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.

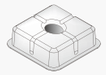
Materials Provided

Test Device (inside foil pouch 1)

Sterile Swab

Tube with Liquid (inside foil pouch 2)

Nozzle Cap



Tube Holder

Needed but not provided:
Timer

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.

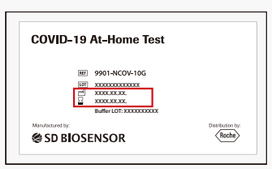
Storage and Stability

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

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 test expiry date on the back of the foil pouches. Do not use if the expiry date has passed.

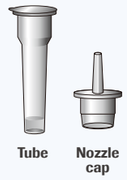


NOTE: Testing should commence immediately after opening the sealed pouches.

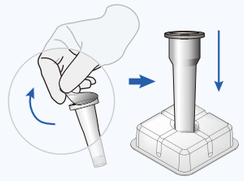
4. Open foil pouch 1 by tearing along the tear-line. Remove the test device and desiccant package from the foil pouch. Place the test device on a flat surface.
5. Ensure that the test device is intact and that there are no green beads in the desiccant package (white and yellow beads are expected). Do not open the desiccant package.

Test Procedure

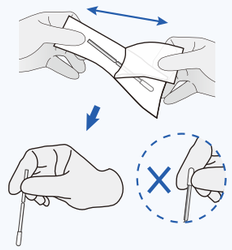
1. Open foil pouch 2 and place one tube and one nozzle cap on the table.



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.

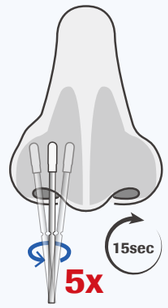


3. Holding the stick end of the swab, gently insert the foam end of the swab into the nostril approximately ¾ of an inch.

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

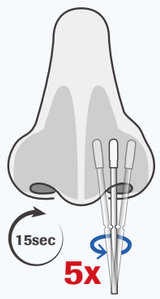
Firmly and slowly rotate the swab **at least 5 times**, brushing against the inside walls of the nostril, for a total of 15 seconds.

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



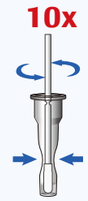
Gently remove the swab and, using the same swab, repeat in the second nostril with the same end of the swab.

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.

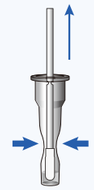


WARNING! Inaccurate test results may occur if the nasal swab specimen is not properly collected.

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.

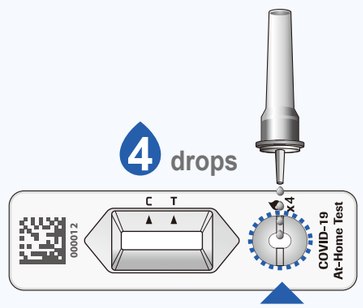


WARNING! Failure to squeeze the tube can lead to incorrect results due to excess buffer in the swab.

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.

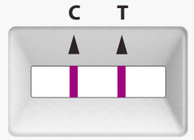
Read and interpret the results

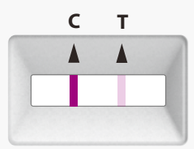
WARNING! Inaccurate test interpretations may occur if results are read before 20 minutes or after 30 minutes.

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 and signals that the test is working properly.

◀ Negative 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.





◀ Positive result

If a test line (T) is visible together with a control line (C), this means that the result 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.

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For FDA Emergency Use Authorization (EUA) only.

- For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-andresponse/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 COVID-19 At-Home Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 6 days of symptom onset.
This test is also authorized for non-prescription home use with adult-collected anterior nasal swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 6 days of symptom onset.

This test is also 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 swab samples from individuals aged 2 years or older, 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.

The 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. Antigen 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 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.

Negative results should be treated as 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 decisions. 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.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-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 healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. 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 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.

Warnings and Precautions

Read instructions carefully 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 aid in the diagnosis of a current SARS-CoV-2 infection. Please consult a healthcare professional to discuss your results and if any additional testing is required.
- Keep test kit and materials out of the reach of children and pets before and after use. If ingested, seek medical advice.
- Children below the age of 14 should not swab themselves and should instead be swabbed by an adult.
- You should wear a face mask if swabbing others.
- Do not use on anyone under two years of age.
- Do not open the kit contents until ready for use.
- Do not use the test after the expiry date shown on the test device pouch.
- Do not use the test if the pouch is damaged or open.
- This test is read visually. Users with impaired vision or color-impaired vision may not be able to read the test.
- 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.
- Use only the components of this test kit.
- 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 one.
- Remove any piercings from the nose before starting the test.
- 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.
- Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.
- Inadequate or improper nasal swab sample collection may yield false negative test results.
- Do not touch the soft pad at the top of the swab when handling the swab.
- The test is intended to be read at 20 minutes. If the test is read before 20 minutes or after 30 minutes, false negative or false positive results may occur, and the test should be repeated with a new test device.
- Do not ingest any kit components.
- Avoid exposure of your skin, eyes, nose, or mouth to the solution in the extraction tube.
- The chemicals in the reagent solution are hazardous to the skin and eye. Please see the table below for safety recommendations for skin and eye irritation. No personal protective equipment is recommended for use.

