CareStart™

COVID-19 Antigen

Rapid Diagnostic Test for the Detection of SARS-CoV-2 Antigen

REF **RCHM-02071**

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

Package Insert
(Instructions for Use)

Intended Use

The *CareStart*™ COVID-19 Antigen test is a lateral flow chromatographic immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasopharyngeal or anterior nasal swab samples collected by a healthcare provider from individuals who are suspected of COVID-19 within the first 5 days of symptom onset when tested at least twice over three days with at least 48 hours between tests and from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 hours between tests. Testing i s limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate o f Waiver, Certificate of Compliance, or Certificate of Accreditation.

The *CareStart*™ COVID-19 Antigen test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in nasopharyngeal or anterior nasal (nares) swab specimens during the acute phase of infection. Positive results indicate th e presence of viral antigens, b ut clinical correlation wi th past medical history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definitive cause of disease. Laboratories w ithin t he United States and its territories are required to report all results to the appropriate public health authorities.
All negative results are presumptive an d confirmation wit h a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control measures such as isolating from others a nd wearing masks. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

The CareStart™ COVID-19 Antigen test is intended for use by medical professionals or operators who are proficient in performing tests in point of care settings. The *CareStart*™ COVID-19 Antigen test is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

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 crises, SARS-CoV-2 has been designated as a pandemic by the World Health Organization (WHO). SARS-CoV-2 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 presence or absence of SARS-CoV-2 antigens in the respiratory specimens taken from patients with signs and symptoms who are suspected of COVID-19, or taken from asymptomatic individuals being tested serially, as described in the authorized intended use. The test is intended to be interpreted visually in both laboratory and near patient testing environments without an instrument.

Principles of the Test

The *CareStart*™ COVID-19 Antigen test is a lateral flow immunochromatographic assay for the detection of extracted nucleocapsid protein antigens specific to SARS-CoV-2 in nasopharyngeal or anterior nasal swab specimens directly collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of symptom onset, or who are asymptomatic and undergoing serial testing, as described in the intended use.

Nasopharyngeal and anterior nasal swabs require a sample preparation step in which the sample is eluted into the extraction buffer solution. Extracted swab sample is added to the sample well of the test device to initiate the test. When the swab sample migrates in the test strip, SARS-CoV-2 viral antigens bind to anti-SARS-CoV-2 nucleocapsid protein antibodies conjugated to indicator and capture particles in the test strip forming an immune complex. The immune complex is then captured by the test line on the nitrocellulose membrane as it migrates through the strip.
Test results are interpreted at 10 minutes. The presence of two-colored lines in the control line region "C" and test line region "T" indicates COVID-19 positive. The presence of one colored line in the control line region "C" indicates COVID-19 negative. No appearance of a colored line in the control region "C" indicates an invalid test

Reagents and Materials Provided

Contents Name	Quantity (in a kit)	Description
Test device	20 each	Foil pouched test device containing one test strip which is encased in plastic device cassette.
Extraction vial / cap	20 vials and caps	The extraction vial contains extraction buffer solution.
Nasal (or nasopharyngeal) swab	20 each	Swabs for specimen collection.
Positive control swab	1 each	Recombinant SARS-CoV-2 nucleocapsid protein antigen is dried on the foam-tipped head.
Negative control swab	1 each	Blank swab
Package insert	1 each	Instructions for use
Quick Reference Instructions (QRI)	1 each	Quick reference instructions

The following materials are needed but not provided:

- Pair of gloves - Timer - Biohazard or sharps container - Micropipette

Warnings, Precautions, and Safety Information

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- For prescription and *in vitro* diagnostic use only.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2 not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under the CLIA that meet the 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.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- If you have had symptoms longer than 5 days you should consider testing at least three times over five days with at least 48 hours between tests.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- Once opened, the test device should be used immediately.
- 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 nasopharynx when collecting specimens.
- **Do not read test results before 10 minutes or after 15 minutes. Results read before 10 minutes or after 15 minutes may lead to a false positive, false negative, or invalid result.**
- Inadequate or inappropriate sample collection, storage, and transport can result in incorrect results. - If specimen storage is necessary, swabs can be placed into extraction buffer for up to four hours. Specimens should not be stored dry.
- Do not use if any of the test kit contents or packaging is damaged.
- Test components are single-use. Do not re-use.
- Do not use kit past its expiration date.
- Do not touch the swab tip.
- Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.
- Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
- Dispose of used contents as biohazardous wastes in accordance with federal, state, and local requirements.
- Wear a safety mask or other face-covering when collecting a specimen from a patient.
- Nitrile or latex gloves should be worn when performing this test.
- The SARS-CoV-2 positive control swabs have been prepared from recombinant viral proteins and do not contain infectious material. Handle all specimens as though they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Reagents contain sodium azide, which is harmful if inhaled, swallowed, or exposed to skin. Contact with acids produces a very toxic gas. If there is contact with skin, wash immediately with plenty of water. Sodium azide may react with lead and copper plumbing to form highly explosive metal azide. On disposal, flush with a large volume of water to prevent azide build-up.
- **Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your skin or eyes. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin or eyes, flush with large amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.**

