COVID-19 Antigen Pen Home Test

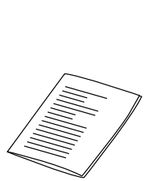
Quick Reference Instructions

For Emergency Use Authorization (EUA) use only.

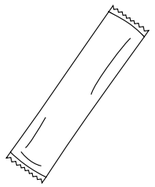
In *vitro* diagnostic use.

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

Kit Contents



Instructions for Use



Foil Package (Containing Test Pen and Base)

Timer (not included)

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.

Prepare for the Test

- For information about current expiration dates for at-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.

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.

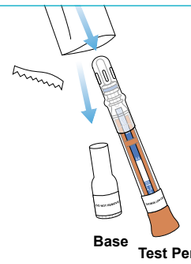
How to Use This Test

- **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

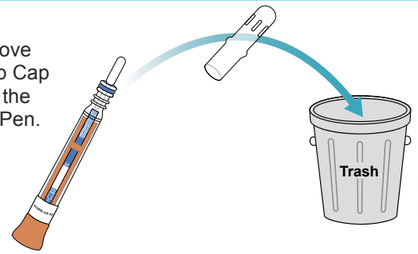
Test Procedure

1 Remove the Test Pen and the Base from the packaging.

USE THE TEST WITHIN 1 HOUR OF OPENING.



2 Remove Swab Cap from the Test Pen.

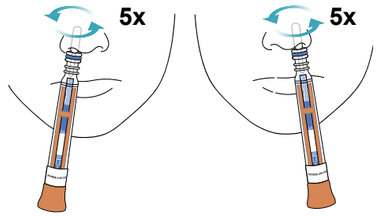


Discard the Swab Cap.

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.

Make sure you have removed the swab cap (see step 2).

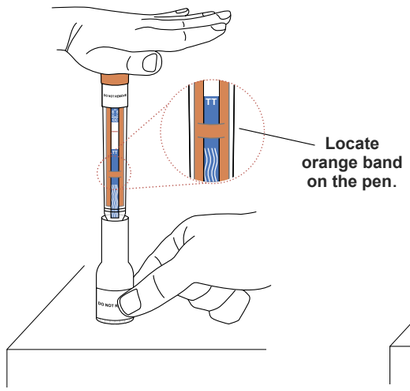


4 Repeat the process with the same swab in the other nostril.

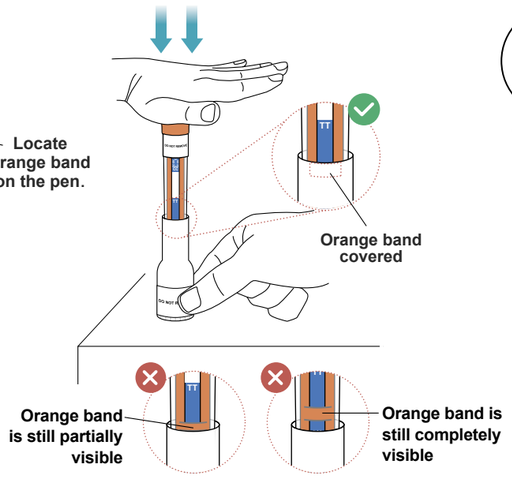
STOP **Did you swab both nostrils? If not, inaccurate results can occur.**

Instructions for swabbing children: 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 hold the child's head while swabbing.

5a Place the Base on a flat surface. Place the swab end of the Pen into the base.

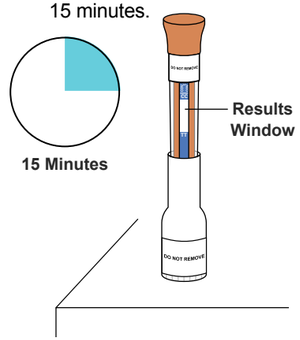


5b **Press firmly** on the test pen to insert it all the way into the base so that the orange band is completely covered by the base.



WARNING: Failure to insert the test pen all the way into the base can lead to inaccurate results.

6 Leaving the test upright, set a timer and read the results at 15 minutes.



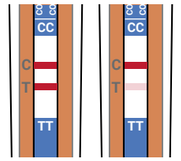
WARNING: Do not read results earlier than 15 minutes. Do not read the results after 30 minutes.

After test is completed, dispose of used materials in trash.

Read and Interpret Your Results

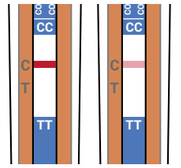
WARNING: Do not read results earlier than 15 minutes. Do not read the results after 30 minutes. Inaccurate test interpretations may occur.

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.



◂ 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 (TT) region with a line in the control (CC) 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).

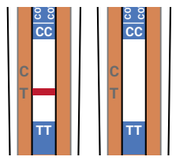


◂ COVID-19 Negative (-)

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: The control line may show up within a few minutes of starting the test. It may take up to 15 minutes for the test line to show up.

Read and Interpret Your Results (Cont'd)

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
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.

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.

Intended Use

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

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 (2) years 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 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 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 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 Fastep COVID-19 Antigen Pen Home Test 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 Fastep COVID-19 Antigen Pen Home Test is intended for non-prescription self-use and/or as applicable, for an adult lay user testing another person 2 years of age or older in a non-laboratory setting. The Fastep COVID-19 Antigen Pen Home Test 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.

Warnings, Precautions, and Safety Information

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in 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.

Warnings, Precautions, and Safety Information Cont'd)

- **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 6 days you should consider testing at least three times over five days with at least 48 hours between tests.**
- 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.
- Ensure that there is sufficient lighting for testing and interpretation
- Do not use on anyone under 2 years of age.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Do not use if any of the test kit contents or packaging is damaged.
- Test components are single-use. Do not re-use.
- Do not use kit past its expiration date.
- Do not touch the swab tip.
- Once opened, the test card should be used within 60 minutes.
- Do not read test results before 15 minutes or after 30 minutes. Results read before 15 minutes or after 30 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 components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water. **If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.**

Chemical Name/CAS	GHS Code for applicable ingredient	Concentration (%)
Sodium Azide/ 26628-22-8	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310	0.02%

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: 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 August 24, 2022 and January 5, 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.

Frequently Asked Questions

WHAT ARE THE KNOWN AND POTENTIAL RISKS AND BENEFITS OF THE TEST?

Potential risks include:

- Possible discomfort during sample collection.
- Possible incorrect test result (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.

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 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 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 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.

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.

Support

For questions, or to report a problem, please call 1-800-281-9867 or email hometest@azure.bio. Additional information is also available for you and your healthcare provider at fastep.azure.bio. The User Instructions, Quick Reference Guide, Fact Sheet for Health Care Provider and Health Care Provider Instructions for Use are also available at fastep.azure.bio. The Fastep COVID-19 Antigen Pen Home Test Letter of Authorization, authorized Fact Sheet, and authorized labeling are available on the FDA website and fastep.azure.bio.

Glossary of Symbols

REF	Catalog Number	IVD	In vitro diagnostic use only
LOT	Lot Number (Batch Code)	Σ	Tests Per Kit
	Use by (Expiration Date)		Manufacturer
	Temperature Limitations (Storage Temperature)		Date of Manufacture
	One Time Use (Single Use Only)		Consult Instructions for Use

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