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 / 3055-99-0 ProClin® 300	Category 3	Skin irritation	Causes mild skin irritation

- If the reagent solution contacts the skin or eye, flush with plenty of water. If irritation persists, seek medical advice. https://www.poison.org/contact-us or 1-800-222-1222.

Limitations

- The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
- 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.
- 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.
- 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.

Frequently Asked Questions

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 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, 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 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: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?
A: 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. detect proteins from the virus. Antigen tests are very specific for the 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 means that there is a higher chance this test will give you a negative result when you have COVID-19. If your test result is negative, you should discuss with your healthcare provider whether an additional molecular test is necessary and if you should continue isolating at home.

Q: HOW ACCURATE IS THIS TEST?
A: The performance of the COVID-19 At-Home Test was established in a prospective clinical study using an EUA authorized molecular test as a comparator method (PPA (95.3%) and NPA (100%)). You can find further information by visiting https://go.roche.com/COVID-Home-Test or by scanning the QR code in this leaflet. The performance of this test is still being studied in patients without signs and symptoms of respiratory infection and for serial screening. Performance may differ in these populations.

Q: WHAT IS SERIAL TESTING?
A: Serial testing is when one person tests themselves multiple times for COVID-19 on a routine basis, such as every day or every other day. By testing more frequently, you may detect COVID-19 more quickly and reduce spread of infection. Serial testing (i.e. testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms. Testing for asymptomatic individuals should be performed at least twice over three days, with at least twenty-four hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.

Q: WHAT IF YOU TEST POSITIVE?
A: A positive test result means that antigens from SARS-CoV-2 were detected and it is very likely you currently have COVID-19. There is a very small chance that this test can give a positive result that is wrong (a false positive result). If you test positive you should self-isolate at home per CDC recommendations to stop spreading the virus to others. Please consult the CDC recommendations regarding self-isolation at www.cdc.gov/coronavirus. 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 IF YOU TEST NEGATIVE?
A: A negative test result indicates no 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 even though the test is negative. If you test negative and continue to experience symptoms of fever, cough and/or shortness of breath you should seek follow up care with your healthcare provider immediately. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. If you are concerned about your COVID-19 status after testing or think you may need follow up testing, please contact your healthcare provider.

Q: WHAT DOES AN INVALID TEST RESULT MEAN?
A: 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 used to collect a new nasal specimen and the test should be run again, using a new test and tube.

Important

This 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.

Healthcare providers

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

Index of Symbols

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

For more information on the COVID-19 At-Home Test please scan this QR code.

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

L20SCR20EN02R1
Issue date: 2022.01

09635807001
V 2.0 Revision date: 2022.01

SD Biosensor, Inc.
Head office: C- 4th & 5th, 16, Deogyeong-daero 1556 beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC of KOREA
Manufacturing site: 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA

Distribution in USA by:
Roche Diagnostics, Indianapolis, IN
US COVID-19 General Support 1.866.987.6243
www.diagnostics.roche.com

COVID-19 At-Home Test

1 TEST KIT

For home testing (ages 2 and up)

RAPID RESULTS
In just 20 minutes

EASY TO USE
With a simple nasal swab

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

UDI Label

IVD

2 °C 36 °F
30 °C 86 °F
1

For symbol glossary, refer to Instructions for Use.

Distribution by:

Roche

COVID-19 At-Home Test

(EN) **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, Quick Reference Instructions (es) x 1
Needed but not provided: Timer

(ES) **Para uso diagnóstico in vitro exclusivamente.**
Conservar entre 36–86 °F (2–30 °C) hasta el uso.
Contenido: Casete de test x 1, tubo de tampón de extracción x 1, capuchón de aguja x 1, torunda estéril x 1, soporte para tubo x 1, Instrucciones de referencia rápida (en) x 1, Instrucciones de referencia rápida (es) x 1
Requerido adicionalmente (no suministrado): Cronómetro

REF 9901-NCOV-10G

GTIN 8800111707520

Cat No.:
99COV200-EN02
Roche order number:
09620702160

Distribution by:

Roche

COVID-19 At-Home Test

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

(ES) Para obtener más información sobre COVID-19 At-Home Test, escanee el código QR o visite el sitio web siguiente:

https://go.roche.com/COVID-Home-Test
US COVID-19 General Support:
1-866-987-6243

Distribution by:

Roche

COVID-19 At-Home Test

- 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 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.

