Medek
Health Systems

FDA Authorized Test Kit

COVID-19 Antigen

Rapid Diagnostic Test

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.

- **Identify acute infection with high sensitivity and 100% specificity**
- **Rapid 10 Minute result**
- **Point of Care Use**
- **Anterior (shallow) Nasal Swab Collection**

EACH KIT CONTAINS

Test Device	Nasal Swab	Vital Holder
Extraction Vial	Control Swab	

MEDEKTESTKITS.COM

131 Waterman Ave
Mount Dora - FL 32757

888-996-3335

The MEDEK supplied test kit is FDA authorized for use without a separate reading machine at the Point of Care.

Product Information and Limitations of Sale:

- Results in 10 minutes w/ rapid testing
- Each set (box) has 20 individual tests
- Expiration dates have been extended by FDA (Attached below)
- For use as an aid in identifying SARS-CoV-2, nucleocapsid protein antigen
- Verification of use case prior to shipping is mandatory

Governance

A. The CareStart™ COVID-19 Antigen test is a lateral flow immunochro-matographic assay intended for the qualitative detection of the nucleocapsid protein antigen from SAR-S CoV-2 in 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. Testing is limited to laborato-ries 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.

B. Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency issued on the web on March 16, 2020 by U.S. Food and Drug Administration (FDA") which may be found here: https://www.fda.gov/media/135659/download

C. The CareStart™ COVID-19 Antigen test is authorized for use using anterior nasal swab specimen collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms.

Compliance

A. All sales of Products are subject to the purchaser's compliance with the Policy and that the Products shall only be used by health professionals as defined in subsection (g)at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=810.2

B. The Products shall not be made available, offered, distributed or marketed, directly or indirectly, to the general public, or made available, sold, distributed or marketed to anyone who the Representative or the Approved Account knows or has any reason to know will make available, offer, distribute or market, directly or indirectly, the Products to the general public.

C. The Products are only for preliminary screening purposes and shall only be used to determine if additional testing is required

Buyer Requirements

A. Qualified parties who agree to follow the guidance in the Policy including, but not limited to, validation, FDA notification, reporting of results, Emergency Use Authorization, clinical testing and distribution

B. Payment must be made prior to shipment

C. Payments accepted: Wire transfer or Credit Card (AMEX Preferred).

D. Order questions: Medek Health Systems, LLC- (352) 516-3072.

E. Wire transfer questions: (352) 383-2111.

F.

BANK:	First National Bank of Mount Dora
ABA:	063104312
BENEFICIARY:	Medek Health Systems, LLC 131 Waterman Avenue Mount Dora, FL 32757
ACCOUNT NO:	30112085

Misc.

A. FDA guidelines for the product are attached below.

B. COVID-19 Antigen Rapid Diagnostic package insert is attached below.

C. Fact sheet for healthcare providers is attached below.

D. Fact sheet for patients is attached below.

July 16, 2021

Sang Joon Han
Associate Principal Scientist / R&D Division
Access Bio, Inc.
65 Clyde Road Suite A
Somerset, NJ 08873

Re: EUA202625/S005
Trade/Device Name: *CareStart* COVID-19 Antigen
Dated: June 18, 2021
Received: June 21, 2021

Dear Sang Joon Han:

This is to notify you that your request to update the shelf-life expiration date of the *CareStart* COVID-19 Antigen test to 12 months at 1–30°C based on the results of your real-time stability study, is granted. Upon review, we concur that the data and information submitted in EUA202625/S005 supports the requested update. By submitting this EUA revision for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the *CareStart* COVID-19 Antigen re-issued on February 1, 2021.

Sincerely yours,

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

October 8, 2020

Sang Joon Han
Associate Principal Scientist / R&D Division
Access Bio, Inc.
65 Clyde Road Suite A
Somerset, NJ 08873

Device:	*CareStart* COVID-19 Antigen test
Company:	Access Bio, Inc.
Indication:	Qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal swab specimens directly collected, or collected in BD universal transport media, from individuals suspected of COVID-19 by their healthcare provider within five days of symptom onset. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate 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.