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

- For more information on EUAs please visit: https://www.fda.gov/emergencypreparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergencyuse-authorization
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

Storage and Stability

- Store the test kit as packaged between 1 ~ 30°C.
- The reagents and materials in the *CareStart*™ COVID-19 Antigen are stable until the expiration date printed on the outer packaging.
- Do not use beyond the expiration date.
- The test device must remain in the sealed pouch until use.
- Do not freeze any contents of the kit.

Quality Control

Internal Quality Control:

The *CareStart*™ COVID-19 Antigen contains a built-in internal procedural control that is included in the test device. A Red-colored line appearing in the control region "C" is designed as an internal procedural control. The appearance of the procedural control line indicates that sufficient flow has occurred, and the functional integrity of the test device has been maintained. If the procedural control line does not develop in 10 minutes, the test result is considered invalid and retesting with a new device is recommended. If the internal procedural control line is still absent in the retest, please contact the Technical Support at +1-888-898-1270 (Available Hours: Mon. to Fri.: 8 a.m. – 5 p.m.) or TShelp@accessbio.net (24/7 available).

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 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 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. to Fri.: 8 a.m. – 5 p.m.) or TShelp@accessbio.net (24/7 available) before testing patient specimens.

Specimen Collection and Handling

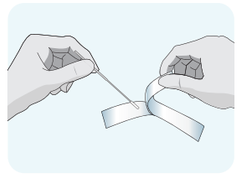
Acceptable specimen type for testing with the *CareStart*™ COVID-19 Antigen is a direct nasopharyngeal and anterior nasal swab specimen. It is essential that correct specimen collection and preparation methods be followed. Inadequate specimen collection, improper specimen handling and/or transport may 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. Refer to the CDC Interim Guidelines for Collecting, Handling, 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

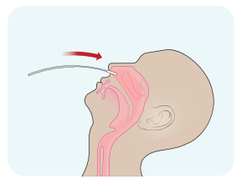
Nasopharyngeal Swab Collection

Procedural Notes

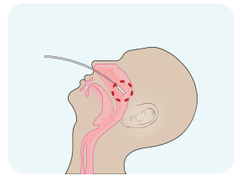
- Process the test sample immediately after collection.
- Use only recommended nasopharyngeal swab for specimen collection.
- Collect the specimen wearing safety gloves to avoid contamination.
- Do not touch the tip (specimen collection area) of the swab.
- Collect samples as soon as possible within 5 days of symptom onset.



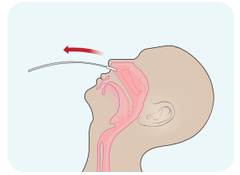
1
Remove a nasopharyngeal swab from the pouch.



2
Tilt patient's head back 70 degrees. Gently and slowly insert the swab into one of the patient's nostrils until it reaches the posterior nasopharynx; keep insert until resistance is encountered or the distance 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.

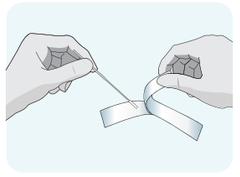


4
Leave swab in place for several seconds to absorb secretions. Slowly remove the swab from the nostril while rotating it.

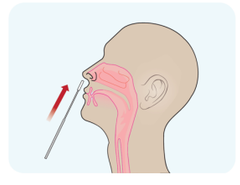
Anterior Nasal Swab Collection

Procedural Notes

- Process the test sample immediately after collection.
- Use only provided or recommended anterior nasal swab for specimen collection.
- Collect the specimen wearing safety gloves to avoid contamination
- Do not touch the tip (specimen collection area) of the swab.
- Collect samples as soon as possible within 5 days of symptom onset.



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.

Description 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, or uses on a single patient during a single procedure.

Use by date
Indicates the date after which the medical device is not to be used.

CONTROL + **Positive control**
Indicates a control material that is intended to verify the results in the expected positive range.

CONTROL − **Negative control**
Indicates a control material that is intended to verify the results in the expected negative range.

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 the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

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.

