REF RCPM - 00171, RCPM - 00271, RCPM-00471, RCPM-02071

ENGLISH

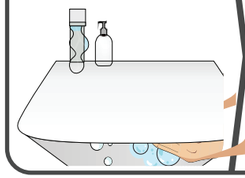
CareStart™ COVID-19 Antigen Home Test — USER INSTRUCTIONS

You must follow the test directions carefully to get an accurate result.
Visit accessbio.net to obtain the complete instructions for use.
FOR USE UNDER EMERGENCY USE AUTHORIZATION (EUA) ONLY.

IVD 1 °C 34 °F 30 °C 86 °F

IMPORTANT: Swabbing the nostrils is critical for obtaining an accurate result. If you do not swab your nose, the device will produce a false negative result.

1 Wash your hands thoroughly for at least 20 seconds before the test.

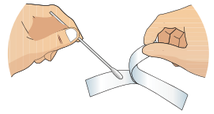


2 Unpack the test components from the tray.

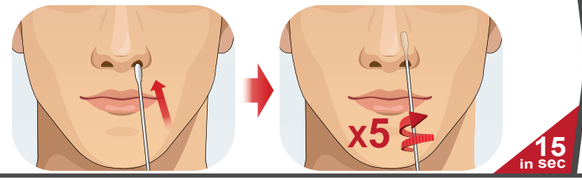
3 Remove the test cassette and place it on a flat, clean surface.

4 Locate the extraction vial and gently peel off the aluminum foil seal, being sure to keep the vial upright and place it in the packaging tray.

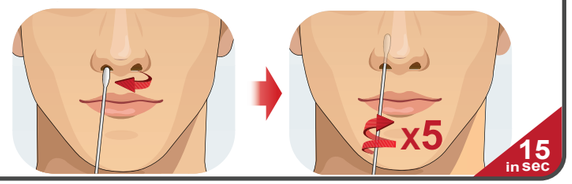
5 Locate a nasal swab and remove from the pouch. Be careful not to touch the swab tip.



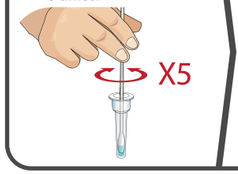
6 Gently insert the swab no more than 3/4 inch into the **LEFT** nostril. Then, slowly rotate the swab at least **5 times** in a circular path for a total of **15 seconds**. If you have questions, see the CDC Guidelines.



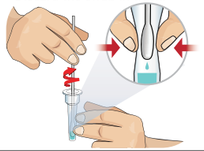
7 Gently remove the swab from the **LEFT** nostril and place directly into the **RIGHT** nostril, repeating the process of rotating at least **5 times** in a circular path for a total of **15 seconds**. Remove the swab from the RIGHT nostril.



8 Place the swab into the extraction vial. Rotate the swab vigorously at least **5 times.**



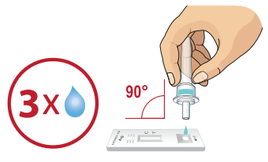
9 Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab. Discard the swab in trash.



10 Close the vial by pushing the cap firmly onto the vial.

11 With your finger, mix thoroughly by flicking the bottom of the vial.

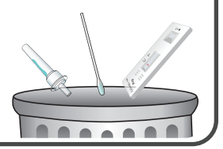
12 Invert the extraction vial and hold the sample vertically above the sample well. Squeeze the vial gently. Allow **THREE (3)** drops of sample to fall into the sample well.



13 Start a timer.
Read the result at **10 minutes**. The test result should not be read after 15 minutes.

IMPORTANT
Do not move or lift the test cassette during this time. Do not exit the mobile app during this process.

Disposal
Dispose of all used test kit components and swab samples in household trash.



Using Mobile Application

Scan the QR code to download

- **Ensure you have an internet connection and download the App prior to starting the test**
- **Ensure you are using a compatible smartphone.**
  (For a list of compatible smartphone OS systems, visit www.accessbio.net/app)
- **Only open the foil pouch packaging of test cassette when the App instructed to do so.**

Please start the test and follow the in-app self-paced, step-by-step test instructions.

1. Download and open App, On/Go™ Mobile Application
Download the App on the App Store or Google Play Store. Ensure you are connected to the internet during your test.

2. Answer a few questions in the App

3. Watch the instructional video.

4. Follow step-by-step instructions for your test.

5. Test result
The App will assist in your visual result interpretation. Please follow the instructions provided in the App. You will be required to take a picture of the test device, and then look at the test cassette and answer questions about the result interpretation.

Results Interpretation

Make sure you wait the full 10 minutes.

You will be able to interpret your test results by following the in-app interpretation instructions or those provided below.

NOTE: The test results should be read by visual and interpreted at 10 minutes after the sample application and interpretation of the results should not exceed 15 minutes as it may yield inaccurate results.

COVID-19 Detected (Positive)

One purple-colored line next to "C" and one blue-colored line next to "T" indicates COVID-19 positive result.

IMPORTANT **Look very closely! The color intensity in the test region will vary. Any faint colored line in the test region should be considered as positive.**

A positive test result indicates that antigens from SARS-CoV-2 were detected, and the patient is very likely to be infected with the virus and presumed to be contagious. Test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions. You should self-isolate at home and avoid contact with others as per CDC recommendations to avoid spreading the virus to others.

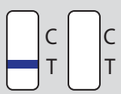
COVID-19 Not Detected (Negative)

One purple-colored line only next to "C" indicates a negative result.

Re-test in 24-48 hours if your first test result is negative.
A negative test result indicates that antigens from SARS-CoV-2 were not detected from the specimen. However, a negative result does not rule out COVID-19 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 COVID19 and confirmed with a molecular assay, if necessary, for patient management.

