Summary and Explanation of the Test

Since the first outbreak reported in December 2019, SARS-CoV-2 has spread rapidly worldwide, and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). Due to its highly contagious nature and global health crisis, SARS-CoV-2 has been designated as a pandemic by the World Health Organization (WHO). The disease continues to have devastating impacts on healthcare systems and the world economy including the U.S.

The CareStart® COVID-19 Antigen is a rapid (approximately 10 minutes) chromatographic immunoassay for the direct detection of the protein antigens specific to SARS-CoV-2 in anterior nasal swab specimens. The Rapid Diagnostic Test for the Detection of SARS-CoV-2 in anterior nasal swab specimens is designed to be used following the appearance of symptoms, such as an individual with a close contact to a patient suspected to be infected, or in communities with low prevalence of infection. The test is intended to be interpreted visually in both laboratory and patient testing environments without an instrument.

Principles of the Test

The CareStart® COVID-19 Antigen test is a rapid, lateral flow chromatographic immunoassay for the detection of nucleocapsid protein antigens specific to SARS-CoV-2 in anterior nasal swab specimens. The test uses recombinant viral proteins and does not contain infectious material. The test is intended for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results for the identification of the SARS-CoV-2 nucleocapsid protein antigen are generally detectable in nasopharyngeal or anterior nasal swab specimens during the acute phase of infection, but the clinical correlation with patient history and other diagnostic information is necessary to determine the cause of the illness. The signs and symptoms of COVID-19 may overlap with other viral and bacterial infections. The appearance of symptoms does not rule out a bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Reagents and Materials Provided

The extraction vial / cap contains extraction buffer which is encased in plastic device cassette. Extraction vials are provided in the kit. The reagents and materials in the kit are not re-usable. If the package is damaged or not used as the base solution for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient’s clinical symptoms, history, and the presence of other signs and symptoms consistent with COVID-19, and confirmed with other clinical laboratory findings if necessary for patient management.

For serologic testing, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such as an individual with an epidemiologic or contact history of SARS-CoV-2 disease with suspected exposure. Additional confirmatory tests with a molecular test for positive results may also be necessary if there is a likelihood of SARS-CoV-2 infection, such as individuals with known exposures to SARS-CoV-2 infected residents or in communities with high prevalence of infection.

In order to obtain accurate results, the test must follow this package insert. Immediately use after opening the test device in the pouch. Remove a nasopharyngeal swab from the pouch. Insert until resistance is encountered or 20 minutes starting the test. If the extraction buffer contains any clots, wash immediately with plenty of water. Do not re-use any contents in the kit as they are single-use only. Do not eat, drink, or smoke in the area where the specimens and kit contents are handled. Do not re-use any contents, only use provided or recommended anterior nasal swab for specimen collection. Technical Support in the U.S. - Tel: +1-888-898-1270 (Available Hours: Mon. - Fri.: 8 a.m. – 5 p.m.) or TShelp@accessbio.net (24/7 available) before testing patient specimens.

Storage and Stability

Store the test kit as packaged between 1–30°C. Do not use the reagents and related vials in the CareStart® COVID-19 Antigen kit, if the expiration date is exceeded. Store the vials and any used kit contents as they are single-use only. Do not disassemble any components of the kit. Do not freeze any contents of the kit. Remove a nasopharyngeal swab from the pouch.

Quality Control

Internal Quality Control: The CareStart® COVID-19 Antigen contains a built-in internal positive control and a built-in internal negative control. Both of these swabs are used with the test device in the pouch. The external control should be placed into extraction buffer for up to 4 hours. Do not re-use any kit contents. Do not eat, drink, or smoke in the area where the specimens and kit contents are handled. Do not use if the package is damaged or not used as the base solution for treatment or patient management decisions, including infection control decisions. Do not open the pouch before use. Do not re-use any kit contents. Do not use beyond the expiration date. Do not position the kit away from the user. Do not open the pouch before use. Do not use if the package is damaged or not used as the base solution for treatment or patient management decisions, including infection control decisions.

External Control: External control is used to demonstrate that the test device and test procedure perform properly. It is recommended that positive and negative external control swabs are run with every new kit, each new user, external positive and negative control swabs are provided in the kit. The external control should be tested using the swab test procedure provided in this package insert or the quick reference instruction card. If the external control results are invalid, please contact the Technical Support at +1-888-898-1270 (Available Hours: Mon. - Fri.: 8 a.m. – 5 p.m.) or TShelp@accessbio.net (24/7 available) before testing patient specimens.

