COVID-19 Antigen Pen Home Test
Quick Reference Instructions

For Emergency Use Authorization (EUA) use only. In vitro diagnostic use.

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

How to Use This Test
• Serial testing should be performed on 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 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 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.

Test Procedure
1 Remove the Test Pen and the Base from the packaging.
2 Remove Swab Cap from the Test Pen.
3 Gently insert the Swab end of the Pen in one nostril about 1/2 - 3/4 of an inch. Firmly rub the swab at least 5 times against the inside walls of the nostril in a circular motion. Do not just spin the swab.
4 Repeat the process with the same swab in the other nostril. Did you swab both nostrils? If not, inaccurate results can occur.
5 Place the Base on a flat surface. Place the swab end of the Pen into the base.
6 Press firmly on the test pen to insert it all the way into the base so that the orange band is completely covered by the base. Leaving the test upright, set a timer and read the results at 15 minutes.

Read and Interpret Your Results
• COVID-19 Positive (+)
If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible line in the test (T) region with a line in the control (C) region 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 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).

• COVID-19 Negative (-)
If the Control (C) line is visible, but the Test (T) 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 the individual has symptoms on the first day of testing.
• Test 2 more times at least 48 hours apart if the individual does 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 the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

• Invalid result
If the Control (C) line is not visible, the test is invalid. Re-test with a new swab and new test device.

WARNING: Do not read results earlier than 15 minutes. Do not read the results after 30 minutes. Inaccurate test interpretations may occur.

Locate the letters CC and TT at the top and bottom of the results window. After the 15 minutes has elapsed, a pink line should always appear at the control (CC) region; this is a control line and signals that the test is working properly.

Note
Do not use this test on children under 2 years of age. Children between 2 and 14 years of age must be aided or supervised by an adult when carrying out the test.

For information about current expiration dates for all-home OTC COVID-19 diagnostic tests, visit http://www.fda.gov/covid-tests
The test should be used at room temperature.
Make sure that all packaging is intact. Do not use the test if the foil packaging is visibly damaged.
Do not open the foil package until you are ready to perform the test. Use the test within 1 hour of opening.
Ensure you have a flat surface area, such as a table top.
Wash your hands with soap and water for 20 seconds or use hand sanitizer.

Storage and Stability
Store the kit at 2-30°C / 36-86°F and protect from direct sunlight. The expiration date of the materials is indicated on the external packaging. Do not freeze the kit.

Kit Contents
Instructions for Use
Fast Package (Containing Test Pen and Base) and Timer (not included)

Prepare for the Test
• For information about current expiration dates for all-home OTC COVID-19 diagnostic tests, visit http://www.fda.gov/covid-tests
• The test should be used at room temperature.
• Make sure that all packaging is intact. Do not use the test if the foil packaging is visibly damaged.
• Do not open the foil package until you are ready to perform the test. Use the test within 1 hour of opening.
• Ensure you have a flat surface area, such as a table top.
• Wash your hands with soap and water for 20 seconds or use hand sanitizer.

Warning: Failure to insert the test pen all the way into the base can lead to inaccurate results.
**Intended Use**

The Fastep COVID-19 Antigen Pen Home Test is a lateral flow immunoassay device intended for the qualitative detection of nucleoprotein antigen from the SARS-CoV-2 virus.

This test is authorized for non-prescription home use with self-collected anterior nasal (nasal) swab samples from individuals aged 14 years or older or adult collected anterior nasal (nasal) swab samples from individuals aged 2 or older. This test is authorized for individuals with symptoms of COVID-19 within the first 6 days of symptom onset when tested at least once every 3 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 Fastep COVID-19 Antigen Pen Home Test does not differentiate between SARS-CoV and SARS-CoV-2. Results are for the identification of SARS-CoV-2 nucleoprotein antigen, which is generally detectable in anterior nasal (nasal) swab specimens during the acute phase of infection. Positive results are presumptively indicative of the presence of virulent antigens, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out SARS-CoV-2 bacterial coinfection or co-infection with other viruses. The agent detected may not be the definitive cause of disease. Individuals who test positive with the Fastep COVID-19 Antigen Pen Home Test should seek appropriate care with their physician or healthcare provider as additional testing may be necessary.

All negative results are presumptive and confirmation with a molecular assay is 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, including infection control measures such as isolating from others and wearing masks. Negative results should be consistent with 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 loss of smell or taste may be retested within a week 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 using the authorized product to relevant public health authorities in accordance with state law, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory Value Interoperability Guidelines (LVIG) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The Fastep COVID-19 Antigen Pen Home Test is intended for non-prescription self-use and/or as applicable, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory Value Interoperability Guidelines (LVIG) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

**Frequently Asked Questions**

**Frequently Asked Questions, Cont'd**

**WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?**

There are different kinds of tests for the SARS-CoV-2 virus that causes COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, such as the Fastep COVID-19 Antigen Pen Home Test, 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.

**HOW ACCURATE IS THIS TEST?**

Clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus or not when you have COVID-19 because proteins from the virus cause COVID-19 infection. Molecular tests are more accurate 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 (FU), available at fastep.azure.bio.

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

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.

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

A negative 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, the antigen test may be negative. You should test again at least 48 hours after your first test. If your second test is negative, it is less likely you have COVID-19. If you test negative and continue to feel ill, contact a healthcare provider.

**WHAT DOES AN INVALID TEST RESULT MEAN?**

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 you should test again with a new test.

**IMPORTANT!** Do not use this test as the only guide to manage your illness. 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 for public health reporting.
For Emergency Use Authorization (EUA) only.

- For in vitro diagnostic use.
- 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. § 360bb-b(1), unless the declaration is terminated or authorization is revoked sooner.
- 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.
- For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit: https://www.fda.gov/covid-tests

For use under the FDA Emergency Use Authorization (EUA) only.

Detailed instructions and warnings are provided in the Instruction for Use documents that came with this test kit.
Box Contents:

- 1 × Instruction for use
- Items necessary to use the test but not provided in the test kit:
  - 20 × Test Pens
  - 20 × Bases
  - Timer

For Emergency Use Authorization (EUA) only.

For in vitro diagnostic use.

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 protein binding to SARS-CoV-2 antigens in a respiratory specimen to aid in the diagnosis of COVID-19.

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.

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.

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

For more information, visit https://www.azurebio.com/covid-19-antigen-test.

Store between 36-86 ℉ (2-30 ℃) until use.