Invalid

Invalid barcode or absence of a purple-colored line next to "C".



Re-test with a COVID-19 test may be needed.
An invalid test result indicates that your test has experienced an error and is unable to interpret the result of the test. You will need to re-test with a new test or consult a healthcare professional. If you still have symptoms, you should self-isolate at home and avoid contact with others prior to the retest.

REF RCPM - 00171, RCPM - 00271, RCPM-00471, RCPM-02071

ESPAÑOL

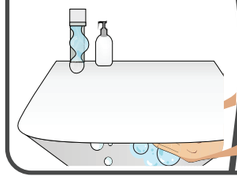
Prueba domiciliaria *CareStart*™ COVID-19 Antigen — INSTRUCCIONES PARA EL USUARIO

Debe seguir cuidadosamente las instrucciones de la prueba para obtener un resultado preciso. Visite accessbio.net para obtener instrucciones de uso completas.
SOLO PARA USO CON LA AUTORIZACIÓN DE USO DE EMERGENCIA (EUA).

IVD 1 °C 34 °F 30 °C 86 °F

IMPORTANTE: Hisopar las fosas nasales es fundamental para obtener un resultado preciso. Si no se hisopa la nariz, el dispositivo generará un resultado falso negativo.

1 Lávese bien las manos durante al menos 20 segundos antes de la prueba.

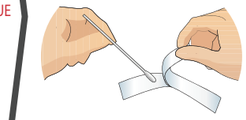


2 Quite los componentes de la prueba del empaque de la bandeja.

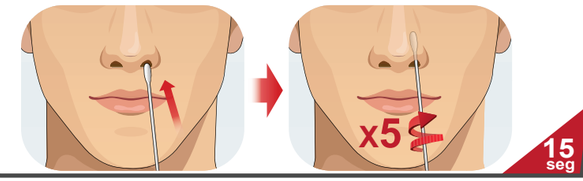
3 Quite el casete de la prueba y colóquelo sobre una superficie plana y limpia.

4 Encuentre el vial de extracción y quite suavemente el sello de papel aluminio, asegurándose de mantener el vial en posición vertical, y colóquelo sobre la bandeja de empaquetado.

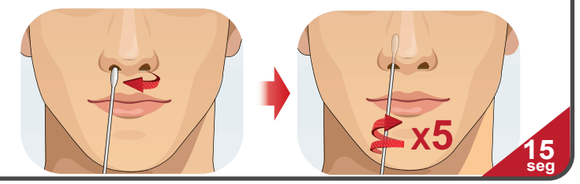
5 Encuentre el hisopo nasal y quítelo de la bolsa. Tenga cuidado de no tocar la punta del hisopo.



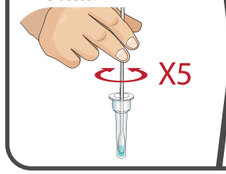
6 Inserte suavemente el hisopo no más de 3/4 pulgadas en la fosa nasal **IZQUIERDA**. Luego, gire el hisopo lentamente al menos **5 veces** de manera circular durante un total de **15 segundos**. Si tiene preguntas, consulte las pautas del CDC.



7 Quite suavemente el hisopo de la fosa nasal **IZQUIERDA** y colóquelo directamente en la fosa nasal **DERECHA**, y repita el proceso de rotar al menos **5 veces** de manera circular durante al menos **15 segundos**. Quite el hisopo de la fosa nasal DERECHA.

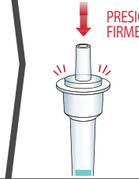


8 Coloque el hisopo en el vial de extracción. Gírelo enérgicamente al menos **5 veces.**



9 Retire el hisopo al girarlo contra el vial de extracción mientras aprieta los lados del vial para liberar el líquido del hisopo. Descarte el hisopo en la basura.

10 Cierre el vial al colocar la tapa firmemente en el vial.



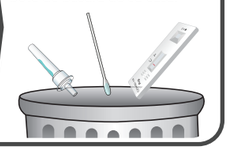
11 Con el dedo, mezcle bien al golpear la parte inferior del vial.

12 Invierta el vial de extracción y sostenga la muestra verticalmente por encima del pocillo de la muestra. Apriete el vial suavemente. Deje caer **TRES (3)** gotas de la muestra en el pocillo de la muestra.

13 Inicie un temporizador.
Lea el resultado a los **10 minutos.** El resultado de la prueba no debe interpretarse pasados los 15 minutos.

IMPORTANTE
No mueva ni levante el casete de la prueba durante este tiempo. No salga de la aplicación móvil durante este proceso.

Desecho
Deseche todos los componentes del kit de prueba utilizados y las muestras del hisopado en el bote de basura de su casa.



Usar la aplicación móvil

Escanee el código QR para descargar

- **Asegúrese de tener conexión a Internet y descargue la aplicación antes de comenzar la prueba.**
- **Asegúrese de utilizar un teléfono inteligente compatible.**
  (Para una lista de teléfonos inteligentes de sistemas OS, visite www.accessbio.net/app)
- **Solo abra el empaque de la bolsa de aluminio del casete de la prueba cuando la aplicacion se lo indique.**

Para comenzar la prueba, siga las instrucciones paso a paso y a su propio ritmo de la aplicación.

1. Descargue y abra la aplicación, On/Go™ Mobile Application
Descargue la aplicación del App Store o del Google Play Store. Asegúrese de estar conectado a Internet durante la prueba.

