

Pilot COVID-19 At-Home Test Frequently Asked Questions

GENERAL QUESTIONS

- **Is the COVID-19 At-Home Test that I received from the US Government the same as the Pilot COVID-19 At-Home Test?**
 - Yes, the Pilot COVID-19 At-Home Test is the new packaging design for the COVID-19 At-Home Test. As we transition to this new brand, you may receive a product with the previous COVID-19 At-Home Test packaging. The Pilot COVID-19 At-Home Test kits contain the same easy-to-use, accurate and reliable rapid antigen tests.
- **What is the Pilot COVID-19 At Home Test and what is it used for?**
 - The Pilot COVID-19 At-Home Test is a lateral flow immunoassay device intended for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus.

The Pilot COVID-19 At-Home Test is authorized to use as follows:

- Serial (repeat) testing at least twice over three days with at least 48 hours between tests for individuals with symptoms of COVID-19
- Serial (repeat) testing at least three times over five days with at least 48 hours between tests for individuals without symptoms or other epidemiological reasons to suspect COVID-19

Patients should use the Pilot COVID-19 At-Home Test if they are experiencing COVID-19 symptoms or believe they have been exposed to COVID-19. If a negative result is received, the patient should conduct serial (repeat) testing. Please refer to the table below for a summary of the testing protocol patients should follow.

Status on first day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive. Consult with a healthcare provider.	N/A	N/A	Positive for COVID-19
	Negative	Positive. Stop serial testing and consult with a healthcare provider.	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive. Consult with a healthcare provider.	N/A	N/A	Positive for COVID-19
	Negative	Positive. Stop serial testing and consult with a healthcare provider.	N/A	Positive for COVID-19
	Negative	Negative	Positive. Stop serial testing and consult with a healthcare provider.	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

- **What are the advantages of the Pilot COVID-19 At-Home Test?**
 - The test can quickly and reliably identify the presence of SARS-CoV-2 or lack thereof. The testing can be performed without specific training and in the comfort of one's home.
- **How often should I perform an antigen self test?**
 - COVID-19 antigen tests perform best when the viral load is at its highest during an infection. Outside of this window, such as at the start of the infection, or late infection, the test may not detect the virus. Therefore, regular testing increases the chance of detecting COVID-19. Serial testing is recommended.

Individuals with symptoms of COVID-19 should test at least twice over three days with at least 48 hours between tests.

Individuals without symptoms of COVID-19 should test at least three times over five days with at least 48 hours between tests.

- **Who can use the self test?**
 - The self test is available for use for ages 2 and up. Individuals ages 14 years and older can self-collect. An adult must collect the sample for individuals ages 2 through 13.
- **Is a prescription required to cover this test?**
 - No, this test is authorized for non-prescription home use.
- **Will the test work if I don't have symptoms, but may have been exposed?**
 - Antigen tests are fairly accurate, particularly when someone is experiencing symptoms and their viral load is very high. However, they can be less accurate when someone has a lower viral load. This could lead to false-negative test results. **If you do not have symptoms of COVID-19, you should test at least three times over five days with at least 48 hours between tests.**
- **Will the accuracy of tests be compromised if they sit in mailboxes or are otherwise stored en route in below-freezing temperatures?**
 - Test performance can be impacted if the Pilot COVID-19 At-Home Test is used while it is still cold from being left outside in freezing temperatures. The Pilot COVID-19 At-Home Test should be stored at temperatures between 36-86 °F (2-30 °C) and brought to room temperature (59-86 °F /15-30 °C) before use. If the test is delivered in below freezing temperatures, the FDA recommends bringing the package inside your home and leaving it unopened at room temperature for at least two hours before opening it to ensure appropriate test performance. Once the package is at room temperature, it can be used in accordance with authorized instructions. If the test lines appear as described in the instructions,

the test is performing appropriately. If the lines do not appear as specified by the instructions, then the results may not be accurate. For more information on this topic, please visit the FDA [website](#).

