**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**
- Sterile Swab
- Tube with Liquid (inside foil pouch 2)
- Nozzle Cap
- Tube Holder

**NOTE:** This test comes in a 1, 4, or 20 test quantity. The number of items supplied in the kit will vary depending on which kit is purchased.

**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. Remove the swab from the packaging. Ensure that you only touch the handle of the swab and not the swab itself.
4. Holding the stick end of the swab, gently insert the foam end of the swab into the nasal passages approximately 1/2 inch.
5. "Swab Both Nostrils" Gently and deeply rotate the swab at least 5 times, brushing against the inside walls of the nostrils, for a total of 15 seconds.
6. "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 minimum depth of insertion into the nostril may be less than 1/2 in. an inch, and you may need to have a second person to hold the child’s head while swabbing.
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 spin 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.

**Storage and Stability**
Store the kit at 36-38 °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-19.

**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 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.

**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.

   **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 8 to 12 hours if you have symptoms on the first day of testing. *Test 2 or 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 much 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 loss of taste or smell) you should seek follow-up care with your health care provider.

   **Positive result**
   - If the Control (C) and Test (T) lines 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 or 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.

**Storage and Stability**
Store the kit at 36-38 °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-19.

**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 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.

**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.

   **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 8 to 12 hours if you have symptoms on the first day of testing. *Test 2 or 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 much 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 loss of taste or smell) you should seek follow-up care with your health care provider.

   **Positive result**
   - If the Control (C) and Test (T) lines 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 or 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.
For FDA Emergency Use Authorization (EUA) only.

• For information on the EUA, please visit: https://www.fda.gov/emergency-preparedness-and-response/novel-coronavirus-2019-ncov-emergency-use-authorization
• For the most up to date information on COVID-19, please visit: www.cdc.gov/coronavirus
• For detailed instructions, please visit: https://www.go.roche.com/Covid-19-Home-Test

Intended Use

The Roche COVID-19 At-Home Test is a lateral flow immunosensor device intended for the qualitative detection of SARS-CoV-2 nucleoprotein antigen which is generally detectable in anterior nasal (nasal) swabs during the acute phase of infection. Positive results indicate the presence of viral antigen, 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 definitive cause of disease.

Indications

• The Roche COVID-19 At-Home Test is intended for use by adults aged 18 years or older.
• The Roche COVID-19 At-Home Test is intended for use only for the detection of SARS-CoV-2 antigens in anterior nasal (nasal) swabs from individuals who have clinical symptoms consistent with COVID-19, consistent with recent guidance from the CDC. The Roche COVID-19 At-Home Test is not intended for use in pregnant women.

Limitations

• There is a higher chance of false negative results with antigen tests than with laboratories that perform reverse transcriptase polymerase chain reaction (RT-PCR) tests due to the sensitivity of the test methodology. This means that there is a higher chance that 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 set of clinical specimens collected in December 2021 and February - March 2022. This clinical performance has not been established for all conceivable scenarios but is anticipated to be reflective of the prevalent strains in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants currently circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

Results

• For all COVID-19 antigen test results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19, and both your test and second test are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.

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

How to Use this Test

• 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 in asymptomatic individuals (tests performed between 3 days to 5 days) for asymptomatic individuals. You may need to purchase additional tests to perform this serial testing.

• If you have had symptoms longer than 5 days, you should consider testing at least one time over five days (with 48 hours between tests) or an anterior nasal swab sample can be collected by an individual age 14 years and older or a child age 2 to 13 years and a second sample should be collected by an adult healthcare provider. All healthcare providers will report test results they receive from individuals who use the authorized public health authorities in accordance with local and federal requirements using appropriate LCDIN and SNOMED codes, as defined by the Laboratory Information Diagnostic (LIDT) Code Mapping for SARS-CoV-2 tests provided by CDC.

• The Roche COVID-19 At-Home Test is intended for use only for the detection of SARS-CoV-2 antigens in anterior nasal (nasal) swabs from individuals who have clinical symptoms consistent with COVID-19, consistent with recent guidance from the CDC.