2. Responda algunas preguntas en la aplicación

3. Mire el video instructivo.

4. Siga las instrucciones paso a paso de la prueba.

5. Resultado de pruebas
La aplicación lo ayudará con la interpretación visual de los resultados. Siga las instrucciones que se proporcionan en la aplicación. Se le pedirá que tome una imagen del dispositivo de prueba y luego observe el casete de la prueba y responda las preguntas sobre la interpretación de resultados.

Interpretación de los resultados

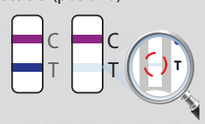
Asegúrese de esperar los 10 minutos completos.

Podrá interpretar los resultados de la prueba siguiendo las instrucciones de interpretación de la aplicación o aquellas que se proporcionan a continuación.

NOTA: Los resultados de la prueba deben leerse e interpretarse mediante lectura visual a los 10 minutos luego de la aplicación e interpretación de la muestra y no deben leerse ni interpretarse pasados los 15 minutos, ya que puede arrojar resultados poco precisos.

COVID-19 detectado (positivo)

Una línea púrpura junto a una "C" y una línea azul junto a una "T" indican un resultado positivo por COVID-19.



IMPORTANTE **¡Mire bien de cerca! La intensidad de color en la región de prueba variará. Todas las líneas de color tenues en las regiones de prueba deben considerarse positivas.**

Un resultado positivo de la prueba indica que se detectaron antígenos del SARS-CoV-2, y que es muy probable que el paciente esté infectado con el virus y pueda contagiar. Los resultados de la prueba siempre deben considerarse en el contexto de las observaciones clínicas y los datos epidemiológicos al realizar un diagnóstico final y al tomar decisiones de manejo del paciente. Debe aislarse en casa y evitar el contacto con los demás conforme a las recomendaciones del CDC para evitar la propagación del virus.

COVID-19 no detectado (negativo)

Una sola línea púrpura junto a una "C" indica un resultado negativo.

Vuelva a analizar en 24 a 48 horas si el primer resultado de la prueba es negativo.
Un resultado negativo de la prueba indica que los antígenos del SARS-CoV-2 no se detectaron en la muestra. Sin embargo, un resultado negativo no descarta el COVID-19 y no debe considerarse como el único fundamento para el tratamiento o la toma de decisiones sobre el manejo de los pacientes, incluidas las decisiones relativas al control de la infección. Los resultados negativos deben considerarse en el contexto de las exposiciones recientes, los antecedentes y la presencia de signos y síntomas clínicos de la persona que sean consistentes con COVID-19, y confirmados con un ensayo molecular, si fuese necesario, para el manejo del paciente.

Inválido

Código de barras inválido o ausencia de una línea de color púrpura junto a una "C".

Es posible que sea necesario volver a analizar con una prueba de COVID-19. Un resultado de prueba inválido indica que la prueba ha arrojado un error y no se pudo interpretar el resultado de la prueba. Tendrá que volver a realizar una nueva prueba o consultar a un profesional de atención médica. Si aún tiene síntomas, debe aislarse en casa y evitar el contacto con los demás antes de volver a realizar la prueba.

Intended Use

The *CareStart*™ COVID-19 Antigen Home Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigens 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 7 days of symptom onset. This test is also authorized for non-prescription home use with adult-collected nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 7 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 (nares) 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.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. The antigen is generally detectable in anterior nasal (nares) swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical 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 definite 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.

Negative results should be treated as presumptive and confirmation with a molecular assay for patient management, may be performed if necessary.

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, 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 COVID-19, 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 (LVID) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The *CareStart*™ COVID-19 Antigen Home Test is authorized for non-prescription self-use and/or, as applicable for an adult lay user testing another person aged 2 years or older. The *CareStart*™ COVID-19 Antigen Home Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Important Note

- For *in vitro* diagnostic use only.
- This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA).
- 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 the 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.

DO's

- Children aged 13 years old and younger should be tested by a parent or legal guardian.
- Wear a safety mask or other face-covering when collecting anterior nares swab specimen from a child or another individual.
- Wash hands thoroughly for at least 20 seconds before and after handling nasal swab samples.
- In order to obtain accurate results, the user must follow the instructions for use.
- Immediately use after opening the test device in the pouch.
- Keep the test device on a flat surface during the testing.
- Keep testing kit and kit components away from children and pets before and after use.
- 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.
- Inadequate or inappropriate sample collection, storage, and transport can result in incorrect results. If specimen storage is necessary, swabs can be placed into the extraction vial for up to four hours. Specimens should not be stored dry.
- When collecting a nasal swab sample, use only the Nasal Swab provided in the kit.
- 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.
- Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
- Handle all specimens as though they contain infectious agents.
- 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.

DON'Ts

- Do not operate your test outside of storage conditions.
- Do not use on anyone under 2 years of age.
- Do not close the App during processing as it may cause an error and you will need a new test kit.
- Do not interpret the test result before 10 minutes and after 15 minutes starting the test.
- Do not use on anyone who is prone to nosebleeds or has had facial or head injury/surgery in the last 6 months.
- Do not use if the test device package is damaged.
- Do not touch the tip (specimen collection area) of the swab.
- Do not use the kit contents beyond the expiration date.
- Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.
- Do not interchange kit contents from different lots.
- Do not re-use any contents in the kit as they are single-use only.
- Eye and skin contact with the extraction solution should be avoided.
- Extraction solution should not be ingested.

Hazardous Ingredients for Liquid Reagent

The extraction solution in the vial contains potentially harmful chemicals (see table below). If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, seek medical advice: https://www.poison.org/contact-us or 1-800-222-1222.