Rx **Prescription-only**

Manufactured by:
Access Bio, Inc.
65 Clyde Road, Suite A.
Somerset, NJ 08873, USA
Tel: 732-873-4040
Fax: 732-873-4043
Email: TShelp@accessbio.net
Website: www.accessbio.net

Technical Support in the U.S.
Tel: +1-888-898-1270 (Toll Free)
Email: TShelp@accessbio.net

Manufactured for:
Intrivo Diagnostics, Inc.
2021 Santa Monica Blvd, #11
Santa Monica, CA 90404, USA
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Fax: 888-965-0302
Email: info@intrivo.com
Website: www.intrivo.com

AccessBio

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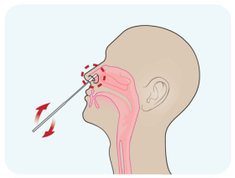
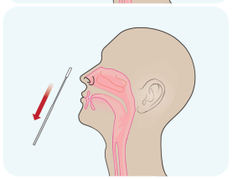


3

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.

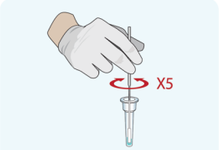
Test Procedures

Procedural Notes

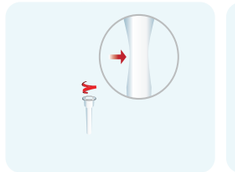
- Allow test devices, reagents, specimens, and/or controls to equilibrate to room temperature (15–30°C) prior to testing.
- Remove the *CareStart*™ COVID-19 Antigen test device and extraction vial from its foil pouch immediately before testing.
- The *CareStart*™ COVID-19 Antigen kit IS INTENDED to be used only with a direct nasopharyngeal or anterior nasal swab specimen.
- The *CareStart*™ COVID-19 Antigen kit IS NOT INTENDED for testing other liquid samples such as nasal wash aspirate samples or samples in viral transport media as results can be compromised by over dilution.

Direct Swab Test Procedure

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



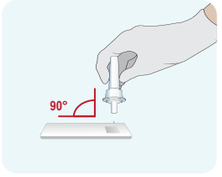
2 Place the swab into the extraction vial. Rotate the swab vigorously at least 5 times.



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 with the provided cap and push 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. 2 drops of the sample are required minimum volume to initiate the test run and invalid results will be obtained if 1 drop of sample is added to the cassette. Leakage of the sample is possible when 6 drops or more of the sample are added.

7 Read and interpret the test result at 10 minutes. The test result should not be read and interpreted after 15 minutes.

⚠ Warning

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

Interpretation of Results

NOTE: Do not read test results before 10 minutes or after 15 minutes. Results read before 10 minutes or after 15 minutes may lead to a false positive, false negative, or invalid result. The test results should not be interpreted using any instruments.

Serial (Repeat) Testing

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

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.

COVID-19 Positive (+) : If the Red-colored Control (C) line and the Blue-colored Test (T) line are visible, the test is positive. Any faint visible Blue-colored Test (T) line with the Red-colored Control (C) line should be read as positive.

Repeat testing does not need to be performed if patients have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self-isolation. There is a very small change that this test can give a positive result tat is incorrect (a false positive). Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the *CareStart*™ COVID-19 Antigen should self-isolate and seek follow up care with their physician or healthcare provider as 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.

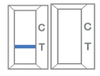
COVID-19 Negative (-) : If the Red-colored Control (C) line is visible, but the Blue-colored Test (T) line is not visible, the test is negative.

To increase the chance that the negative result for COVID-19 is accurate, you should:
- **Test again in 48 hours if the individual has symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.**

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.
All negative test results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. 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.

Invalid:

If the Red-colored Control (C) line is not visible, the test is invalid. Re-test with a new swab and new test device.



Limitations

1. The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between September 2020 and December 2020. The clinical performance has not been established for all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
2. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
3. 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 (>10mg per day). Biotin levels of 2.5 µg/mL have been demonstrated to result in false negative test results.
4. All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.
5. If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed.
6. If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and the individual likely has COVID-19.
7. This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
8. Incorrect test results may occur if a specimen is incorrectly collected or handled.
9. This test detects both viable (live) and nonviable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.
10. If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
11. Extracted specimens are stable for 4 hours in extraction buffer at room temperature.
12. Results from antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to determine infection status.
13. The detection of SARS-CoV-2 nucleocapsid antigen is dependent upon proper specimen collection, handling, storage, and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results.
14. Results from the device should be correlated with the clinical history, epidemiological data and other data available to the clinician evaluating the patient.
15. This device has been evaluated for use with human specimen material only.
16. False-negative results may occur if the concentration of the target antigen in the clinical specimen is below the detection limits of the device.
17. This device is a qualitative test and does not provide information on the viral concentration present in the specimen.
18. This test cannot rule out diseases caused by other bacterial or viral pathogens.
19. The prevalence of infection will affect the test's predictive values.
20. Positive and negative predictive values are highly dependent on prevalence. False-negative test results are more likely during peak activity when the prevalence of the disease is high. False-positive test results are more likely during the periods of low SARS-CoV-2 activity when prevalence is moderate to low.

