasal Swab
Results in 15 Minutes

Scan QR code with phone camera to learn more.

Rapid Test for Home Use
COVID-19 Antigen

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- For Emergency Use Authorization (EUA) only
- For in vitro diagnostic use
- For ages 2 and up
- Items necessary to use the kit but not provided: Timer

For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit https://www.fda.gov/covid-tests

Contents:
25 Nasal Swab
25 Test Solution Capsule
1 Quick Reference Instructions

Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.
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:
- Instructions for use
- Test device in foil pouch
- Reagent capsule
- Extraction Well
- Result Window
- Swab tip
- Swab Stand
- Test Control
- Quick Reference Guide

In vitro diagnostic use
Rapid Test for Home Use
Status™ COVID-19 Antigen

MT Promedt Consulting GmbH, St. Ingbert, Germany

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

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

Open reagent capsule
Twist the tab at the top.

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

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.

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.

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

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.

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

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.

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).

If the control (Ctrl) line is not visible, the result 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.

If the Control (Ctrl) line is visible, but the Test (CoV19) line is not visible, the test is negative.

You do not need to perform follow up care with your health care provider.

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.

Read test results at 15 minutes.

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.

Negative result
If the Control (Ctrl) line is visible, but the Test (CoV19) line is not visible, the test is negative.

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).

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

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.

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.

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Use-by date
Batch code
Manufacturer
Catalogue number
Consult instructions for use
does not apply
Use-by date
Batch code
Consult instructions for use
does not apply
For in vitro diagnostic use
Distributed by
www.poisonhelp.org or 1-800-222-1222.
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 could. 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.
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 nature of antigen tests, there may be a higher chance this test will give you a false negative result when you have COVID-19 than a molecular test could.
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 many tests detected in your sample. You should self-isolate from others and contact a healthcare provider for medical advice about your positive result.
Q: WHAT IS A VALID 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 positive, the proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19. If 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 ten times more with 48 hours in between each test. If you have a negative result, it does not rule out COVID-19 infection. It may not be detected by the 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. 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. For symptomatic individuals or in the presence of clinical 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 and/or contact tracing setting. 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 not for in vitro diagnostic use under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the Performance of this test was established based on the evaluation of a linear range of clinical specimens collected between January 2020 and 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 of clinical evaluation. Testing at the time of the test does not necessarily signify that the test is positive or negative. Performance of the test may vary depending on the circulating variants, including related to 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. Depending on your circumstances, you should contact healthcare provider for medical advice about your positive or negative result.