Chemical Name	GHS Code for each Ingredient	Concentration
Triton X-100	H315, skin irritation	1.5%
N-Lauroylsarcosine sodium salt	H315, skin irritation	0.15%

Frequently Asked Questions

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

What are the symptoms of COVID-19?
Many individuals with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), although some individuals experience only mild symptoms or even no symptoms at all. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that, when present, symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste or smell, nausea or vomiting or diarrhea. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, with the median time to symptom onset is approximately 5 days.

What is serial testing?
Serial testing is when a single person is tested for COVID-19 more than once. Because antigen tests are less sensitive than other COVID-19 tests and false results may occur, repeated testing may identify more individuals with COVID-19 infection than a single test. 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. By repeating testing, it may be possible to more quickly identify cases of COVID-19 infection and reduce spread of infection. Additional testing with molecular COVID-19 test may be necessary, depending on your individual risk factors and test results. It is important that you work with your healthcare provider to help you understand the next steps you should take.

What if I have a positive test result?
If you have a positive test result, it is very likely that you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. 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 with the *CareStart*™ COVID-19 Antigen Home Test you should self-isolate and seek follow-up care with your healthcare provider as additional testing may be necessary. 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.

What are the known and potential risks and benefits of the test?
Potential risks include:
- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below 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.

What if I have a negative test result?
A negative test result means that proteins from the virus that causes COVID-19 was not found in your sample. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means you could possibly still have COVID-19 even though the test is negative. The amount of antigen in a sample may decrease the longer you have symptoms of infection. In symptomatic people, specimens collected after you have had symptoms for more than five days may be more likely to be negative compared to a molecular assay. 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 you test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath you should seek follow up care with your healthcare provider. For example, 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 infection status after testing or think you may need follow up testing, please contact your healthcare provider.

How accurate is this test?
A study evaluating the clinical performance characteristics of the *CareStart*™ COVID-19 Antigen Home Test was conducted at 7 different locations in the U.S. between March 2021 and May 2021. Among 153 subjects enrolled to the study with signs and symptoms of COVID-19 within the first 7 days of symptom onset, individuals aged 14 and older self-collected and aged 13 and younger adult collected anterior nasal swab samples, and the samples were tested with the *CareStart*™ COVID-19 Antigen Home Test. The results compared against an FDA Emergency Use Authorized RT-PCR molecular assay demonstrated that the *CareStart*™ COVID-19 Antigen Home Test correctly identified 87% of positive samples and 98% of negative samples.

Explanation of Symbols

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

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Uso previsto

La prueba casera *CareStart*™ COVID-19 Antigen es un inmunoensayo de flujo lateral que pretende detectar de manera cualitativa los antígenos de la proteína de la nucleocápside del SARS-CoV-2.

Esta prueba está autorizada para uso domiciliario sin prescripci n médica con muestras de hisopos nasales anteriores (narinas) recolectadas por ellos mismos de personas de 14 a os o más con síntomas de COVID-19 dentro de los primeros 7 días de la aparici n de los síntomas. Esta prueba también está autorizada para uso doméstico sin receta con muestras de hisopos nasales (narinas) recolectadas por adultos de personas de 2 a os o más con síntomas de COVID-19 dentro de los primeros 7 días de la aparici n de los síntomas.

Esta prueba también está autorizada para uso domiciliario sin prescripci n médica con muestras de hisopos nasales anteriores (narinas) recolectadas por ellos mismos de personas de 14 a os o más u obtenidas por un adulto de personas de 2 a os o más, con o sin síntomas u otros motivos epidemiológicos que den sospecha de infecci n por COVID-19 cuando se prueba dos veces durante tres días con al menos 24 horas (y no más de 48 horas) entre pruebas.

El objetivo es identificar la proteína de la nucleocápside del antígeno de SARS-CoV-2. Por lo general, el antígeno se detecta en muestras de hisopados nasales anteriores (narinas) durante la fase aguda de la infecci n. Los resultados positivos indican la presencia de antígenos virales, pero para determinar el estado de la infecci n se requiere la correlaci n clínica con el historial médico anterior y otra informaci n de diagn stico. Los resultados positivos no descartan una infecci n bacteriana o una coinfecci n con otros virus y es posible que el agente detectado no sea la causa definitiva de la enfermedad. Las personas que arrojan resultado positivo con la prueba domiciliaria *CareStart*™ COVID-19 Antigen deben aislarse y buscar atenci n de seguimiento con su médico o proveedor de atenci n médica, ya que es posible que se necesiten pruebas adicionales.

Los resultados negativos deben tratarse como presuntos y es posible que se realice una confirmaci n con un ensayo molecular para el manejo de los pacientes, de ser necesario. Los resultados negativos no descartan la infecci n por el SARS-CoV-2 y no deben considerarse como el nico fundamento para el tratamiento o la toma de decisiones sobre el manejo de los pacientes, incluidas las decisiones relativas al control de la infecci n. Los resultados negativos deben analizarse en funci n de la exposici n reciente de la persona, sus antecedentes y la presencia de signos y síntomas clínicos compatibles con COVID-19.

En el caso de los programas de pruebas en serie, es posible que sean necesarias pruebas de confirmaci n adicionales con una prueba molecular de resultados negativos, si hay una alta probabilidad de infecci n por COVID-19, como un individuo con contacto estrecho de COVID-19 o con una supuesta exposici n a COVID-19, o en comunidades con una alta prevalencia de infecci n. También es posible que sean necesarias pruebas de confirmaci n adicionales con una prueba molecular para detectar resultados positivos, si hay una baja probabilidad de infecci n por COVID-19, como en el caso de individuos sin exposiciones conocidas a COVID-19 o que residen en comunidades con una baja prevalencia de infecci n.

