Pilot® COVID-19 At-Home Test

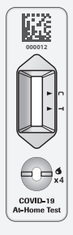
Quick Reference Instructions for patients

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

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

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

Needed but not provided: Timer
Optional (for use with telehealth proctor only): Internet enabled device with audio and video capabilities

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. 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 Bring test kit to room temperature (59-86 °F / 15-30 °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.

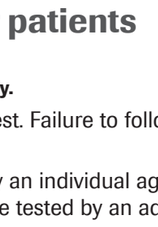
NOTE: Testing should commence immediately after opening the sealed pouches.

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.

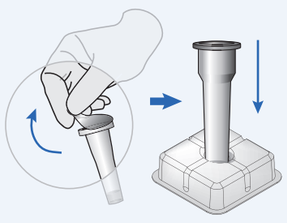
5 Ensure that the test device is intact and that there are no green beads in the desiccant package (white and yellow beads are expected). Do not open the desiccant package.

Test Procedure

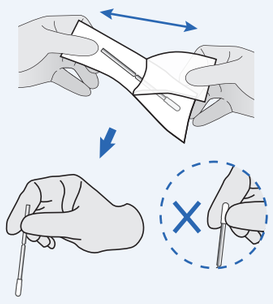
1 Open foil pouch 2 and place one tube and one nozzle cap on the table.



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.



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



3 Holding the stick end of the swab, gently insert the foam end of the swab into the nostril approximately ¾ of an inch.

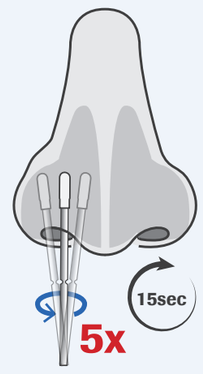
4 ****Swab Both Nostrils****

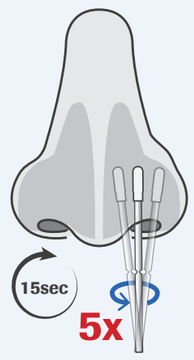
Firmly and slowly rotate the swab **at least 5 times**, brushing against the inside walls of the nostril, for a total of 15 seconds.

****Do not just spin the swab.****

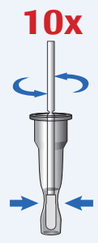
Gently remove the swab and, using the same swab, repeat in the second nostril with the same end of the swab.

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.

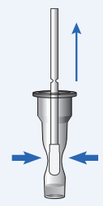




5 Insert the swab into the tube until the soft pad is in the liquid. Squeeze the tube at the bottom and hold it tight. Then stir the swab **more than 10 times.**
This is to transfer the biological material from the swab to the liquid.

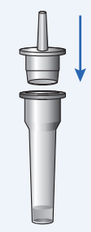


6 Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.



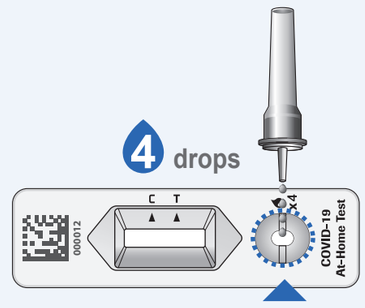
WARNING! Failure to squeeze the tube can lead to incorrect results due to excess buffer in the swab.

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.

Read at 20 mins.
Do not read after 30 mins.

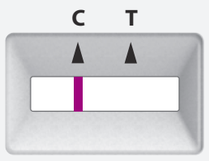
WARNING! Do not move or lift the test device during this time.

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

Read and interpret the results

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

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 signals that the test is working properly.

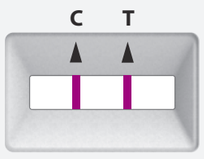


◀ Negative result

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.**

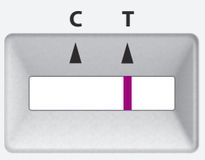
A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results 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.



◀ Positive result

If the Control line (C) and the Test line (T) are visible, the test is positive. Any faint visible colored test (T) line with the control line (C) 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).



◀ 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.

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.

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

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

For FDA Emergency Use Authorization (EUA) only.

- 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
- For detailed instructions, please visit: https://go.roche.com/COVID-Home-Test

Intended Use

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.

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 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.
This test can be performed with or without the supervision of a telehealth proctor.
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 which is generally detectable in anterior nasal (nares) 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 co-infection with other viruses. The agent detected may not be the definite 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 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 from 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 Pilot® COVID-19 At-Home Test is authorized for non-prescription self-use and/or as applicable, for an adult lay user testing another aged 2 years or older in a non-laboratory setting.

The Pilot® COVID-19 At-Home Test is only for use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

Warnings and Precautions

- 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.
- **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.
- 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.
- Use only the components of this test kit.
- Do not use kit past its expiration date.
- Do not open the kit contents until ready for use.
- Testing should commence immediately after opening the sealed pouches.
- Do not touch the swab tip.
- Do not read test results before 20 minutes or after 30 minutes. Results read before 20 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.
- The control line may show up within a few minutes of starting the test. It may take up to 20 minutes for a test line to show up.
- Make sure there is sufficient light when testing.
- Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.
- In the event of a spillage, ensure it is cleaned thoroughly using a suitable disinfectant.
- If you suspect the presence of blood on the swab, discard the swab, make sure you are not bleeding, and repeat the test with a fresh swab.
- Remove any piercings from the nose before starting the test.
- Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.
- Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your skin and eyes. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below).

Chemical Name / CAS	Hazard Category (mixture)	Hazard Statement for Mixture	Labeling of Harm(s)
Sodium chloride / 7647-14-5 L-Arginine / 74-79-3	Category 2	Eye irritation	May cause eye irritation
Polidocanol / 9002-92-0 ProClin® 300	Category 3	Skin irritation	Causes mild skin irritation

- If the solution contacts your skin and eyes, flush with large amounts of water. **If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.**

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 in December 2021 and February - March 2022. 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.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- The test should be used for the detection of SARS-CoV-2 antigen in human nasal swab samples.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- This is a qualitative test, therefore quantitative values of SARS-CoV-2 antigen concentration cannot be determined.
- False negative test results (i.e., an existing infection is not detected) may occur if the antigen level in the specimen is less than the minimum detection limit of the test.
- False negative test results may occur if the specimen swab is not mixed well in the tube (step 5 in the test procedure section).
- The immune response cannot be evaluated using this test. Other test methods are required for that purpose.
- The test does not differentiate between SARS-CoV and SARS-CoV-2.

How to Use this Test

- Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd time after an additional 48 hours. 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 your test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

Frequently Asked Questions

Q: WHAT ARE THE KNOWN POTENTIAL RISKS AND BENEFITS OF THIS TEST?
A: Potential risks include:
- Possible discomfort during sample collection.
- 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 EUAs go here: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?
A: 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?
A: 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 https://go.roche.com/COVID-Home-Test.

Q: WHAT IF I HAVE A POSITIVE TEST RESULT?
A: 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: 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.

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.

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.

More Information

For more information on the Pilot® COVID-19 At-Home Test, 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

If you have any questions about using the test or reading the results, please call US COVID-19 General Support 1.866.987.6243

Healthcare Providers

Please visit https://go.roche.com/COVID-Home-Test to obtain the complete instructions for use and fact sheet for healthcare providers.

Index of Symbols

REF	Reference number	IVD	In vitro Diagnostics
LOT	Batch code		Consult Instructions for use
	Manufacturer		Do not use if package is damaged
Σ	Contains Sufficient for <n> Tests		Date of manufacture
	Use-by date		Do not re-use
	Caution		Temperature limit
	Keep dry		Keep away from sunlight

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