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 SARS-CoV-2 antigens in anterior nasal swabs from individuals who have clinical symptoms consistent with COVID-19, consistent with recent guidance from the CDC.

• 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 in asymptomatic individuals (tests performed between 3 days to 5 days) for asymptomatic individuals. You may need to purchase additional tests to perform this serial testing.

• If you have had symptoms longer than 5 days, you should consider testing at least one time over five days (with 48 hours between tests) or an anterior nasal swab sample can be collected by an individual age 14 years and older or a child age 2 to 13 years and a second sample should be collected by an adult healthcare provider. All healthcare providers will report test results they receive from individuals who use the authorized public health authorities in accordance with local and federal requirements using appropriate LCDIN and SNOMED codes, as defined by the Laboratory Information Diagnostic (LIDT) Code Mapping for SARS-CoV-2 tests provided by CDC.

• The Roche COVID-19 At-Home Test is intended for use only for the detection of SARS-CoV-2 antigens in anterior nasal (nasal) swabs from individuals who have clinical symptoms consistent with COVID-19, consistent with recent guidance from the CDC.

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 Reat (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/emergency-preparedness-and-response/medical-countermeasures/emergency-use-authorization/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 cause COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, such as the Roche 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 are more accurate in certain situations, especially when 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 uses antigen testing to help identify infected individuals for those at high risk and helps reduce the risk of reinfection. 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 (PII), available at https://support.roche.com/COVID-19-Home-Test.

Q: WHAT IF I HAVE A POSITIVE TEST RESULT?

A: A positive result means that it is likely you have COVID-19 because problems from the virus that causes COVID-19 were found in your sample. You should isolate yourself from others and contact your 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 the virus from the sample that causes COVID-19 was 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 receive 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, do 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 perform if you have COVID-19 or test if the test is invalid, a new swab should be used to collect a new nasal sample and you should have a new test.

Important

Do not consider this the only guide to managing your illness. Consult your healthcare provider if your symptoms persist or become worse.

Individuals who result in a mixed positive/negative result should consult their healthcare provider for further evaluation.

For more information on the Roche COVID-19 At-Home Test, please review the test instructions, scan this QR code or visit the website below.

https://www.roche.com/covid-19-at-home-test

For your own question about using the test or reading the test instructions, please call US 1-866-987-2472.

More Information

© 2022 Roche all rights reserved.
The PilotTM 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.

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

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
COVID-19 At-Home Test

www.sdbiosensor.com


Distribution by: Roche Diagnostics, Indianapolis, IN

For symbol glossary, refer to Quick Reference Instructions.

For more information on the PilotTM COVID-19 At-Home Test 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

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 PilotTM COVID-19 At-Home Test.
Rapid antigen test for ages 2 and up

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


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

For in vitro diagnostic use only.
Store between 36-86 °F (2-30 °C) until use.

Contents:
Test device x 4, Extraction buffer tube x 4, Nozzle cap x 4, Sterile swab x 4, 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.

Scan or Visit to learn more about COVID-19 and treatment options

Test Positive?
For in vitro diagnostic use only.

Store between 36-86 °F (2-30 °C) until use.

Contents:
1) Test device x 25
2) Extraction buffer tube x 25
3) Nozzle cap x 25
4) Sterile swab x 25
5) Tube holder x 5
6) Quick Reference Instructions (en) x 5

Needed but not provided: Timer

Rapid antigen test for ages 2 and up
For use under the Food & Drug Administration’s Emergency Use Authorization (EUA). For use under the EUA, this product has not been FDA cleared or approved; but has been authorized for use by FDA under an EUA.

• In the USA, this product has not been FDA cleared or approved.
• 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 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.
• The emergency use of this product is authorized only under the EUA 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.

Quick Results
In as few as 20 minutes
Quick Reference Instructions
For symbol glossary, refer to Quick Reference Instructions.

Test Positive?
Scan or Visit

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

IVD

TAKE CONTROL
For more information on the Pilot™ COVID-19 At-Home Test 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

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.

Not intended for use by persons with hearing impairments.
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.