B01SCR20EN02R1
Issue date: 2022.01

09621954001(01)

COVID-19 At-Home Test

SD BIOSENSOR
Head office: C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
Manufacturing site: 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA
www.sdbiosensor.com

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

COVID-19 At-Home Test

4 TESTS KIT

Distribution by:

Roche

- 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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- 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.

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

(ES) Para obtener más información sobre COVID-19 At-Home Test, escanee el código QR o visite el sitio web siguiente.

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

Distribution by:

Roche

REF 09015-NCOV-10G

GTIN 08800111707728

Roche Order No.: 09666672160

Cat No.: 99COV200L-EN02

09667199001(01)
B04SCRZ0LEN02R0
Issue date: 2022.01

(EN) **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, Needed but not provided: Timer

(ES) **Para uso diagnóstico in vitro exclusivamente.**
Conservar entre 36-86 °F (2-30 °C) hasta el uso.
Contenido: Casete de test x 4, tubo de tampón de extracción x 4, capuchón de aguja x 4, torunda estéril x 4, soporte para tubo x 1, Instrucciones de referencia rápida (en) x 1, Instrucciones de referencia rápida (es) x 1, Requerido adicionalmente (no suministrado): Cronómetro

SD BIOSENSOR
Head office: C-4th & 5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA

Manufacturing site: 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA
www.sdbiosensor.com

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

COVID-19 At-Home Test

4 TESTS KIT

For home testing (ages 2 and up)

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

>> US COVID-19 General Support: 1-866-987-6243

IVD 2 °C 36 °F 30 °C 86 °F 4

For symbol glossary, refer to Instructions for Use.

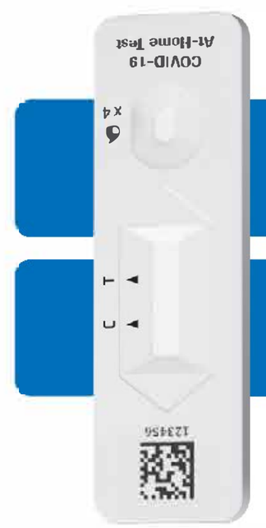
Distribution by:

Roche

COVID-19 At-Home Test

25 TESTS KIT

For home testing (ages 2 and up)



RAPID RESULTS
In just 20 minutes

EASY TO USE
With a simple nasal swab

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

>> US COVID-19 General Support: 1-866-987-6243

IVD | 2 °C 36 °F – 30 °C 86 °F | 25

For symbol glossary, refer to Instructions for Use.

Distribution by:

Roche

COVID-19 At-Home Test

25 TESTS KIT

(EN)

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

CONTENTS

1) Test devices x 25
2) Extraction buffer tubes x 25
3) Nozzle caps x 25
4) Sterile swabs x 25
5) Tube holders x 5
6) Quick Reference Instructions (en) x 5
7) Quick Reference Instructions (es) x 5

Needed but not provided: Timer

(ES)

Para uso diagnóstico in vitro exclusivamente.
Conservar entre 36-66 °F (2-30 °C) hasta el uso.

CONTENIDO

1) Casetes de test x 25
2) Tubos de tampón de extracción x 25
3) Capuchones de eguja x 25
4) Torundas estériles x 25
5) Soportes para tubos x 5
6) Instrucciones de referencia rápida (en) x 5
7) Instrucciones de referencia rápida (es) x 5

Requerido adicionalmente (no suministrado): Cronómetro

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

(ES) **Para obtener más información sobre COVID-19 At-Home Test, escanee el código QR o visite el sitio web siguiente.**

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

Distribution by:

Roche

COVID-19 At-Home Test

REF 9901-NCOV-10G
GTIN 8800111707513
Cat No.: 99COV200D-EN02
Roche order number: 09620729160

UDI Label

Distribution by:

Roche

COVID-19 At-Home Test

25 TESTS KIT

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

(ES) **Para obtener más información sobre COVID-19 At-Home Test, escanee el código QR o visite el sitio web siguiente.**

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

- 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 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

B25SCR20DEN02R1
Issue date: 2022.01

09621989001(01)

COVID-19 At-Home Test

SD BIOSENSOR
Head office: C-4th & 5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
Manufacturing site: 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA
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