**USER INSTRUCTIONS**

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

2. **Unpack the test components from the tray.**

3. **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.**

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

5. **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.**

6. **Remove the swab from the LEFT nostril and place directly into the extraction vial.**

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.**

8. **Close the vial by pushing the cap firmly onto the vial.**

9. **Locate 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.**

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

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

12. **Locate the extraction vial and place it on a flat, clean surface.**

13. **Start a timer. Read the result at 10 minutes.**

   - The test result should not be read after 15 minutes.
   - 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.

**Interpretation**

- **COVID-19 Detected (Positive)**
  - One purple-colored line next to “C” and one blue-colored line next to “T” indicates COVID-19-positive result.

- **COVID-19 Not Detected (Negative)**
  - One purple-colored line only next to “C” indicates a negative result.

- **Invalid**
  - Invalid barcode or absence of a purple-colored line next to “C”.

**Results**

- The test results will be interpreted by visual reading following the in-app interpretation instructions or provided Quick Reference Instructions.

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

**Using Mobile Application**

- Ensure you have an internet connection and download the App prior to start the test.
- Ensure you are using a compatible smartphone.
- Only open the foil pouch packaging when the App instructed to do so.

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

1. Download and open App, on/go™ Mobile Application
2. Answer a few questions in the App
3. Watch the instruction video.
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.

**Important**

- Test results should be read by visual and interpreted at 10 minutes after the sample application and the reading and interpretation of the results should not exceed 15 minutes as it may yield inaccurate results.
- The test results will be interpreted by visual reading following the in-app interpretation instructions or provided Quick Reference Instructions.
- Make sure you wait the full 10 minutes.

For more detailed instructions, please see the CDC Guidelines.
The CareStart™ COVID-19 Antigen Home Test is a rapid, lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigens from individuals with or without symptoms to help identify individuals who may be infected with SARS-CoV-2. It is a self-collected direct anterior nasal (nares) swab samples from individuals aged 14 years or older and is only intended for use by individuals when under the care of a healthcare provider.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. The antigen is generally detectable in anterior nasal 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 isolate themselves and seek follow-up care with their veterinarian or healthcare provider as additional testing may be necessary.

Negative results should be treated with caution and confirmation with a molecular test for negative results may also be necessary, if there is a low 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 veterinarian or healthcare provider.

Individuals should provide all results obtained with this product to their veterinarian or healthcare provider for public health reporting. All healthcare providers will report all test results from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOCAL and SNOMED codes, as defined by the Laboratory in Vitro Diagnostics (LVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The CareStart™ COVID-19 Antigen Home Test is an authorized non-prescription self-use and/or, as applicable for an adult lay user testing another person aged 2 years or older in a non-laboratory setting. 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 shown to detect 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(1)(A), 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 mucous on the swab specimen may interfere with test performance and may yield a false-negative 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 with 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 kit contents.
- Handle all specimens as though they contain infectious agents.

**Hazards for Ingredients of 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.poisongroup.com/contact-us or 1-800-222-1222.

<table>
<thead>
<tr>
<th>Hazardous Ingredient</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium N-acetyl-β-D-glucosaminidase</td>
<td>2.0%</td>
</tr>
<tr>
<td>Sodium N-acetyl-β-D-glucosaminidase</td>
<td>10.0%</td>
</tr>
</tbody>
</table>

**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 mild to severe illness, although some severely ill COVID-19 patients have been reported to 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 you are sick, but even when you are asymptomatic if you show signs 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 no symptoms at all. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that, when present, symptoms may include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste or smell, nausea or vomiting. Many people with 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, and 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. Using 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. 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.

Explanation of Symbols

- Each symbol describes a diagnosis.
- The test is sensitive and accurate when performed with the IVD. Tel: 888-898-1270 (Toll Free)
- Indicates a medical device that is intended to be used as an IVD. Tel: 732-873-4040
- Indicates the medical device manufacturer.
- Indicates the total number of IVD tests that can be performed with the IVD. Tel: 732-873-4040
- Indicates the medical device is for use in vitro diagnostics.
- Indicates the need for the user to consult the accompanying documents.
- Indicates a medical device that should not be used on or near mucosal tissue.
- Indicates a medical device that is intended for healthcare professionals.