CONDITIONS of AUTHORIZATION for LABORATORY

The *CareStart*™ COVID-19 Antigen test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas. However, to assist clinical laboratories using the *CareStart*™ COVID-19 Antigen test ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:
A. Authorized laboratories[1] using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may b e used, which may include mass media.
B. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from t he authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
C. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
D. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
E. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and ACCESS BIO, INC. (Technical Support at +1-888-898-1270 or TShelp@accessbio.net) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
F. All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
G. ACCESS BIO, INC., authorized distributors, and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

[1] The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high or waived complexity tests. This test 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" as "authorized laboratories."

Performance Characteristics

Clinical Performance – Nasopharyngeal Swab

The clinical performance characteristics of the *CareStart*™ COVID-19 Antigen test using nasopharyngeal swab specimen were evaluated in a multi-site prospective study in the U.S. between September 2020 and November 2020 against an FDA Emergency Use Authorized RT-PCR molecular assay as a comparator method. A total of three (3) POC investigational sites throughout the U.S. participated in the study. To be enrolled in the study, patients had to be presenting at the participating study centers with COVID-19 like symptoms and meet inclusion/exclusion criteria. All patients presented with fever or at least two symptoms of COVID-19 infection. The patients presenting the COVID-19 like symptoms within five (5) days of symptom onset at the study sites were enrolled.
The first collected nasopharyngeal or anterior nasal swab was collected from one nostril from each subject using standard collection methods for the comparator method. The second collected nasopharyngeal swab from the same nostril was tested directly on the *CareStart*™ COVID-19 Antigen test to demonstrate the agreement with the comparator method.
Testing was performed by six (6) operators with no laboratory experience and who were representative of the intended users. Operators were only using the QRI for the test without any training provided.
A total of 180 nasopharyngeal swab specimens collected from individual symptomatic patients (within 5 days of onset) were considered evaluable. The performance of the *CareStart*™ COVID-19 Antigen test compared to the comparator method is presented in the tables below.

***CareStart*™ COVID-19 Antigen nasopharyngeal clinical performance within 5 days of symptom onset against the comparator method**

CareStart™ COVID-19 Antigen	Comparator		
	Positive	Negative	Total
Positive	30	1	31
Negative	2	147	149
Total	32	148	180
Positive Percent Agreement (PPA)	93.75% (95% CI: 79.85% – 98.27%)		
Negative Percent Agreement (NPA)	99.32% (95% CI: 96.27% – 99.88%)		

The performance of this test has not yet been clinically validated for use in patients without signs and symptoms of respiratory infection or for serial screening applications, and performance may differ in these populations.

Patient Demographics

Age Group	*CareStart*™ COVID-19 Antigen		
	Total #	Positive	Prevalence
≤5 Years of Age	0	0	0.00%
6-21 Years of Age	22	3	13.64%
22-59 Years of Age	134	27	20.15%
≥60 Years of Age	24	2	8.33%

Positive results broken down by days since symptom onset:

Days Since Symptom Onset	Cumulative RT-PCR Positive (+)	Cumulative *CareStart*™ COVID-19 Antigen Positive (+)	PPA	95% Confidence interval	
1	0	0	-	-	-
2	7	7	100.00%	64.57%	100.00%
3	15	15	100.00%	79.62%	100.00%
4	23	22	95.65%	79.01%	99.23%
5	32	30	93.75%	79.85%	98.27%

Clinical Performance – Anterior Nasal Swab

The clinical performance characteristics of the *CareStart*™ COVID-19 Antigen test using anterior nasal swab specimen were evaluated in a multi-site prospective study in the U.S. between November 2020 and December 2020 against an FDA Emergency Use Authorized RT-PCR molecular assay as a comparator method. A total of three (3) Point-of-Care investigational sites throughout the U.S. participated in the study. To be enrolled in the study, patients had to be presenting at the participating study centers with COVID-19 like symptoms and meet inclusion/exclusion criteria. All patients presented with fever or at least two symptoms of COVID-19 infection. The patients presenting the COVID-19 like symptoms within five (5) days of symptom onset at the study sites were enrolled. Clinical studies in asymptomatic patients undergoing serial testing are ongoing to establish the clinical performance.
Two nasal swabs (2) nasal swabs were collected using the provided swabs. One (1) swab was tested on the *CareStart*™ COVID-19 Antigen test and the second swab was processed in transport media for the comparator method. Collection order for the swab to be tested on the *CareStart*™ COVID-19 Antigen test and the swab for reference testing was randomized.
Testing was performed by eight (8) operators with no laboratory experience and who were representative of the intended users. Operators were only using the QRI for the test without any training provided.
A total of 92 nasal swab specimens collected from individual symptomatic patients (within 5 days of onset) were considered evaluable. The performance of the *CareStart*™ COVID-19 Antigen test compared to the comparator method is presented in the tables below.