KIT COMPONENTS

- **What are the kit components?**
 - Each test kit contains everything you need in order to perform a test. The components that you need to perform a test are:
 - Test device
 - Tube with liquid
 - Nozzle cap
 - Sterile swab
 - Tube holder
 - Quick Reference Instructions
- **How many tests come in a kit?**
 - The Pilot COVID-19 At-Home Test is currently being distributed in kits containing components to perform four tests.

TEST SPECIFICATIONS

- **How accurate is the Pilot COVID-19 At-Home Test?**
 - Relative sensitivity: 93.2%, Relative specificity: 100%
- **What do relative sensitivity and relative specificity mean?**
 - Relative sensitivity: Percent of samples with positive results that were also positive when tested with an FDA emergency use authorized comparator method. **The test's ability to detect a true positive.**
 - Relative specificity: Percent of samples with negative results that were also negative when tested with an FDA emergency use

authorized comparator method. **The test's ability to detect a true negative.**

○ **How long does the test take to deliver results?**

- Test results are available 20-30 minutes after performing the test procedure. Test results read after 30 minutes may be inaccurate.

○ **When does my Pilot COVID-19 At-Home Test expire?**

- The Pilot COVID-19 At-Home Test, distributed by Roche, has been granted another three month shelf-life extension by the U.S. Food and Drug Administration (FDA). This extends the shelf-life of the tests to a total of twelve months.

To confirm the expiration date of your test, access [our convenient search tool](#) to find your test by its lot number

○ **Can I use the test after the expiration date?**

- No, the test should not be used when the expiration date has passed. To confirm the expiration date for your COVID-19 At-Home Test, access [our convenient search tool](#) to find your test by its lot number.

○ **Does the Pilot COVID-19 At-Home detect Omicron and Delta variants?**

- The Pilot COVID-19 At-Home Test detects SARS-CoV-2, including current variants of concern including Omicron and Delta variants, among others.

○ **How do I perform a nasal swab?**

- Firmly and slowly rotate the swab at least 5 times, brushing against the inside walls of the nostril, for a total of 15 seconds. Do not spin the swab. Gently remove the swab and, using the same swab, repeat in the second nostril with the same end of the swab.

○ **Is it sufficient to take the sample from only one nostril?**

- No, the sample must be collected from both nostrils using the same swab.

- **Can people who have been vaccinated use this test?**
 - Yes, the Pilot COVID-19 At-Home Test can be used by vaccinated individuals.

HOW TO HANDLE THE TEST

- **Where and how should I store the test?**
 - The test should be stored in a dry, cool place without direct sunlight exposure.
- **The swab fell on the floor. Can I still use it?**
 - No. Swabs must be sterile for your own safety.
- **I accidentally applied more than 4 drops to the test device. Does this affect the test result?**
 - According to the Quick Reference Instructions, exactly 4 drops of the extracted sample should be added to the test device. If more than 4 drops are added and the subsequent result is negative, repeat the testing with a new test strip to confirm the results.
- **I waited more than 30 minutes before I read the result. Is the test result still valid?**
 - No. Inaccurate test interpretations may occur if results are read before 20 minutes or after 30 minutes.
- **How do I dispose of the test?**
 - Dispose of the test in the household trash. Do not flush or pour liquids down a drain.

RESULT INTERPRETATION

- **My test result is positive. What steps do I need to take?**
 - A positive test result means it is very likely that you have COVID-19. Refer to your healthcare provider for more information and refer to federal, state, and local guidelines.
- **My test result is negative. What do I do?**
 - 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 doctor/primary care physician.

- **I have a negative test result but have symptoms of illness. How do I proceed?**
 - **Individuals with symptoms of COVID-19 should test again in 48 hours if you had symptoms on the first day you tested. If you continue to test negative and suspect that you have an infection (i.e., if you have prolonged symptoms or if your symptoms are worsening), contact your doctor/primary care physician.**
- **I received an invalid test result and need to repeat the test. What should I do?**

- Carefully read the Quick Reference Instructions and repeat the test on a different test device. If your test result is still invalid, please contact your doctor/primary care physician..
- **The control line is very faint. What should I do?**
 - As long as you can see the control line visible with the naked eye, there is no concern and the test should be considered valid.