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

Pilot® COVID-19 At-Home Test

Sprig test kit to room temperature (32-46 °F / 0-8 °C).

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.

Check the test expiry date indicated on the external packaging. Do not use if the expiry date has passed.

NOTE: Testing should commence immediately after opening the sealed pouches.

Storage and Stability

Store the kit at 32-46 °F / 0-8 °C and protect from direct sunlight. The expiry date of the materials is indicated on the external packaging. Do not freeze the kit. For more information on expiration dating of COVID-19 antigen tests, please refer to http://www.fda.gov/covid-tests.

Prepare to perform the test

1. 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.

2. 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.

3. Open foil pouch 2 by tearing along the tear-line. Place the test device on the foil pouch. Set the timer and read the test result at 20 minutes. Do not read the test result after 30 minutes.

4. **Do not apply the liquid in the rectangular result window.**

5. Hold the tube upright above the sample well. Drop 4 drops onto the sample well.

6. Dispose of the swab and seal the tube securely with the nozzle cap.

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

Prepare the test

1. Bring test kit to room temperature (32-46 °F / 0-8 °C).

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 the test expiry date indicated on the external packaging. Do not use if the expiry date has passed.

NOTE: Testing should commence immediately after opening the sealed pouches.

Testing 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 and one nozzle cap on the table.

3. Remove the swab from the packaging. Ensure that you only touch the handle of the swab and not the soft pad at the tip.

4. Holding the stick end of the swab, gently insert the foam end of the swab into the nostril up to 2 inches. Do not move or lift the swab during this time.

5. **Swab Both Nostrils.**

   - Firmly and slowly rotate the swab 10 times. This is to transfer the biological material from the swab to the liquid.

   - **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 swabs.

   - NOTE: With children, the maximum depth of insertion into the nostril may be less than ½ inch, and you may need to have a second person to hold the child's head while avoiding

7. 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 air the swab more than 10 times. This is to transfer the biological material from the swab to the liquid.

8. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

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

Read and interpret the results

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

1. 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 signal that the test is working properly.

2. **Negative result**

   - If the Control line (C) is visible, but the Test line (T) 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 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 health care provider.

3. **Positive result**

   - If the Control line (C) and the Test line (T) are visible, the test is positive. Any faintly visible colored test (T) line with the control (C) line 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/premer care provider 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).

4. **Invalid result**

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

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

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<th>Status on First Day of Testing</th>
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Results should be considered in the context of an individual’s recent exposure, history, and the presence of clinical signs and symptoms consistent with COVID-19.

NOTE: Repeat your test result. For more information on the mobile app, please scan the QR code on the next page.

Regrettably helps public health teams understand COVID-19 spread in your area and across the country and informs public health decisions.

Materials Provided

- Sterile Swab (inside foil pouch 1)
- 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.
The Pilot® COVID-19 At-Home Test is a lateral flow immuno-chemical device intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 virus in anterior nasal swab samples.

This test is authorized for non-prescription use home with self-collected anterior nasal (nasal) swab samples from individuals aged 2 years or older. The test is not authorized for individuals with symptoms of COVID-19 within the first 5 days of symptom onset when tested at least twice over four days with at least 48 hours between tests, and for asymptomatic 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 test can be performed with or without the supervision of a healthcare provider.

The Pilot® COVID-19 At-Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen that is generally detectable in anterior nasal (nasal) swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or coinfection with other viruses. The agent detected may not be the definitive cause of disease.

Individuals who test positive with the Pilot® COVID-19 At-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 confirm 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 exposure 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 cough or shortness of breath may still have SARS-CoV-2 infection and should seek follow-up care from their primary care physician.

Individuals should provide all results obtained with this product to their healthcare provider. If you have questions about the results, please call 1.866.987.6243 for FDA Emergency Use Authorization (EUA) only. 510(k) #K173608 | EUA #EUA-2020-0002.

False negative test results may occur if the specimen swab is not mixed well in the test circuit (step 5 in the test procedure section).

False negative test results may occur if the specimen swab is not mixed well in the test tube (step 5 in the test procedure section).