***CareStart*™ COVID-19 Antigen anterior nasal clinical performance within 5 days of symptom onset against the comparator method**

CareStart™ COVID-19 Antigen	Comparator		
	Positive	Negative	Total
Positive	34	0	34
Negative	5[b]	53	58
Total	39	53	92
Positive Percent Agreement (PPA)	87.18% (34/39) (95% CI: 73.29%-94.40%)		
Negative Percent Agreement (NPA)	100.00% (53/53) (95% CI: 93.24%-100.00%)		

[b]*COVID-19 was not detected in 0/5 False Negative specimens using an alternative FDA-EUA molecular Assay*

The performance of this test has not yet been clinically validated for use in patients without signs and symptoms of respiratory infection or for serial screening applications, and performance may differ in these populations.

Patient Demographics

Age Group	*CareStart*™ COVID-19 Antigen		
	Total #	Positive	Prevalence
≤5 Years of Age	1	1	100.00%
6-21 Years of Age	38	13	34.21%
22-59 Years of Age	47	20	42.55%
≥60 Years of Age	6	0	0%

Positive results broken down by days since symptom onset:

Days Since Symptom Onset	Cumulative RT-PCR Positive (+)	Cumulative *CareStart*™ COVID-19 Antigen Positive (+)	PPA	95% Confidence interval	
0	3	3	100.00%	43.85%	100.00%
1	11	10	90.91%	62.27%	98.38%
2	24	21	87.50%	69.00%	95.66%
3	33	29	87.88%	72.68%	95.19%
4	37	32	86.49%	72.02%	94.09%
5	39	34	87.18%	73.30%	94.40%

Clinical Performance (Asymptomatic Population)

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule. Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 – 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.ttOut of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RTPCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing. Performance of the antigen test with serial testing in individuals is described in the table below.

Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

DAYS AFTER FIRST PCR POSITIVE TEST RESULT	ASYMPTOMATIC ON FIRST DAY OF TESTING			ASYMPTOMATIC ON FIRST DAY OF TESTING		
	Ag Positive / PCR Positive (Antigen Test Performance % PPA)					
	1 Test	2 Test	3 Test	1 Test	2 Test	3 Test
0	9/97 (9.3%)	35/89 (39.3%)	44/78 (56.4%)	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	17/34 (50.0%)	23/34 (67.6%)	25/32 (78.1%)	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	16/21 (76.2%)	15/20 (75.0%)	13/15 (86.7%)	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	20/28 (71.4%)	21/27 (77.8%)	16/18 (88.9%)	37/44 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	13/23 (56.5%)	13/22 (59.1%)	4/11 (36.4%)	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	5/9 (55.6%)	5/8 (62.5%)		4/9 (44.4%)	3/7 (42.9%)	

1 Test = one (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.
2 Tests = two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.
3 Tests = three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

Analytical Sensitivity: Limit of Detection (LoD)

The LoD for direct swab was established using heat-inactivated SARS-CoV-2 isolate USA-WA1/2020 (NR-52286). To prepare the positive sample, the strain was spiked into the pooled human nasal swab matrix obtained from multiple healthy volunteers eluted in VTM and confirmed as SARS-CoV-2 negative by RT-PCR. 50 µl of each positive sample dilution was dispensed onto a dry swab and was tested. The estimated LoD found from the initial two-fold serial dilution test was confirmed by testing 20 replicates. The confirmed LoD for direct swab was 8 x 10^2 $TCID_{50}$/ml. Based upon the testing procedure for this study the LoD of 8x10^2 $TCID_{50}$/mL equates to 4x10^1 $TCID_{50}$/swab.

NIH/RADx® Variant Testing

The performance of this device in the detection of the Omicron variant of SARS-CoV-2 was evaluated in a dilution series of clinical specimens which were positive for the Omicron variant. This testing was conducted by the National Institutes of Health (NIH) as a component of the Rapid Acceleration of Diagnostics (RADx®) initiative. Specimen pools were prepared by the RADx® team using clinical pooled samples from currently circulating Omicron strains and tested by RADx® to assess performance with the Omicron variant.
Results from this dilution series cannot be compared to other specimen pools and do not indicate that a test will have different clinical performance compared to other EUA authorized tests. Compared to an EUA authorized RT-PCR method, the *CareStart*™ COVID-19 Antigen test detected 100% of live virus Omicron samples at a Ct-value of 22.4 (n=5). Testing was also compared to two additional EUA-authorized OTC antigen tests (Assay #1 and Assay #2). Omicron dilutions at lower viral concentrations (Ct-values greater than 22.4) were not detected by the *CareStart*™ COVID-19 Antigen test in this study.