What are the known and potential risks and benefits of using this product?

Potential risks include:

- Possible discomfort or other complications that can happen during testing.
- 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 from your family and others in your community.

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 spreading the virus to others. There is a very small chance that this test can give a positive result even if you do not have COVID-19. Additional testing may be necessary. Your healthcare provider as additional testing may be necessary. Your healthcare provider will work with you to determine how best to care for you and any COVID-19 test result(s) along with your medical history, and your symptoms.

What if I have a negative test result?

A negative test result means that proteins from the virus that causes COVID-19 were not found in your sample. It is possible for this test to be negative even if you have COVID-19 (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.

If you test negative and continue to experience COVID-19 like symptoms, you may continue to spread the virus. If you breathe 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.
For use with or without symptoms
COVID-19 HOME TEST

Rapid Diagnostic Test for the Detection of SARS-CoV-2 Antigen
- For use under an Emergency Use Authorization (EUA) only
- For in vitro diagnostic use only
- The intermittent use of test twice over two or three days with at least 24 hours and no more than 48 hours between tests.
- Do Not Use
  - On anyone under 2 years of age
  - If you have had a facial or head injury/surgery in the last 6 months
  - If you are prone to nosebleeds
- Test result
  - Results in 10 minutes
  - 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.
- 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.
- For use under an Emergency Use Authorization (EUA).

Store between 34-86°F (1-30°C) until use
Made in the USA  www.accessbio.net

Access Bio, Inc.
65 Clyde Road, Suite A
Somerset, NJ 08873, USA
732-873-4040

www.accessbio.net
For use with or without symptoms
COVID-19 HOME TEST

Kit Components
- CareStart™ COVID-19 Antigen Extracţion Vial Tube - 4ea
- Home Test - 4ea
- Nasal Swab - 4ea
- Extracţion Vial Cap - 4ea
- Quick Reference Instructions & Fact Sheet for Individuals Included

Using Mobile Application
You will need to download the mobile App and follow the test instructions for testing:
1. Download and open App, on/app
   - 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 result interpretation.
   - You will be required to take a picture of the test device and answer some questions to the result interpretation.

FAST RESULT
Results in 10 minutes
EASY TESTING
A Simple Nasal Swab

Rapid Diagnostic Test for the Detection of SARS-CoV-2 Antigen
- For use under an Emergency Use Authorization (EUA) only
- For in vitro diagnostic use only
- The Antigen test is for use twice over two to three days with at least 24 hours and no more than 48 hours between tests.

Do Not Use
- On anyone under 2 years of age
- 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.
- 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 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 under Section 564(b)(1) of the Federal Food, Drug and Cosmeţic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.

Store between 34-86°F (1-30°C) until use
Made in the USA www.accessbio.net
Rapid Diagnostic Test for the Detection of SARS-CoV-2 Antigen

20 Tests

Using Mobile Application

For use under an Emergency Use Authorization (EUA) only

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

For in vitro diagnostic use only

The intended use for test twice over two or three days with at least 24 hours and no more than 48 hours between tests.

Download and open App, on/go CareStart COVID-19 Ag Extraction Vial Tube - 20ea

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.

Answer a few questions in the App

Do Not Use

If you are prone to nosebleeds

Follow step-by-step instructions for your test

Nasal Swab - 20ea

Extraction Vial Cap

Extraction Vial - 20ea

Quick Reference Instructions & Fact Sheet for Individuals Included

HOME TEST

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.

Test result

Quick Reference Instructions & Fact Sheet for Individuals Included

HOME TEST

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.

Test result

www.accessbio.net

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.

This test does not determine if you had COVID-19 in the past or if you have immunity.

Limit of performance

For use with or without symptoms

It detects proteins from the SARS-CoV-2 virus.

UDI Print Here

If you have had a facial or head injury/surgery in the last 6 months

Take the test device and follow the instructions provided in the App.

Printed Instructions

Answer a few questions in the App

Do Not Use

If anyone under 2 years of age

Follow step-by-step instructions for your test

Nasal Swab - 20ea

Extraction Vial Cap

Extraction Vial - 20ea

Quick Reference Instructions & Fact Sheet for Individuals Included

HOME TEST

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Test result

www.accessbio.net