Dear Sang Joon Han:

This letter is in response to your[1] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[2] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Access Bio, Inc..
[2] For ease of reference, this letter will use the term "your product" to refer to the *CareStart* COVID-19 Antigen test used for the indication identified above.

vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[3]

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is contained in the Instructions for Use (identified below).

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19 and that the known and potential benefits of your product when used for such a use, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[4]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details

Your product is a visually read a lateral flow immunochromatographic assay for the detection of from SARS-CoV-2 in nasopharyngeal swab specimens directly collected, or collected in BD universal transport media, from individuals suspected of COVID-19 by their healthcare provider within five days of symptom onset. The SARS-CoV-2 viral antigen is generally detectable in nasopharyngeal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but the clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out a bacterial infection or co-infection with other viruses.

---

[3] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 7, 2020).

[4] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

Negative results are presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

Testing is limited to laboratories certified under CLIA that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the POC, i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

To use your product, the patient sample, either the direct swab or swab in viral transport media is transferred to the extraction vial, during which time the virus particles in the sample are disrupted, exposing internal viral nucleoproteins. Extracted swab sample is then 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 *CareStart* COVID-19 Antigen test includes the following materials or other authorized materials: Test devices, Extraction vials and caps, Nasopharyngeal swabs, Positive control swab, Negative control swab, Package insert, and Quick Reference Instructions (QRI).

Your product requires various types of quality control, including the Internal Quality Control and the External Control materials, or other authorized control materials (as may be requested under Condition K. below), that are processed in the same way as the patient samples. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the Instructions for Use:

- Positive Control Swab: Recombinant SARS-CoV-2 nucleocapsid protein antigen is dried on the foam-tipped head
- Negative Control Swab: Blank Universal Viral Transport media (BD UVT) is dried on the foam-tipped head

Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and are described in the Instructions for Use.

The labeling labeling entitled "*CareStart* COVID-19 Antigen Package Insert (Instructions for Use)" and the "Quick Reference Instructions for *CareStart* COVID-19 Antigen" (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas), and the following fact sheets pertaining to the emergency use, which are required to be made available as set forth in the Conditions of Authorization (Section IV), are collectively referred to as "authorized labeling":

- Fact Sheet for Healthcare Providers: Access Bio, Inc.- *CareStart* COVID-19 Antigen

- Fact Sheet for Patients: Access Bio, Inc.- *CareStart* COVID-19 Antigen

The above described product, with the authorized labeling as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Access Bio, Inc. (You) and Authorized Distributor(s)[5]

[5] "Authorized Distributor(s)" are identified by you, Access Bio, Inc., in your EUA submission as an entity allowed

A. Your product must comply with the following labeling requirements under FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. You and authorized distributor(s) will make your product available with the authorized labeling to authorized laboratories.

C. You and authorized distributor(s) will make available on your website(s) the authorized labeling.

D. You and authorized distributor(s) will include a physical copy of the authorized Quick Reference Instructions with each shipped kit of your product to authorized laboratories, and will make the authorized Instructions for Use electronically available with the opportunity to request a copy in paper form, and after such request, promptly provide the requested information without additional cost.

E. You and authorized distributor(s) will inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product, authorized labeling and authorized Fact Sheets.

F. Through a process of inventory control, you and authorized distributor(s) will maintain records of the authorized laboratories to which they distribute the test and number of tests they distribute.

G. You and authorized distributor(s) will collect information on the performance of your product. You will report to FDA any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware.

H. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

Access Bio, Inc. (You)

I. You will notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

J. You will provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).

---

to distribute your product.

K. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) and require appropriate authorization from FDA prior to implementation.

L. You will comply with the following requirements under FDA regulations: Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

M. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the tests released for distribution have the clinical and analytical performance claimed in the authorized labeling.

N. If requested by FDA, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.

O. You will evaluate the analytical limit of detection and assess traceability[6] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

P. You will further evaluate the clinical performance of your product in an FDA agreed upon post authorization clinical evaluation study within 4 months of the date of this letter (unless otherwise agreed to with DMD/OHT7- OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you will update authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

Q. You will have a process in place to track adverse events, including any occurrence of false results with your product, and report to FDA pursuant to 21 CFR Part 803.