Omicron Pool 1 - Live Omicron Clinical Samples	Average N2 Ct (n=9)	Assay #1 Percent Positive (n = 5)	Assay #2 Percent Positive (n = 5)	*CareStart*™ COVID-19 Antigen Test Percent Positive (n=5)
Dilution 1	19.4	100	100	100
Dilution 2	20.6	100	100	100
Dilution 3	21.6	100	100	100
Dilution 4	22.4	100	100	100
Dilution 5	23.3	100	100	0
Dilution 6	24.5	0	100	0
Dilution 7	25.6	0	100	0
Dilution 8	26.5	0	0	0
Dilution 9	27.7	0	0	0
Dilution 10	28.5	0	0	0
Dilution 11	29.4	0	0	0
Dilution 12	30.3	0	0	0

Analytical Specificity: Cross Reactivity (Exclusivity) and Microbial Interference

The potential cross-reactivity (exclusivity) of a panel of common organisms was evaluated with SARS-CoV-2 negative samples using the *CareStart*™ COVID-19 Antigen test. Potential microbial interference was evaluated with samples containing heat-inactivated SARS-CoV-2 isolate USA-WA1/2020 at approximately 3x LoD. A total of 8 bacteria were tested at a target concentration of approximately 10^7 cfu/ml with the exception of *Mycoplasma pneumoniae*, which was tested at a final concentration of 1.5 x 10^3 cfu/ml. The 18 viruses were tested at concentrations between.
$10^{5.2}$ and $10^{7.9}$ $TCID_{50}$/ml. All negative samples gave negative results at the concentrations of the potentially cross-reactive common organisms tested showing no cross-reactivity with *CareStart*™ COVID-19 Antigen assay. All samples with SARS-CoV-2 strain tested positive showing no microbial interference at the concentrations of the potentially interfering common organisms tested.

Potential Cross-Reactant		
Adenovirus 1	MERS-Coronavirus, Irradiated Lysate	*Bodetella pertussis*
Adenovirus 7	Parainfluenza virus type 1	*Candida albicans*
Enterovirus 71, Taiwan/4643/1998	Parainfluenza virus type 2	*Chlamydophila pneumoniae*
Human coronavirus(OC43)	Parainfluenza virus type 3	*Haemophilus influenzae*
Human coronavirus(229E)	Parainfluenza virus type 4	*Legionella pneumophila*
Human coronavirus(NL63)	Respiratory syncytial virus Type B	*Mycoplasma pneumoniae*
Human metapneumovirus(hMPV)	Rhinovirus	*Staphylococcus aureus*
Influenza A/Michigan/45/2015	SARS-Coronavirus	*Staphylococcus epidermidis*
Influenza B/Wisconsin/01/2010	Pooled human nasal wash	*Streptococcus pneumoniae*
		Streptococcus pyogenes, Group A

To estimate the likelihood of cross-reactivity with SARS-CoV-2 of organisms that were not available for wet testing, in silico analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology. https://blast.ncbi.nlm.nih.gov/Blast.cgi?PAGE=Proteins&PROGRAM=blastp&BLAST_PROGRAMS=blastp&PAGE_TYPE=BlastSearch&BLAST_SPEC=blast2seq&DATABASE=n/a&QUERY=&SUBJECTS=
- The homology between SARS-CoV-2 nucleocapsid protein and human coronavirus HKU1 nucleocapsid protein is relatively low, at 36.7% across 86.4% of sequences, but cross-reactivity cannot be ruled out.
- The homology between SARS-CoV-2 nucleocapsid protein and Mycobacterium tuberculosis total protein (3,991 proteins) is relatively low, homology-based cross-reactivity can be ruled out.
- The homology between SARS-CoV-2 nucleocapsid protein and Pneumocystis jirovecii total protein (3,745 proteins) is relatively low, homology-based cross-reactivity can be ruled out.
- The homology between SARS-CoV-2 nucleocapsid protein and human coronavirus 229E nucleocapsid protein is relatively low, at 28.8% across 72.1% of sequences, but cross-reactivity cannot be ruled out. However, a result of the cross-reactivity wet study showed that *CareStart*™ COVID-19 Antigen had no cross-reactivity against human coronavirus 229E.
- No homologous protein was detected as a result of in silico assay with all the proteins (686 proteins) of Mycoplasma pneumoniae and the nucleocapsid protein (NP) of SARS-CoV-2.