Las personas que arrojan resultado negativo y siguen experimentando síntomas de COVID, como fiebre, tos y dificultad para respirar a n podrían tener infecci n por SARS-CoV-2 y deben buscar atenci n de seguimiento de su proveedor de atenci n médica.

Las personas deben proporcionar todos los resultados obtenidos con este producto a su proveedor de atenci n médica para fines de informes a la salud p blica. Todos los proveedores de atenci n médica informarán todos los resultados de las pruebas que reciben de las personas que usen el producto autorizado a las autoridades de salud p blica relevantes conforme a los requisitos locales, estatales, y federales, mediante los c digos LOINC y SNOMED apropiados, tal como lo define el Mapeo de c digos de prueba de diagn stico in vitro de laboratorio (Laboratory In Vitro Diagnostics, LVID) para las pruebas de SARS-CoV-2 proporcionadas por el CDC.

La prueba domiciliaria *CareStart*™ COVID-19 Antigen está autorizada para uso personal sin receta o, seg n corresponda, para un adulto que le realice la prueba a un ni o de 2 a os de edad o más. La prueba domiciliaria *CareStart*™ COVID-19 Antigen solo puede utilizarse de conformidad con la Autorizaci n de uso de emergencia de la Administraci n de Medicamentos y Alimentos.A

Nota importante

- Solo para uso *in vitro* y diagnóstico.
- Este producto no ha sido aprobado por la FDA, pero ha sido autorizado por la FDA en virtud de una Autorizaci n de uso de emergencia (Emergency Authorization Use, EUA).
- Este producto ha sido autorizado solo para la detecci n de proteínas de SARS-CoV-2, no para otros virus o pat genos.
- El uso de emergencia de este producto solo está autorizado para la duraci n de la declaraci n de que existen circunstancias que justifican la autorización del uso de emergencia de pruebas de diagnóstico in vitro para la detección o el diagnóstico de COVID-19 de conformidad con la Secci n 564(b)(1) de la Ley Federal de Alimentos, Medicamentos y Cosméticos de Estados Unidos, Secci n 360bbb-3(b)(1) del Título 21 del C digo de los Estados Unidos, a menos que se haya cancelado antes la declaraci n o se haya revocado antes la autorizaci n.

SÍ

- Los ni os de 13 a os de edad o menos deben ser analizados por el padre, la madre o el tutor legal.
- Utilice una máscara de seguridad o otro tipo de mascarilla cuando obtenga muestras de hisopado nasal anterior de un ni o u otra persona.
- Lávese las manos minuciosamente durante al menos 20 segundos antes y después de manipular muestras de hisopado nasal.
- Para obtener resultados precisos, el usuario debe seguir las instrucciones de uso.
- Debe usarse inmediatamente después de abrir el dispositivo de prueba de la bolsa.
- Mantenga el dispositivo de prueba sobre una superficie plana durante la prueba.
- Mantenga el kit de prueba y los componentes del kit lejos de los ni os y las mascotas antes y después del uso.
- El exceso de sangre o mucosidad en la muestra del hisopado puede interferir con el rendimiento de la prueba y dar un resultado falso positivo. Evite tocar las áreas de sangrado de la cavidad nasal al recolectar las muestras.
- La obtenci n, el almacenamiento y el transporte inadecuadoA oA inapropiadoA de muestras puede dar lugar a resultados incorrectos. Si el almacenamiento de la muestra es necesario, los hisopos se pueden colocar en el vial de extracci n hasta por cuatro horas. Las muestras no deben guardarse en un lugar seco.
- Al obtener la muestra de hisopado nasal, utilice nicamente el hisopo nasal que se incluye en el kit.
- Mantenga las sustancias extra as y los productos de limpieza del hogar lejos de la prueba durante el proceso de prueba. El contacto con sustancias extra as y productos de limpieza del hogar puede dar lugar a un resultado de prueba incorrecto.
- Tome las precauciones adecuadas durante la recolecci n, manipulaci n, almacenamiento y desecho de las muestras de los pacientes y del contenido del kit que se haya utilizado.
- Manipule todas las muestras como si contuvieran agentes infecciosos.
- Las pruebas para individuos asintomáticos deben realizarse al menos dos veces durante tres días, con al menos 24Ahoras y no más de 48 horas entre pruebas. Es posible que deba comprar pruebas adicionales para realizar esta prueba en serie (repetici n).

NO

- No manipule su prueba fuera de las condiciones de almacenamiento.
- No utilizar en personas menores de 2 a os de edad.
- No cierre la aplicaci n durante el procesamiento, ya que podría causar un error y necesitará un nuevo kit de prueba.
- No interprete el resultado de la prueba antes de los 10 minutos ni después de 15 minutos de iniciarla.
- No lo utilice en personas con tendencia a sangrado nasal o que tuvieron una cirugía o lesi n facial o de cabeza en los l timos 6 meses.
- No lo utilice si el paquete del dispositivo de prueba está da ado.
- No toque la punta (área de recolecci n de la muestra) del hisopo.
- No use el contenido del kit pasada la fecha de caducidad.
- No coma, beba ni fume en el área de manipulaci n de las muestras y el contenido del kit.
- No intercambie el contenido del kit de diferentes lotes.
- No reutilice ning n contenido del kit ya que está destinado para un solo uso.
- Se debe evitar el contacto de ojos y piel con la soluci n de la extracci n.
- No se debe ingerir la soluci n de la extracci n.

Ingredientes peligrosos para el reactivo líquido

La soluci n de extracci n en el vial contiene sustancias químicas potencialmente nocivas (consulte la tabla a continuaci n). Si la soluci n entra en contacto con la piel o los ojos, lávese con abundante cantidad de agua. Si la irritaci n persiste, busque asesoramiento médico: https://www.poison.org/contact-us o llame al 1-800-222-1222.

