

# **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 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 with symptoms of COVID-19 within the first 6 days of symptom onset.

This test is also 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 swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

- **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 (such as every few days) increases the chance of detecting COVID-19.
- **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, such as in someone without symptoms. This could lead to false-negative test results. If you suspect you have COVID-19, test twice over three days with at least 24 hours (no more than 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
  
- **What should I do in case one of the components is missing or damaged?**
  - Test kits with damaged or missing components should not be used. Use a new test kit containing each component described in the 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
- Relative specificity: Percent of samples with negative results that were also negative when tested with an FDA emergency use authorized comparator method
- **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 a shelf-life extension of three months by the U.S. Food and Drug Administration (FDA). This extends the shelf-life of these tests to a total of nine months from the manufactured date.  
  
To confirm the shelf-life for 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 min 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?**
  - A negative test result indicates no antigens for SARS-CoV-2 were detected. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19, and negative results are presumptive and may need to be confirmed with a molecular test. This means that you could possibly still have COVID-19 even though the test is negative. If you test negative and continue to experience symptoms of fever, cough and/or shortness of breath you should seek follow up care with your healthcare provider immediately. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. If you are concerned about your COVID-19 status after testing or think you may need follow up testing, please contact your healthcare provider.
- **I have a negative test result but have symptoms of illness. How do I proceed?**
  - If you 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.