**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

**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. 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 the same end of the swab.

   NOTE: With children, the maximum depth of insertion into the nostril may be less than ⅛ 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.

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.

**Read and interpret the results**

**Invalid result**

If a control line (C) is not visible (regardless of whether faint or strong), the test is not working correctly. Many factors (including age, symptoms, infection stage, etc.) may result in a false or invalid result.

**Negative result**

If a control line (C) is visible (regardless of whether faint or strong), this means that the test is working correctly. 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 test result is negative, you should test again with at least 24 hours and no more than 48 hours between tests.

**Positive result**

If a test line (T) is visible together with a control line (C), this means that the test is positive. Look carefully at the result: The test should be considered positive if two lines are visible - even if they are faint.

A positive test result means it is very likely that you have COVID-19. Please contact your doctor / primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation.

Your doctor may require you to undergo a molecular PCR test to confirm the result.

There is a very small chance that this test can give a positive result that is incorrect (a false positive).

**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.

A positive result means it is very likely that you have COVID-19. Your doctor may require you to undergo a molecular PCR test to confirm the result.

There is a very small chance that this test can give a positive result that is incorrect (a false positive).

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

**Test Procedure**

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

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   Gently remove the swab and, using the same swab, repeat the same end of the swab.

   NOTE: With children, the maximum depth of insertion into the nostril may be less than ⅛ 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.

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9. Set the timer and read the test result at 20 minutes. Do not read the result 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 and signals that the test is working properly.

**Read and interpret the results**

**Invalid result**

If a control line (C) is not visible (regardless of whether faint or strong), the test is not working correctly. Many factors (including age, symptoms, infection stage, etc.) may result in a false or invalid result.

**Negative result**

If a control line (C) is visible (regardless of whether faint or strong), this means that the test is working correctly. 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 test result is negative, you should test again with at least 24 hours and no more than 48 hours between tests.

**Positive result**

If a test line (T) is visible together with a control line (C), this means that the test is positive. Look carefully at the result: The test should be considered positive if two lines are visible - even if they are faint.

A positive test result means it is very likely that you have COVID-19. Please contact your doctor / primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation.

Your doctor may require you to undergo a molecular PCR test to confirm the result.

There is a very small chance that this test can give a positive result that is incorrect (a false positive).

**WARNING! Inaccurate test interpretations may occur if results are read before 20 minutes or 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.
**Q: WHAT IS COVID-19?**

COVID-19 is an acute respiratory infectious disease caused by the SARS-CoV-2 virus, a novel Betacoronavirus. SARS-CoV-2 is most broadly spread person-to-person, both by individuals with symptoms of COVID-19 and by infected people without symptoms. Based on the current understanding, the incubation period is 1 to 14 days, mostly 3-5 days. Symptoms include fever, fatigue, and cough. For a full list of symptoms, see: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

**Q: WILL THIS TEST HURT?**

A: No, the nasal swab is not sharp, and it should not hurt. Sometimes the swab can feel slightly uncomfortable. If you feel pain, please stop the test and seek advice from your healthcare provider.

**Q: WHAT IF YOU TEST POSITIVE?**

A: A positive test result means that antigens from SARS-CoV-2 were detected and 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, and the test result does not mean that you are safe. If you test positive, you should self-isolate and seek CDC recommendations for stopping the spread of the virus to others. Please consult the CDC recommendations regarding self-isolation at www.cdc.gov/coronavirus. Follow-up care with your healthcare provider immediately. Your healthcare provider will work with you to determine how best to care for you based on your test result(s) along with your medical history, and your symptoms.

**Q: WHAT IF YOU TEST NEGATIVE?**

A: A negative test result means that the 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, and the test result does not mean that you are safe. If you test negative, you should seek follow-up care with your healthcare provider immediately. Your healthcare provider will work with you to determine how best to care for you based on your test result(s) along with your medical history, and your symptoms.

**Q: WHAT DOES AN INVALID TEST RESULT MEAN?**

A: If no control line shows up on the test, the test 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 used to collect a new nasal specimen and the test should be run again, using a new test and tube.

**Warnings and Precautions**

Instructions are carefully performed before performing a test. Failure to follow directions may produce inaccurate test results.