	Código GHS para cada ingrediente	Concentración
Triton X-100	H315, irritación de la piel	1.5%
N-Sal sódica de lauroilsarcosina	H315, irritación de la piel	0.15%

Preguntas frecuentes

¿Qué es el COVID-19?
El COVID-19 es causado por el virus SARS-CoV-2 que es un nuevo virus en humanos que causa una enfermedad respiratoria contagiosa. El COVID-19 se puede presentar con enfermedad de leve a grave, aunque algunas personas infectadas por COVID-19 podrían no tener ning n síntoma. Los adultos mayores y las personas de cualquier edad que tienen afecciones médicas subyacentes tienen mayor riesgo de padecer una enfermedad grave a causa del COVID-19. Los desenlaces graves del COVID-19 incluyen la hospitalizaci n y la muerte. El virus SARS-CoV-2 se puede propagar hacia los demás no solo cuando uno está enfermo, sino incluso antes de que una persona muestre signos o síntomas de estar enfermo (por ejemplo, fiebre, tos, dificultad para respirar, etc.). En el siguiente enlace se puede encontrar una lista completa de los síntomas del COVID-19: https://www.cdc.gov/coronavirus/2019-ncov/symptom s-testing/symptoms.html.

¿Cuáles son los síntomas del COVID-19?
Muchas personas con COVID-19 confirmado desarrollaron fiebre o síntomas de enfermedades respiratorias graves (p. ej., tos, disnea), aunque algunas personas solo experimentan síntomas leves o no presentan ning n síntoma en absoluto. La información actual disponible para caracterizar el espectro de la enfermedad clínica asociada con el COVID-19 sugiere que, cuando están presentes, los síntomas incluyen tos, dificultad para respirar o disnea, fiebre, escalofríos, mialgias, dolor de cabeza, dolor de garganta y nueva pérdida del gustó u olfato, náuseas, v mitos o diarrea. El COVID-19 se puede presentar con enfermedad de leve a grave, aunque algunas personas infectadas por COVID-19 podrían no tener ning n síntoma. Los signos y síntomas pueden aparecer en cualquier momento entre 2 y 14 días después de la exposici n al virus, y el tiempo medio de aparici n de los síntomas es de aproximadamente 5 días.

¿Qué es la prueba en serie?
La prueba en serie es cuando una nica persona es analizada para detectar COVID-19 más de una vez. Dado que las pruebas de antígenos son menos sensibles que otras pruebas de COVID-19 y que pueden producirse resultados falsos, la repetición de pruebas puede identificar a más personas con infecci n por COVID-19 que una nica prueba. Al repetir la prueba, puede ser posible identificar los casos de infecci n por COVID-19 más rápido y reducir la propagaci n de la infecci n. Es más probable que las pruebas en serie (es decir, pruebas todos los días o cada dos días) detecten COVID-19, especialmente cuando no tiene ning n síntoma. Las pruebas adicionales con pruebas de COVID-19 moleculares pueden ser necesarias, dependiendo de los factores de riesgos individuales y los resultados de la prueba. Es importante que trabaje con su proveedor de atenci n médica para ayudarlo a comprender los pasos a seguir.

¿Qué tan precisa es esta prueba?
Entre marzo de 2021 y mayo de 2021 se llev a cabo un estudio que evalu las características de rendimiento clínico de la prueba casera *CareStart*™ COVID-19 Antigen en 7 lugares diferentes de los EE. UU. Entre 153 sujetos inscritos en el estudio con signos y síntomas de COVID-19 en los primeros 7 días de la aparici n de los síntomas, los individuos de 14 a os o más recogieron la muestra por sí mismos, y de 13 a os o menos, adultos recogieron muestras de frotis nasal anterior y las muestras se analizaron con la prueba casera *CareStart*™ COVID-19 Antigen. Los resultados comparados con un ensayo molecular RT-PCR autorizado para uso de emergencia de la FDA demostraron que la prueba casera *CareStart*™ COVID-19 Antigen identific correctamente el 87% de las muestras positivas y el 98% de las negativas.

¿Cuáles son los posibles riesgos y beneficios conocidos de la prueba?
Los posibles riesgos incluyen los siguientes:
- Posible molestia u otras complicaciones que pueden ocurrir durante la obtenci n de la muestra.
- Posible resultado incorrecto de la prueba (consulte a continuaci n para obtener más informaci n).

Los posibles beneficios incluyen los siguientes:
- Los resultados, junto con otra informaci n, pueden ayudarlo a usted y a su proveedor de atenci n médica a realizar recomendaciones informadas acerca de su atenci n.
- Los resultados de esta prueba pueden ayudarlo a limitar la posible propagaci n del COVID-19 a su familia y a los demás en su comunidad.

¿Qué sucede si tengo un resultado de prueba positivo?
Si tiene un resultado de prueba positivo, es muy probable que tenga COVID-19, porque las proteínas del virus que causa el COVID-19 se hallaron en la muestra. Por lo tanto, también es probable que lo aíslen para evitar la propagaci n del virus a los demás. Hay una mínima posibilidad de que esta prueba arroje un resultado positivo er neo (un resultado falso positivo). Si usted arroja resultado positivo con la prueba domiciliaria *CareStart*™ COVID-19 Antigen, debe aislarse y buscar atenci n de seguimiento con su médico o proveedor de atenci n médica, ya que es posible que se necesiten pruebas adicionales. Su proveedor de atenci n médica trabajará con usted para determinar c mo ocuparse mejor de usted en funci n de los resultados de la prueba, junto con sus antecedentes médicos, y sus síntomas.

