

The CareStart[™] COVID-19 Antigen 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 7 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 CareStart™ COVID-19 Antigen Home Test does not differentiate between SARS-CoV or SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal (nares) samples 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 and the agent detected may not be the definitive cause of disease. Individuals who test positive with the CareStart™ COVID-19 Antigen 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 with 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 requ using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Page 2 of 19 Mapping for SARS-CoV-2 Tests provided by CDC.

The CareStart[™] COVID-19 Antigen Home Test is intended 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 CareStart[™] COVID-19 Antigen Home Test is only for *in vitro* diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

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 - The performance of this test was established based on the evaluation of a limited number of clinical performance as 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 headth or the second tests are negative. 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

- Incorrect test results may occur if a specimen is incorrectly collected or handled.

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.

Warnings, Precautions, and Safety Information

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 7 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.

Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your skin or eyes. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin or eyes, flush with large amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.

Chemical Name/CAS	Harms (GHS Code) for each Ingredient	Concentration
Boric Acid/ 10043-35-3	H360 May damage fertility or the unborn child.	0.38%
Ethylenediaminetetraacetic acid (EDTA)/13235-36-4	H302 Harmful if swallowed. H318 Causes serious eye damage.	0.08%
Sodium Chloride (NaCl)/ 7647-14-5	None	4.38%
Triton X-100/9002-93-1	H302 Harmful if swallowed. H315 Causes skin irritation. H318 Causes serious eye damage. H410 Very toxic to aquatic life with long-lasting effects.	1.50%
N-Lauroylsarcosine sodium salt/137-16-6	H315 Causes skin irritation. H318 Causes serious eye damage. H330 Fatal if inhaled.	0.15%

- Once opened, the test device should be used immediately.

- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual. Wash hands thoroughly for at least 20 seconds before and after handling nasal swab samples.

Keep the test device on a flat surface during the testing.

 Keep foreign substances and household cleaning products away from the test during the testing
process. Contact with foreign substances and household cleaning products may result in an incorrect test result

- False negative results may occur if a specimen is incorrectly collected or handles, or inadequately stored. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false-positive result. Avoid touching any bleeding areas of the nasal cavity when collecting specimens.

- False negative results may occur if a specimen is incorrectly collected or handled, or inadequately stored.

- When collecting a pasal swab sample use only the Nasal Swab provided in the kit

- Do not touch the swab tip (specimen collection area of the swab).

- Do not operate your test outside of storage conditions.

- Do not close the App during processing as it may cause an error and you will need a new test kit. Do not read test results before 10 minutes or after 15 minutes. Results read before 10 minutes or after 15 minutes may lead to a false positive, false negative, or invalid result.
 Do not use if any of the test kit contents or packaging is damaged.

Test components are single-use. Do not re-use.

- Do not use kit past its expiration date.

- Do not interchange kit contents from different lots.

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

Explanation of Symbols	In vitro diagnostic medical device Indicates a medical device that is intended to be used as an <i>in vitro</i> diagnostic medical device	Manufacturer Indicates the medical device manufacturer.	Do not re-use Indicates a medical device that is intended for one use.	REF Catalog number Indicates the manufacturer's catalog number so that the medical device can be identified.	Date of manufacture Indicates the date when the medical device was manufactured.	Do not use if the package is damaged Indicates a medical device that should not be used if the package has been damaged or opened.
	Consult instructions for use Indicates the need for the user to consult the instructions for use.	LOT Batch code Indicates the manufacturer's batch code so that the batch or lot can be identified.	Use by date Indicates the date after which the medical device is not to be used.	▲ Caution Indicates the need for the user to consult accompanying documents	Temperature limit Indicates the temperature limits to which the medical device can be safely exposed.	Contains sufficient for <n> tests Indicates the total number of IVD tests that can be performed with the IVD.</n>

Explicación de los símbolos

Fabricante Designa el fabricante del dispositivo médico. Código de lote Designa el código de lote del fabricante para poder identificar el lote. No reutilice Indica un dispositivo médico destinado a Fecha de caducidad Indica la fecha a partir de la cual no debe utilizarse el dispositivo médico. REF Número de catálogo Designa el número de catálogo del fabricante Precaución Señala la necesidad de que el usuario consulte los documentos acompañan



CareStart[™] COVID-19 Antigen Home Test

WHAT ARE THE KNOWN AND POTENTIAL RISKS AND BENEFITS OF THE TEST?

Potential risks include:

-Possible discomfort during sample collection.

-Possible incorrect test result (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 recommendations about your care. -The results of this test may help limit the potential 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-respose/mcm-le-gal-regulatory-and-policy-framework/emergency-use-authorization

WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?

There are different kinds of tests for the SARS-CoV-2 virus that causes COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, such as the CareStart™ COVID-19 Antigen 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.

HOW ACCURATE IS THIS TEST?

Clinical studies have shown that antigen tests more accurately, determine whether you are infected with the virus that causes COVID-19 when taken multiple times across several days. Repeat testing improves test accuracy, while the several days are infected with the several days. 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://accessbio.net/products/covid-19-detection-kits/carestart-covid-19-antigen-home-test/home-kit-usa.

WHAT IF I HAVE A POSITIVE TEST RESULT?

A positive result means that it is very likely you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. You should selfisolate from others and contact a healthcare provider for medical advice about your positive result.

WHAT IF I HAVE A NEGATIVE TEST RESULT?

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 may still be infected and you may still be nfect others. It is important that you work with your healthcare provider to help you understand the next steps you should take

WHAT IF I HAVE AN INVALID TEST RESULT?

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.

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