- **Follow directions for use.**
- **Use the test kit once only. Do not use with multiple specimens.**
- **The test is intended to be used in the diagnosis of a current SARS-CoV-2 infection.**

Use best before the label expiration date and use by the manufacturer’s recommended date. The negative test results obtained with this test must be used 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 test to their healthcare provider for public health reporting. All healthcare providers will report all test results they receive from individuals who use the authorized test device to public health authorities, in accordance with local laws and regulations, as defined by the Laboratory at IV Diagnostics (LVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

**Limitations**

- The test procedure, precautions and interpretation of results must be followed strictly as directed.
- 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.
- The immune response cannot be evaluated using this test. Other methods are required for that purpose.
- The test does not differentiate between SARS-CoV-2 and SARS-CoV-1.

**Important**

The COVID-19 At-Home 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 test to their healthcare provider for public health reporting.

**Healthcare providers**


**Frequently Asked Questions**

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

No, the nasal swab is not sharp, and it should not hurt. Sometimes the swab can feel slightly uncomfortable. If you feel pain, please stop the test and seek advice from your healthcare provider.

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

**A:** COVID-19 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 and by infected people without symptoms. Based on the current understanding, the incubation period is 1 to 14 days, mostly 3-5 days. Symptoms include fever, fatigue, and cough. For a full list of symptoms, see: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

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A: No, the nasal swab is not sharp, and it should not hurt. Sometimes the swab can feel slightly uncomfortable. If you feel pain, please stop the test and seek advice from your healthcare provider.

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

There are different kinds of tests for COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests, such as the COVID-19 At-Home Test, detect proteins from the virus. Detection of SARS-CoV-2 virus but are not as sensitive as molecular tests. 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 product has been authorized only for the detection of an infection from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the testing of asymptomatic individuals 18 years of age and over. The test should only be used on nasal swab specimens collected from persons aged 2 years or older with symptoms of COVID-19 within the first 6 days of symptom onset. The test should be used for the detection of SARS-CoV-2 antigen in human nasal swab samples. 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. The immune response cannot be evaluated using this test. Other methods are required for that purpose. The test does not differentiate between SARS-CoV-2 and SARS-CoV-1.

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

COVID-19 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 and by infected people without symptoms. Based on the current understanding, the incubation period is 1 to 14 days, mostly 3-5 days. Symptoms include fever, fatigue, and cough. For a full list of symptoms, see: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

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**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 the result interpretation section).

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.

**Q: HOW IS SERIAL TESTING DONE?**

Serial testing is the act of testing another person 2 years or older in a non-laboratory setting. The COVID-19 At-Home Test is authorized for non-prescription self-use and/or as applicable an adult lay user testing another person 2 years or older in a non-laboratory setting. The COVID-19 At-Home Test is only for use under the Food and Drug Administration’s Emergency Use Authorization.

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COVID-19 At-Home Test

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

For further information, please scan this QR code or visit the website provided below.

For Symbol Glossary, refer to Instructions for Use.

For美术 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
- Instrucciones de referencia rápida (en) x 1
- Instrucciones de referencia rápida (es) x 1
- Required (not provided): Timer

For home testing (ages 2 and up)

For more information on the COVID-19 At-Home Test, please scan this QR Code or visit the website provided below.

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


For in vitro diagnostic use only.

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Roche order number: 09620702160

Issue date: 2022.01

Roche Diagnostics, Indianapolis, IN
www.diagnostics.roche.com

The COVID-19 At-Home Test is a lateral flow immunoassay that uses antibodies to detect nucleocapsid protein from SARS-CoV-2 in anterior nasal swabs from those with symptoms of COVID-19 within the first 6 days of symptom onset or those 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.

If you have symptoms of COVID-19, you can use a single test. If you do not have symptoms of COVID-19, you will need at least two tests per person. 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 an 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.
The COVID-19 At-Home Test is a lateral flow immunoassay that uses antibodies to detect nucleocapsid protein from SARS-CoV-2 in anterior nasal swabs from those with symptoms of COVID-19 within the first 6 days of symptom onset or those 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.

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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
- Quick Reference Instructions (es) x 1
- Timer required but not provided

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

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

For symbol glossary, refer to Instructions for Use.

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