Specimen Collection and Handling

Acceptable specimen type for testing with the CareStart® COVID-19 Antigen is a direct nasopharyngeal and anterior nasal swab specimens. It is essential that correct specimen collection and preparation methods be followed. Inadequate specimen collection, improper specimen handling and/or transport may yield false results; therefore, specimen collection requires specific training and guidance due to the importance of specimen quality to obtain accurate test results. Specimens are stable for 4 hours in extraction buffer. It is recommended to follow the guidelines for a molecular diagnostic assay for the detection and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19): https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html.

Swab Sample Collection Procedure

Nasopharyngeal Swab Collection

Procedures

1. Remove a nasopharyngeal swab from the pouch.

2. Insert the swab into one of patient’s nostrils. Remove the swab from the nostril without rotating.

3. Gently rotate 3–5 times the swab over the surface of the posterior naopharynx.

4. Leave swab in place for several seconds to absorb secretions. Slowly remove the swab from the nostril while rotating.

Anterior Nasal Swab Collection

Procedures

1. Collect the specimen wearing safety gloves to avoid contamination.

2. Collect the specimen without touching the ear to the nostril of the patient.

3. Slowly rotate 3–5 times the swab over the surface of the posterior naopharynx.

4. Leave swab in place for several seconds to absorb secretions. Slowly remove the swab from the nostril while rotating.

Open the nasal passage and gently insert the swab to the point of resistance, avoid applying excessive suction. Do not use beyond the expiration date. Do not position the kit away from the user. Do not open the pouch before use. Do not use if the package is damaged or not used as the base solution for treatment or patient management decisions, including infection control decisions.

Additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at accessbio.net.

Reagents and Materials Provided

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasal swab</td>
<td>Specimen collection material used for the test device.</td>
</tr>
<tr>
<td>Extraction vial / cap</td>
<td>Contains extraction buffer for up to four hours.</td>
</tr>
<tr>
<td>Biohazard or sharps container</td>
<td>Contains sodium azide form highly explosive metal azides.</td>
</tr>
<tr>
<td><a href="mailto:TShelp@accessbio.net">TShelp@accessbio.net</a></td>
<td>(24/7 available) before testing patient specimens.</td>
</tr>
<tr>
<td>Data Sheet (SDS) located at</td>
<td>Website: <a href="http://www.intrivo.com">www.intrivo.com</a></td>
</tr>
<tr>
<td>AccessBio.net</td>
<td>Tel: +1-888-965-0302</td>
</tr>
<tr>
<td>Website</td>
<td>Fax: 888-965-0302</td>
</tr>
<tr>
<td>Tel: 888-965-0301</td>
<td>Somerset, NJ 08873, USA</td>
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</tr>
<tr>
<td>Phone</td>
<td>732-873-4040</td>
</tr>
</tbody>
</table>

For use under the Emergency Use Authorization (EUA) only for in vitro diagnostic use only for prescription use only

Package Insert (Instructions for Use)

Indicate the medical device manufacturer.

Antigen is only for use under the Food and Drug Administration’s (FDA) Emergency Use Authorization.

The agent detected may not be the definite cause of disease. The results of this test are not intended to rule out a bacterial infection or co-infection with other viruses.

For serologic testing, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such as an individual with an epidemiologic or contact history of SARS-CoV-2 disease with suspected exposure. Additional confirmatory testing with a molecular test for positive results may also be necessary if there is a likelihood of SARS-CoV-2 infection, such as individuals with known exposures to SARS-CoV-2 infected residents or in communities with high prevalence of infection.

The CareStart® COVID-19 Antigen is intended for use in point of care and healthcare settings, and is not intended for healthcare professionals or individuals specifically instructed in the use of the CareStart® COVID-19 Antigen and proper infection control procedures. The CareStart® COVID-19 Antigen is only for use under the Food and Drug Administration’s Emergency Use Authorization.

Do not eat, drink, or smoke in the area where the specimens and kit contents are handled. Do not re-use any contents in the kit as they are single-use only. Do not use beyond the expiration date. Do not position the kit away from the user. Do not open the pouch before use. Do not use if the package is damaged or not used as the base solution for treatment or patient management decisions, including infection control decisions.