¿Qué sucede si tengo un resultado de prueba negativo?
Un resultado de prueba negativo indica que las proteínas del virus que causa el COVID-19 no se hallaron en la muestra. Es posible que esta prueba arroje un resultado negativo que sea incorrecto (falso negativo) en algunas personas con COVID-19. Esto significa que posiblemente podría a n tener COVID-19, incluso si la prueba es negativa. La cantidad de antígeno en una muestra puede disminuir cuanto más tiempo tenga síntomas de infecci n. En personas sintomáticas, las muestras obtenidas después de haber tenido los síntomas durante más de cinco días son más propensas a ser negativas en comparaci n con un ensayo molecular. Existe una mayor probabilidad de resultados falsos negativos con las pruebas de antígenos que con las pruebas moleculares de laboratorio. Esto significa que existe una mayor probabilidad de que esta prueba le dé un resultado negativo cuando sí tiene COVID-19. Si usted arroja resultado negativo y sigue experimentando síntomas de COVID-19, como fiebre, tos y dificultad para respirar, debe buscar atenci n de seguimiento de su proveedor de atenci n médica. Por ejemplo, su proveedor de atenci n médica podría sugerir que necesita otra prueba para determinar si ha contraído el virus que causa el COVID-19. Si le preocupa el estado de su infecci n por COVID-19 después de la prueba o cree que podría necesitar prueba de seguimiento, comuníquese con su proveedor de atenci n médica.

Explicaci n de los símbolos

- IVD — **Dispositivo médico de diagnóstico *in vitro*** — Señala un dispositivo médico previsto para su utilización como dispositivo médico de diagnóstico *in vitro*.
- **Consulte las instrucciones de uso** — Señala la necesidad de que el usuario consulte las instrucciones de uso.
- **Fabricante** — Designa el fabricante del dispositivo médico.
- LOT — **Código de lote** — Designa el código de lote del fabricante para poder identificar el lote.
- **No reutilice** — Indica un dispositivo médico destinado a un solo uso.
- **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 para poder identificar el dispositivo médico.
- **Precaución** — Señala la necesidad de que el usuario consulte los documentos acompañantes.
- **Fecha de fabricación** — Señala la fecha de fabricación del dispositivo médico.
- **Límite de temperatura** — Señala los límites de temperatura a los cuales puede exponerse el dispositivo médico de forma segura.
- **No lo utilice si el paquete está dañado** — Señala un dispositivo médico que no debe utilizarse si el paquete ha sido dañado o abierto.
- **Contiene cantidad suficiente para <n> pruebas** — Señala la cantidad total de pruebas de diagnóstico *in vitro* que se pueden realizar con el dispositivo.

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Soporte técnico
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Correo electrónico: TShelp@accessbio.net

FACT SHEET FOR INDIVIDUALS

Access Bio, Inc.
***CareStart*™ COVID-19 Antigen Home Test**

Updated: November 22, 2021A

Coronavirus Disease 2019 (COVID-19)

You are provided this Fact Sheet because you obtained the *CareStart*™ COVID-19 Antigen Home Test for testing yourself or dependents for the proteins from the virus that causes COVID-19. The intended use of this test is for testing twice over two or more days with at least 24 hours and no more than 48 hours between tests.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the detection of proteins from the virus that causes COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage: https://www.cdc.gov/COVID19

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

What is the *CareStart*™ COVID-19 Antigen Home Test?
The *CareStart*™ COVID-19 Antigen Home Test is a type of test called an antigen test. Antigen tests are designed to detect proteins from the virus that causes COVID-19 in anterior nasal swabs.

The *CareStart*™ COVID-19 Antigen Home Test is intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 from individuals with or without symptoms tested twice over two or three days with at least 24 hours and no more than 48 hours between tests.

What are the known and potential risks and benefits of the test?

Potential risks include:
- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below 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

What does it mean if I have a positive test result?
If you have a positive test result, it is very likely that you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. 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 with the *CareStart*™ COVID-19 Antigen Home Test you should self-isolate and seek follow-up care with your healthcare provider as additional testing may be necessary. 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.

What are the differences between antigen tests and other COVID-19 tests?
There are different kinds of tests for diagnosing COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests detect proteins from the virus. Antigen tests are very specific for the 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.

If your test result is negative, you should discuss with your healthcare provider whether an additional molecular test would help with your care, and when you should discontinue home isolation. If you will not have an additional test to determine if you are contagious, the CDC currently recommends that you should stay home until three things have happened:

- You have had no fever for at least 24 hours (that is one full day of no fever without the use of medicine that reduces fevers)

AND

- Other symptoms of COVID-19 are improving (for example, when your cough or shortness of breath has improved) **Loss of taste and smell may persist for weeks or months after recovery and need not delay the end of isolation

AND

- At least 10 days have passed since your symptoms first appeared.

For more information, the CDC has provided guidelines on how to prevent the spread of COVID-19 if you are sick: https://www.cdc.gov/coronavirus/2019-ncov/downloads/sick-with-2019-nCoV-fact-sheet.pdf.

Is this test FDA-approved or cleared?
No. This test is not yet approved or cleared by the United States FDA. FDA may issue an Emergency Use Authorization (EUA) when certain criteria are met, which includes that there are no adequate, approved, available alternatives. The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency of IVDs, unless it is terminated or authorization is revoked by FDA (after which the test may no longer be used).

What are the approved alternatives?
There are no approved available alternative antigen tests. Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases. A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov.

Where can I go for updates and more information?
The most up-to-date information on COVID-19 is available at the CDC General webpage: https://www.cdc.gov/COVID19. In addition, please also contact your healthcare provider with any questions/concerns.