Authorized Laboratories

R. Authorized laboratories using your product will include with test result reports, all

[6] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

S. Authorized laboratories using your product will use your product as outlined in the authorized labeling. Deviations from the 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.

T. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.

U. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

V. Authorized laboratories will 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 you (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.

W. 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.

Access Bio, Inc. (You), Authorized Distributors and Authorized Laboratories

X. You, authorized distributors, and authorized laboratories using your product will 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.

Conditions Related to Printed Materials, Advertising and Promotion

Y. All descriptive printed matter, including advertising and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

Z. No descriptive printed matter, including advertising or promotional materials, relating to the use of your product may represent or suggest that this test is safe or effective for the detection and differentiation of SARS-CoV-2, influenza A and influenza B.

AA. All descriptive printed matter, including advertising and promotional materials, relating to the use of your product shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;

- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and
- This test 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 authorization is terminated or revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

_____
RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure

FACT SHEET FOR HEALTHCARE PROVIDERS

Access Bio, Inc. **October 8, 2020**

***CareStart*™ COVID-19 Antigen**

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the *CareStart*™ COVID-19 Antigen test.

The *CareStart*™ COVID-19 Antigen test is authorized for use using nasopharyngeal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: Access Bio, Inc. – CareStart™ COVID-19 Antigen.

What are the symptoms of COVID-19?
Many patients with 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 include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat, new loss of taste or smell, nausea or vomiting or diarrhea. 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. For further information on the symptoms of COVID-19 please see the link provided in "*Where can I go for updates and more information?*" section.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States. Please check the CDC COVID-19 webpage (see link provided in "*Where can I go for updates and more information?*" section at the end of this document) or your local jurisdictions website for the most up to date information.

What do I need to know about COVID-19 testing?
Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "*Where can I go for updates and more information?*" section).

This test is to be performed only using nasopharyngeal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms.

- The *CareStart*™ COVID-19 Antigen test can be used to test nasopharyngeal swab specimens directly collected or collected in BD universal transport media.
- The CareStart™ COVID-19 Antigen test should be ordered for the detection of COVID-19 in individuals who are suspected of COVID-19 by their healthcare provider and who are within the first five days of onset of symptoms.
- The *CareStart*™ COVID-19 Antigen test is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high, moderate or waived complexity tests.
- The *CareStart*™ COVID-19 Antigen 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.

Specimens should be collected with appropriate infection control precautions. Current guidance is available at the CDC's website (see links provided in "*Where can I go for updates and more information?*" section).

When collecting and handling specimens from individuals suspected of being infected with COVID-19, appropriate personal protective equipment should be used as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)*. For additional information, refer to CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19)* (see links provided in "*Where can I go for updates and more information?*" section).

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

What does it mean if the specimen tests positive for the virus that causes COVID-19?
A positive test result for COVID-19 indicates that antigens from SARS-CoV-2 was detected, and therefore the patient is infected with the virus and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in making a final diagnosis and patient management decisions. Patient management should be made by a healthcare provider and follow current CDC guidelines.

The *CareStart*™ COVID-19 Antigen test has been designed to minimize the likelihood of false positive test results. In the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, limits in the ability to work, delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

All laboratories using this test must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen tests negative for the virus that causes COVID-19?
A negative test result for this test means that SARS-CoV-2 antigens were not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Antigen tests are known to be less sensitive than molecular tests that detect viral nucleic acids. The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 5 of illness may be more likely to be negative compared to a RT-PCR assay. Therefore, negative results are presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed. It is possible to test a person too early or too late during COVID-19 infection to make an accurate diagnosis via the *CareStart*™ COVID-19 Antigen test.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing or testing with molecular methods should be considered by healthcare providers in consultation with public health authorities. Additional testing may be helpful to ensure testing was not conducted too early.