The immune response cannot be evaluated using this test. Other test methods are needed to determine the severity of illness and the need for hospitalization.

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 providers.

If your test is positive, then proceeds from the virus that causes COVID-19 have been found in the sample and you likely have COVID-19.

This test is a visual test and has not been validated for use by those with impaired vision or color-restricted vision.

The test should be used for the detection of SARS-CoV-2 antigen in human nasal swab samples.

In the event of a spillage, ensure it is cleaned thoroughly using a suitable disinfectant.

Frequently Asked Questions

A: Potential risks include:

• Possible incorrect test results (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 decisions about your care.

• The results of this test may help limit the spread of COVID-19 to your family and others in your community.

For more information on EUA go here: https://www.fda.gov/medical-devices/emergency-use-authorizations-euas/coronavirus-disease-2019-covid-19-
emergency-use-authorizations

Q: 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 you receive an invalid 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.

Q: 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 Pilot® COVID-19 At-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.

Q: 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 over several days. Repeating 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 (PI), available at https://www.gc.com/covid19-home-test.

Q: 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.

Q: WHAT IF I HAVE A NEGATIVE TEST RESULT?

A negative test result indicates that you are not infected with the virus that causes COVID-19. However, a negative test result does not rule out COVID-19 infection. If you have symptoms of COVID-19 in your first test and your negative test result is after 48 hours since antigen tests are not as sensitive as molecular tests. If you do not have symptoms and received a negative test result, you should take 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.

Q: WHAT DOES AN INVALID TEST RESULT MEAN?

A: 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.

For more information on the Pilot® COVID-19 At-Home Test, information on how to use the mobile application for recording and exporting test results, or to access a Spanish translation of the instructions, scan this QR code or visit the website below.

https://go.com/covid19-home-test

If you have any questions about using the test or reading the results, please call US COVID-19 General Support 1-866-987-6243.
For in vitro diagnostic use only. Store between 36-86 °F (2-30 °C) until use.

Contents:
- Test device x 1
- Extraction buffer tube x 1
- Nozzle cap x 1
- Sterile swab x 1
- Tube holder x 1
- Quick Reference Instructions (en) x 1

Needed but not provided: Timer

• The Pilot® COVID-19 At-Home 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 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.

• 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.

• In the USA, this product has not been FDA cleared or approved; but has been authorized for use 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.

• This test does NOT determine if you had COVID-19 in the past or if you have immunity.

• 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.

Distribution by: Roche Diagnostics, Indianapolis, IN
www.diagnostics.roche.com
US COVID-19 General Support 1-866-987-6243

For symbol glossary, refer to Quick Reference Instructions.

For more information on expiration dating for COVID-19 antigen tests, please refer to http://www.fda.gov/covid-tests.

QUICK RESULTS
In as few as 20 minutes
EASY TO USE
With a simple nasal swab
TAKE CONTROL

Test Positive?
Scan or Visit covid19knowmore.com to learn more about COVID-19 and treatment options

The information provided using this QR Code is only intended to be general summary information to the public and is not intended to take the place of professional medical advice or treatment. Always seek the advice of your physician or other qualified health provider with any questions you may have regarding your health. The owner of www.covid19knowmore.com does not have any role in the design, manufacture or distribution of the Pilot® COVID-19 At-Home Test.
COVID-19 At-Home Test

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

Quick Results
• In the USA, this product has not been FDA cleared or approved; but has been authorized for use by FDA under an EUA.
• This product has been authorized only for the detection of SARS-CoV-2 proteins, not for any other viruses or pathogens.
• This test does NOT determine if you had COVID-19 in the past or if you have immunity.
• The emergency use of this product is only authorized if the declaration is terminated or authorization is revoked sooner by FDA.

For more information on the Pilot® COVID-19 At-Home Test, for use under the FDA EUA, information on how to use the mobile application for recording and reporting test results, or to access a Spanish translation of the test instructions, scan this QR code or visit the website below.

https://go.roche.com/COVID-Home-Test

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