Endogenous Interfering Substances Effect

To assess substances with the potential to interfere with the performance of the *CareStart*™ COVID-19 Antigen, positive and negative samples were tested with the addition of potentially interfering substances. The SARS-CoV-2 target concentration in the positive samples was approximately 2x LoD. All samples tested produced expected results, demonstrating that the *CareStart*™ COVID-19 Antigen test performance was not affected by any of the 30 potentially interfering substances listed in the table below at the concentrations tested.

Potential Interfering Substances	Concentration	Potential Interfering Substances	Concentration
Acetaminophen	10 mg/ml	Mometasone	1 mg/ml
Acetyl salicylic acid	15 mg/ml	Mucin	2%
Beclomethasone	0.5 mg/ml	Mupirocin	1 mg/ml
Benzocaine	5 mg/ml	OTC Throat drop (Halls)	15%
Budesonide	2 mg/ml	OTC Throat drop (Ricola)	15%
Chlorpheniramine maleate	5 mg/ml	OTC Nasal spray (Afrin)	15%
Dexamethasone	1 mg/ml	OTC Nasal spray (VicksSinex)	15%
Dextromethorphan HBr	2 mg/ml	OTC Nasal spray (Zicam)	15%
Diphenhydramine HCl	5 mg/ml	Oxymetazoline HCl	10 mg/ml
Ephedrine HCl	10 mg/ml	Phenylephrine HCl	5 mg/ml
Flunisolide	5 mg/ml	Phenylpropanolamine	5 mg/ml
Fluticasone	1 mg/ml	Tobramycin	1 mg/ml
Guaiacol Glyceryl Ether	20 mg/ml	Triamcinolone	1 mg/ml
Histamine Dihydrochloride	10 mg/ml	Whole Blood	4%
Menthol	10 mg/ml	Zanamivir	1 mg/ml

The interfering effects of biotin concentrations ranging between 625 ng/mL and 10 µg/mL were tested in a separate study. Biotin concentrations up to 1.25 µg/ml did not lead to false results. Biotin concentrations ≥2.5 µg/ml can cause false-negative COVID-19 results with the *CareStart*™ COVID-19 Antigen.

High-dose Hook Effect

The *CareStart*™ COVID-19 Antigen was tested up to 10^5 $TCID_{50}$/ml of heat-inactivated SARS-CoV-2 strain and no high-dose hook effect was observed.

Point of Care Use

The *CareStart*™ COVID-19 Antigen was demonstrated at near patient or Point of Care (POC) testing that non-laboratory personnel can perform the test accurately in the intended use environment. In addition, the robust use of the *CareStart*™ COVID-19 Antigen for near patient or Point of Care (POC) testing was demonstrated by thirteen (13) Flex studies.

Technical Support

For questions, or to report a problem, please call Technical Support at +1-888-898-1270 (Available Hours: Mon. to Fri.: 8 a.m. – 5 p.m.) or TShelp@acessbio.net (24/7 available).

Test system problems may also be reported to the FDA using the MedWatch reporting system (phone: 1-800 FDA-1088; fax: 1-800 FDA-1078: or http://www.fda.gov/medwatch).

REF **RCHM-02071**

QRI-RCHM-E / Rev. E / Jan 17, 2023

Quick Reference Instructions for *CareStart*™ COVID-19 Antigen

Rapid Diagnostic Test for Detection of SARS-CoV-2 Antigen

For prescription use only For *in vitro* diagnostic use

Rx Only IVD 30°C 1°C

For Emergency Use Authorization (EUA) Only

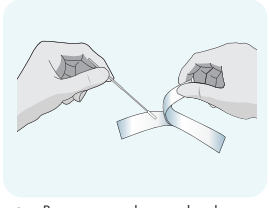
The *CareStart*™ COVID-19 Antigen test is a lateral flow chromatographic immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasopharyngeal or anterior nasal swab samples collected by a healthcare provider from individuals who are suspected of COVID-19 within the first 5 days of symptom onset when tested at least twice over three days with at least 48 hours between tests and from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 hours between tests.

IMPORTANT!

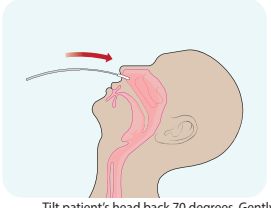
- Refer to the Package Insert (Instructions for Use) for Warnings and Precautions, Specimen Collection Procedures, Storage and Handling Conditions, and Quality Control Recommendations.
- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- If you have had symptoms longer than 5 days you should consider testing at least three times over five days with at least 48 hours between test.
- 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.
- Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

SPECIMEN COLLECTION AND HANDLING

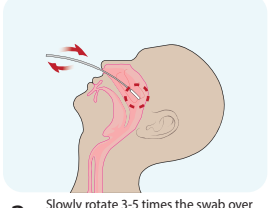
Nasopharyngeal (NP) Swab Collection



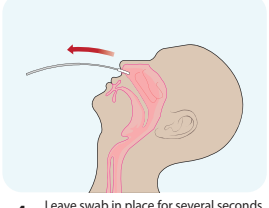
1 Remove a nasopharyngeal swab from the pouch.