Risks to a patient of a false negative test result include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

A negative antigen test should not be the sole basis used to determine if a patient can end isolation precautions. For additional recommendations regarding infection control, refer to CDC's *Discontinuation of Isolation for Persons with COVID-19 Not in Healthcare Settings* (Interim Guidance) (see links provided in "Where can I go for updates and more information" section).

What is an EUA?
The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved

or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in diagnosing COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

What are the approved available alternatives?
There are no approved available alternative tests. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

Where can I go for updates and more information?

CDC webpages:

General: https://www.cdc.gov/COVID19
Symptoms:
https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html
Healthcare Professionals:
https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html
Information for Laboratories:
https://www.cdc.gov/coronavirus/2019-nCoV/guidance-laboratories.html
Laboratory Biosafety: https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html
Isolation Precautions in Healthcare Settings:
https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html
Specimen Collection: https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html
Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html
Discontinuation of Isolation:
https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html
Influenza: https://www.cdc.gov/flu/index.htm

FDA webpages:

General: www.fda.gov/novelcoronavirus
EUAs: (includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

Access Bio, Inc.:

65 Clyde Road, Suite A
Somerset, NJ 08873 USA

Telephone: 732-783-4040
Fax: 732-873-4043
Website: www.accessbio.net
Email: info@accessbio.net

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

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

FACT SHEET FOR PATIENTS

Access Bio, Inc.

***CareStart*™ COVID-19 Antigen**

October 8, 2020

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the *CareStart*™ COVID-19 Antigen test.

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

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

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

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

.
Why was my sample tested?
You were tested because your healthcare provider believes you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and/or other risk factors and you are within the first five days of the onset of symptoms.

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

Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community

What does it mean if I have a positive test result?
If you have a positive test result, it is very likely that you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. You should follow CDC guidance to reduce the potential transmission of disease. There is a very small chance that this test can give a positive result that is wrong (a false positive result) particularly when used in a population without many cases of COVID-19 infection. Your healthcare provider will work with you to determine how best to care for you based on the test results along with medical history, and your symptoms.

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

What does it mean 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. However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID- 19 even though the test is negative. If your test result is negative, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. The amount of antigen in a sample may decrease the longer you have symptoms of infection. Specimens collected after you have had symptoms for more than five days may be more likely to be negative compared to a molecular assay.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

What are the differences between antigen tests and other COVID-19 tests?
There are different kinds of tests for diagnosing COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests detect proteins from the virus. Antigen tests are very specific for the virus, but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection.

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

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

AND

- Other symptoms have improved (for example, when your cough or shortness of breath has improved)

AND

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

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

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

What are the approved alternatives?
There are approved influenza tests, but there is not yet an approved available alternative test for influenza combined with COVID-19 in one test. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

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

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 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. Testing is 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 of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the identification of the SARS-CoV-2 nucleocapsid protein antigen. The antigen is generally detectable in nasopharyngeal or anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but the clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do 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.

Negative results should be treated as presumptive, and do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management.

For serial testing programs, 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 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 SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.

The *CareStart*™ COVID-19 Antigen is intended for use in point of care settings and operated by healthcare professionals or trained users 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.

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 and Precautions

- For prescription and *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) 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.
- 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 diagnostic tests 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 been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- Immediately use after opening the test device in the pouch.
- In order to obtain accurate results, the test must follow this package insert.
- 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 interpret the test result before 10 minutes and after 15 minutes starting the test.
- 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 the test device package is damaged.
- Do not use the kit contents beyond the expiration date.
- Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.
- 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.
- Nitrile or latex gloves should be worn when performing this test.
- If the extraction buffer contacts the skin or eye, flush with copious amounts of water.
- 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 azides. On disposal, flush with a large volume of water to prevent azide build-up.
- Do not interchange kit contents from different lots.
- Do not re-use any contents in the kit as they are single-use only.
- For 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.

