Pilot™ COVID-19 At-Home Test
Quick Reference Instructions for patients

For In Vitro Diagnostic (IVD) use.
For use under the Emergency Use Authorization (EUA) only.

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.

Materials Provided

- Test Device (inside foil pouch 1)
- Sterile Swab
- Tube with Liquid (inside foil pouch 2)
- Nozzle Cap
- Tube Holder

NOTE: This test comes in a 1, 4 or 25 test quantity. The number of items supplied in the kit will vary depending on which kit is purchased.

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

Prepare to perform the test

2. Wash your hands with soap and water, or use hand sanitizer before performing the test. Make sure you rinse thoroughly and your hands are dry before starting.
3. Check test expiry date on the back of the foil pouches. Do not use if the expiry date has passed.
4. Open foil pouch 1 by tearing along the tear-line. Remove the test device and desiccant package from the foil pouch. Place the test device on a flat surface.
5. Ensure that the test device is intact and that there are no green beads in the desiccant package (white and yellow beads are expected). Do not open the desiccant package.

Test Procedure

1. Open foil pouch 2 and place one tube and one nozzle cap on the table.
2. Open the seal of the tube carefully without spilling the liquid inside the tube. Place the tube in the tube holder. If any liquid spills, do not use the tube.
3. Holding the stick end of the swab, gently insert the foam end of the swab into the nostril approximately % of an inch.
4. **Swab Both Nostrils**
   - 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 just spin the swab.**
   - Gently remove the swab and, using the same swab, repeat in the second nostril with the same end of the swab.
   - NOTE: With children, the maximum depth of insertion into the nostril may be less than ¾ of an inch, and you may need to have a second person to hold the child’s head while swabbing.
5. Insert the swab into the tube until the soft pad is in the liquid. Squeeze the tube at the bottom and hold it tight. Then stir the swab more than 10 times. This is to transfer the biological material from the swab to the liquid.
6. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
7. Dispose of the swab and seal the tube securely with the nozzle cap.
8. Hold the tube upright above the sample well. Drop 4 drops onto the sample well.
   - **Do not apply the liquid in the rectangular result window**
9. Set the timer and read the test result at 20 minutes. Do not read the result after 30 minutes.

WARNING! Inaccurate test interpretations may occur if results are read before 20 minutes or after 30 minutes.

Read and interpret the results

10. Look at the result window and locate the letters C and T on the top side of the window. A colored line should always appear at the C position; this is the control line and signals that the test is working properly.

- **Positive result**
  - If a control line (C) is visible (regardless of how faint it is) and a test line (T) is not visible, this means that the result is negative. It is unlikely that you have COVID-19. However, even if your test is negative, continue to observe all hygiene and safety measures. If you suspect that you have an infection (i.e., if you have prolonged symptoms or if your symptoms worsen), contact your doctor/primary care physician. You may have another infection, or your test result may be false. Negative results do not rule out COVID-19. This means you could possibly still have COVID-19 even though the test is negative. If you do not have COVID-19 symptoms and your result is negative, you should test again with at least 24 hours and no more than 48 hours between tests.

- **Negative result**
  - If a control line (C) is visible and a test line (T) is not visible, this means that the result is negative. It is unlikely that you have COVID-19. However, even if your test is negative, continue to observe all hygiene and safety measures. If you suspect that you have an infection (i.e., if you have prolonged symptoms or if your symptoms worsen), contact your doctor/primary care physician. You may have another infection, or your test result may be false. Negative results do not rule out COVID-19. This means you could possibly still have COVID-19 even though the test is negative. If you do not have COVID-19 symptoms and your result is negative, you should test again with at least 24 hours and no more than 48 hours between tests.

- **Invalid result**
  - If a control line (C) is not visible, the result must be considered invalid. The test is not working correctly and you should perform another test using a different test kit. You may have performed the test incorrectly. Carefully read the Quick Reference Instructions and repeat the test. If your test result is still invalid, please contact your doctor or a COVID-19 test center.

WARNING! Do not move or lift the test device during this time.

NOTE: Dispose of the used test in the household trash. Do not flush or pour test liquids down a drain.

WARNING! Inaccurate test interpretations may occur if results are read before 20 minutes or after 30 minutes.

WARNING! Failure to squeeze the tube can lead to incorrect results due to excess buffer in the swab.

Set the timer and read the test result at 20 minutes. Do not read the result after 30 minutes.

WARNING! Do not move or lift the test device during this time.

NOTE: Dispose of the used test in the household trash. Do not flush or pour test liquids down a drain.

WARNING! Inaccurate test interpretations may occur if results are read before 20 minutes or after 30 minutes.
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 virus in human nasal swab specimens. This test is only for use under the Food and Drug Administration’s Emergency Use Authorization and is not a substitute for medical advice. The test should only be used with a new test device. Do not ingest any kit components. Always follow the instructions in this package. Do not use nasal sprays for at least 30 minutes before collecting a nasal sample. This test is read visually. Users with impaired vision or color-impaired vision may not be able to read the test. Do not use on anyone under two years of age. Follow directions for use. This test is for the detection of SARS-CoV-2 nucleic acid. RESULTS: If no control line shows up on the test, the result is invalid (even if any test line shows up). 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 collected and the test should be run again, using a new test tube and test device.

**Frequently Asked Questions**

**Q:** **WHAT IS COVID-19?**

A: COVID-19 (Coronavirus disease 2019) is an acute respiratory infectious disease caused by the SARS-CoV-2 virus, a novel Betacoronavirus. SARS-CoV-2 is mostly spread person-to-person, both by individuals with symptoms of COVID-19 infection and by infected people without symptoms. Based on the current knowledge, the incubation period is 1 to 14 days, mostly 4-5 days. Symptoms include fever, cough, and shortness of breath. This 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 the test should be run again, using a new test tube and test device.

**Q:** **WHAT IS THE PERFORMANCE OF THE PILOT™ COVID-19 AT-HOME TEST?**

A: The performance of the Pilot™ COVID-19 At-Home Test was established in a prospective clinical study using an EUA authorized molecular test as a comparator method (PPA). This study was performed under the Food and Drug Administration's Emergency Use Authorization and is not a substitute for medical advice. The test should only be used with a new test device. Do not ingest any kit components. Always follow the instructions in this package. Do not use nasal sprays for at least 30 minutes before collecting a nasal sample. This test is read visually. Users with impaired vision or color-impaired vision may not be able to read the test.

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

There are different kinds of tests to detect COVID-19. Some of these tests detect genetic material from the virus, such as the Pilot™ COVID-19 At-Home Test, detect proteins from the virus, and are very specific as antigens or as antibodies. This means that a positive result is highly accurate, but a negative result does not rule out infection. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that the test may be able to detect proteins from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the detection and diagnosis of SARS-CoV-2 in humans. This product has been authorized only for the detection of nucleic acid from SARS-CoV-2 in individuals with symptoms of COVID-19 who are being tested at enrollment in clinical trials for possible COVID-19 vaccination. The test is intended to be used as an aid in the clinical diagnosis of a current SARS-CoV-2 infection. Do not use this test as the only guide to manage your illness. Please consult your healthcare provider if your symptoms persist or become more severe, or if you are concerned at any time. Individuals should provide all results obtained with this product to their healthcare provider for public health reporting.

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