Do not re-use any kit contents. Do not use beyond the expiration date. Do not position the kit away from the user. Do not open the pouch before use. Do not use if the package is damaged or not used as the base solution for treatment or patient management decisions, including infection control decisions.
**Emergency Use Authorization.**

Antigen is only for use under the Food and Drug Administration’s (FDA) specifically instructed in the use of the CareStart™ COVID-19 Antigen Test ("your product") in the conditions below, which may include mass media.


However, to assist clinical laboratories using the CareStart™ COVID-19 Antigen test in the conditions below, the relevant clinical characteristics are acceptable.

**Interpretation of Results**

Note: The test results should be read and interpreted at 10 minutes after the test has been performed. If the test results are not read and interpreted at 10 minutes after the test has been performed, the test should not exceed 15 minutes. The results should not be interpreted using an extended incubation time.

**Positive:**

Two distinct colored lines appear.

Contains colorless line next to “T” and and colored line next to “C”.

Note: The color ratio in the negative result will be dependent on the amount of SARS-CoV-2 nucleocapsid antigen in the sample. Any line color ratio in the control band region considered to be positive.

Note: The two distinct colored lines in the main test region ("C") do not indicate a positive result.
Quick Reference Instructions for CareStart™ COVID-19 Antigen

For Emergency Use Authorization (EU A) Only

The CareStart™ COVID-19 Antigen test is a lateral flow immunochromatographic assay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal or anterior nasal swab specimens directly collected from individuals who are either suspected of COVID-19 by their healthcare provider within first five days of symptom onset, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests.

IMPORTANT!
- Refer to the Package Insert for Warnings and Precautions, Specimen Collection Procedures, Storage and Handling Conditions, and Quality Control Recommendations.
- Warning and Precautions - All kit components can be discarded as Biohazard waste according to local guidelines. Refer to the product safety data sheet for risk and safety phrases and disposal information.
- Biotin interference: False negative results may occur in patients who have indicated or whose clinical status or history would indicate they are currently taking high doses of biotin (> 10 mg per day). Biotin levels of 2.5 µg/ml have been demonstrated to result in false negative test results.
- The extracted sample must be used within 4 hours of preparation when stored at room temperature.

SPECIMEN COLLECTION AND HANDLING

**Nasopharyngeal (NP) Swab Collection**

1. Remove a nasopharyngeal swab from the pouch.
2. Tilt patient’s head back 70 degrees. Gently and slowly insert the swab into one of patient’s nostrils until it reaches the posterior nasopharynx; keep insert until resistance is equivalent to that from the ear to the nostril of the patient.
3. Slowly rotate 3–5 times the swab over the surface of the posterior nasopharynx.
4. Leave swab in place for several seconds to absorb secretions. Slowly remove the swab from the nostril while rotating it.

**Anterior Nasal Swab Collection**

1. Remove a nasal swab from the pouch.
2. Insert the swab into one of patient’s nostrils up to 1 inch from the edge of the nostril.
3. Slowly roll the swab 5 times over the surface of the nostril. Using the same swab, repeat this collection process in the other nostril. Take approximately 15 seconds to collect the specimen.
4. Slowly remove the swab from the nostril while rotating it.

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Website: www.accessbio.net

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. § 362a, that meet requirements to perform moderate, high or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. In the USA, the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use in vitro diagnostics for detection and/or diagnosis of the virus that causes 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.
Quick Reference Instructions for CareStart™ COVID-19 Antigen

TEST PROCEDURES

1. Peel off aluminum foil seal from the top of the extraction vial containing the extraction buffer.

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

3. Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab. Properly discard the swab.

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

5. Mix thoroughly by flicking the bottom of the tube.

6. 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.

NOTE: Refer to the Package Insert for the cautions.

Result Interpretation

Start the timer

Read the result at 10 minutes. The test result should not be read after 15 minutes.

Warning
The false positive, false negative, or invalid results may occur if the test is interpret outside of the interpretation window.

External Control Swab: It is recommended that positive and negative external control swabs are run once with every new lot, shipment, and each new user. External positive and negative control swabs are provided in the kit. The external control should be tested using the nasopharyngeal swab test procedure provided in this package insert or the quick reference instruction card.

If used on asymptomatic individuals for serial testing, a second test should be performed with at least 24 hours (and no more than 48 hours) between tests. For serial testing, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such as, an individual with a close contact or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.