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For use with or without symptoms
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Results in 10 minutes
10min
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A Simple Nasal Swab
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IVD
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Store between
34-86° F (1-30° C) until use
This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA). This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
This 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 authorization is terminated or revoked sooner.
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.
Access Bio, Inc.
65 Clyde Road, Suite A
Somerset, NJ 08873, USA
732-873-4040
www.accessbio.net
Kit Components
1 CareStart™ COVID-19 Ag Home Test - 1ea
2 Nasal Swab - 1ea
3 Extraction Vial Tube - 1ea
4 Extraction Vial Cap - 1ea
5 Quick Reference Instructions & Fact Sheet for Individuals included
Using Mobile Application
Please start the test follows the in-app self-paced, step-by-step test instructions.
1 Download and open App, on/go™
Download the App on the App Store or Google Play Store or scan the QR code. Ensure you are connected to the internet during your test.
2 Answer a few questions in the App
3 Watch the instruction video
4 Follow step-by-step instructions for your test
5 Test result
Your test result appears on your screen after 10 minutes of wait time and selection of visual result interpretations.
For a list of compatible smartphone OS systems, visit www.accessbio.net/app
Self Test for SARS-CoV-2 Antigen Detection (Ages 2 and Up)
Do Not Use
• If you are prone to nosebleeds.
• If you have had a facial or head injury/surgery in the last 6 months.
Limit of performance
This test does not determine if you had COVID-19 in the past or if you have immunity It detects proteins from the SARS-Cov-2 virus.
CareStart™
COVID-19
ANTIGEN
HOME TEST

Using Mobile Application

Please start the test follows the in-app self-paced, step-by-step test instructions.

1. **Download and open App, on/go™**
   Download the App on the App Store or Google Play Store or scan the QR code. Ensure you are connected to the internet during your test.
2. **Answer a few questions in the App**
3. **Watch the instruction video**
4. **Follow step-by-step instructions for your test**
5. **Test result**
   The App will assist in the visual result interpretation. Please follow the instructions provided in the App. You will be required to take a picture of the test device, and then look at the device and answer some questions to the result interpretation.

For a list of compatible smartphone OS systems, visit www.accessbio.net/app

Kit Components

1. *CareStart*™ COVID-19 Ag Home Test - 2ea
2. Nasal Swab - 2ea
3. Extraction Vial Tube - 2ea
4. Extraction Vial Cap - 2ea
5. Quick Reference Instructions & Fact Sheet for Individuals Included

UDI Print Here

REF RCPM-00271

8 50010 22431 2

IVD OTC

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Self Test for SARS-CoV-2 Antigen Detection (Ages 2 and Up)

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Limit of performance
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CareStart™
COVID-19
ANTIGEN
HOME TEST

AccessBio

2 Tests

CareStart™
COVID-19
ANTIGEN
HOME TEST

FAST RESULT
Results in 10 minutes
10min

EASY TESTING
A Simple Nasal Swab

For use with or without symptoms

Made in the USA

www.accessbio.net

www.accessbio.net

For use with or without symptoms

AccessBio

CareStart™ COVID-19 ANTIGEN HOME TEST

CareStart™ COVID-19 ANTIGEN HOME TEST

AccessBio

CareStart™ COVID-19 ANTIGEN HOME TEST

CareStart™ COVID-19 ANTIGEN HOME TEST

Kit Components

1 *CareStart*™ COVID-19 Ag Home Test - 4ea

3 Extraction Vial Tube - 4ea

2 Nasal Swab - 4ea

4 Extraction Vial Cap - 4ea

5 Quick Reference Instructions & Fact Sheet for Individuals Included

UDI Print Here

Store between 34-86° F (1-30° C) until use

Made in the USA

www.accessbio.net

Using Mobile Application

You will need to download the mobile App and follow the test instructions for testing.

1 Download and open App, on/go™

Download the App on the App Store or Google Play Store or scan the QR code, Ensure you are connected to the internet during your test.

For a list of compatible smartphone OS systems, visit www.accessbio.net/app

2 Answer a few questions in the App

3 Watch the instruction video

4 Follow step-by-step instructions for your test

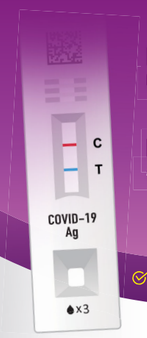
5 Test result

The App will assist in the visual result interpretation. Please follow the instructions provided in the App. You will be required to take a picture of the test device and then look at the device and answer some questions to the result interpretation.

REF RCPM-00471

8 50010 22432 9

CareStart™ COVID-19 ANTIGEN HOME TEST



FAST RESULT
Results in 10 minutes
10min

EASY TESTING
A Simple Nasal Swab

For use with or without symptoms

4 Tests

Self Test for SARS-CoV-2 Antigen Detection (Ages 2 and Up)

Do Not Use

- If you are prone to nosebleeds
- If you have had a facial or head injury/surgery in the last 6 months

Limit of performance

This test does not determine if you had COVID-19 in the past or if you have immunity. It detects proteins from the SARS-Cov-2 virus.

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1 °C 34 °F — 30 °C 86 °F IVD Σ4 OTC

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Made in the USA
For use with or without symptoms
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AccessBio
20 Tests
CareStart™
COVID-19
ANTIGEN
HOME TEST
FAST RESULT
Results in 10 minutes
10min
EASY TESTING
A Simple Nasal Swab
x3
C
T
COVID-19
Ag
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CareStart™
COVID-19
ANTIGEN
HOME TEST
REF RCPM-02071
UDI Print Here
Individual tests are not to be sold separtately.
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T
COVID-19
Ag
x3
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