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.

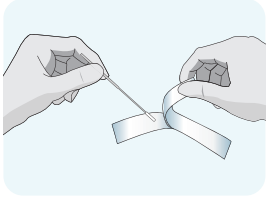


3 Slowly rotate 3-5 times the swab over the surface of the posterior nasopharynx.

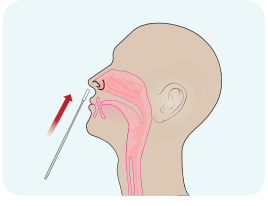


4 Leave swab in place for several seconds to absorb secretions. Slowly remove the swab from the nostril while rotating it.

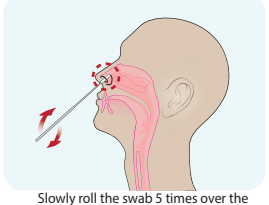
Anterior Nasal Swab Collection



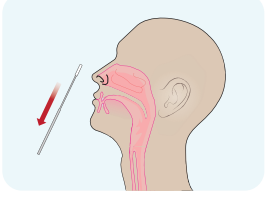
1 Remove a nasal swab from the pouch.



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.

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.

Access Bio, Inc.
65 Clyde Road, Suite A
Somerset, NJ 08873, USA

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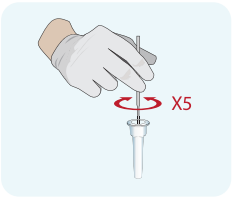
Email: TShelp@accessbio.net

Quick Reference Instructions for *CareStart*™ COVID-19 Antigen

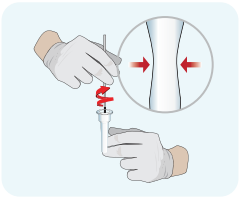
Rapid Diagnostic Test for Detection of SARS-CoV-2 Antigen

TEST PROCEDURES

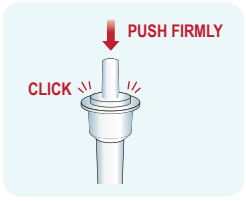
1 Peel off aluminum foil seal from the top of the extraction vial containing the extraction buffer.



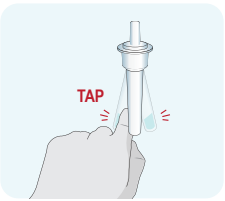
2 Place the swab into the extraction vial. Rotate the swab vigorously at least 5 times.



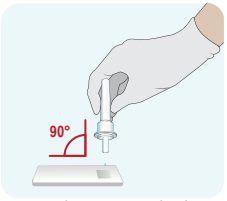
3 Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab. Properly discard the swab.



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



5 Mix thoroughly by flicking the bottom of the tube.

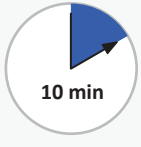


6 Invert the extraction vial and hold the sample vertically above the sample well. Squeeze the vial gently. Allow three (3) drops of sample to fall into the sample well.

NOTE: Refer to the Package Insert for the cautions.

RESULT INTERPRETATION

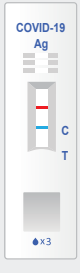
Start the timer



Do not read test results before 10 minutes or after 15 minutes. Results read before 10 minutes or after 15 minutes may lead to a false positive, false negative, or invalid result.

Warning

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



COVID-19 Positive (+)

If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible blue test (T) line with the red control line (C) should be read as positive.

You do not need to perform repeat testing if you have a positive result at any time.

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely you have COVID-19 and are contagious. Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

Individuals tested positive with the *CareStart*™ COVID-19 Antigen should self-isolate and seek follow up care with their physician or healthcare provider as 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.

COVID-19 Negative (-)

If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.

To increase the chance that the negative result for COVID-19 is accurate, you should:

- Test again in 48 hours if you have symptoms on the first day of testing.

- Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.

A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If you test negative and continue to experience COVID-19-like symptoms, (e.g., fever, cough, and/or shortness of breath) you should seek follow up care with your health care provider.

Invalid

If the control (C) line is not visible, the test is invalid. Re-test with a new swab and new test device.

External Control Swab Test

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.

Serial (Repeat) Testing

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

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.