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

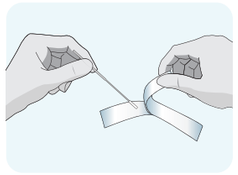
Acceptable specimen type for testing with the *CareStart*™ COVID-19 Antigen is a direct nasopharyngeal and anterior nasal swab specimen. It is essential that correct specimen collection and preparation methods be followed. Inadequate specimen collection, improper specimen handling and/or transport may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

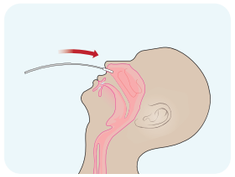
Nasopharyngeal Swab Collection

Procedural Notes

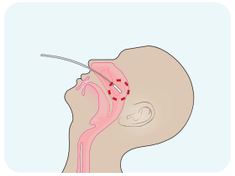
- Process the test sample immediately after collection.
- Use only recommended nasopharyngeal swab for specimen collection.
- Collect the specimen wearing safety gloves to avoid contamination.
- Do not touch the tip (specimen collection area) of the swab.
- Collect samples as soon as possible within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



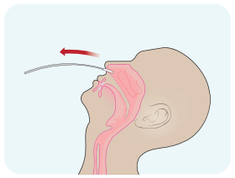
1
Remove a nasopharyngeal swab from the pouch.



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.

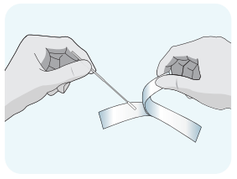


4
Leave swab in place for several seconds to absorb secretions. Slowly remove the swab from the nostril while rotating it.

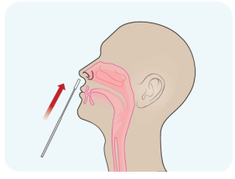
Anterior Nasal Swab Collection

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.	LOT	**Batch code** Indicates the manufacturer's batch code so that the batch or lot can be identified.	CONTROL +	**Positive control** Indicates a control material that is intended to verify the results in the expected positive range.
	Consult instructions for use Indicates the need for the user to consult the instructions for use.		**Do not re-use** Indicates a medical device that is intended for one use, or uses on a single patient during a single procedure.	CONTROL −	**Negative control** Indicates a control material that is intended to verify the results in the expected negative range.
	Manufacturer Indicates the medical device manufacturer.		**Use by date** Indicates the date after which the medical device is not to be used.	REF	**Catalog number** Indicates the manufacturer's catalog number so that the medical device can be identified.

	Caution Indicates the need for the user to consult 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.		**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.
	Date of manufacture Indicates the date when the medical device was manufactured.		**Contains sufficient for <n> tests** Indicates the total number of IVD tests that can be performed with the IVD.
	Temperature limit Indicates the temperature limits to which the medical device can be safely exposed.	Rx	**Prescription-only**

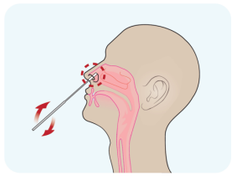
Manufactured by:
Access Bio, Inc.
65 Clyde Road, Suite A.
Somerset, NJ 08873, USA
Tel: 732-873-4040
Fax: 732-873-4043
Email: info@accessbio.net
Website: www.accessbio.net

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

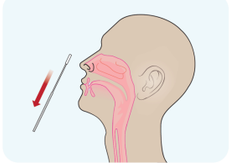
Manufactured for:
Intrivo Diagnostics, Inc.
2021 Santa Monica Blvd, #11
Santa Monica, CA 90404, USA
Tel: 888-965-0301
Fax: 888-965-0302
Email: info@intrivo.com
Website: www.intrivo.com

AccessBio

Document number: IFU-RCHM71-E Revision number: E Effective date: Apr. 15, 2021



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.

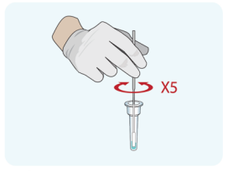
Test Procedures

Procedural Notes

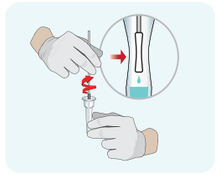
- Allow test devices, reagents, specimens, and/or controls to equilibrate to room temperature (15~30°C) prior to testing.
- Remove the *CareStart*™ COVID-19 Antigen test device and extraction vial from its foil pouch immediately before testing.
- The *CareStart*™ COVID-19 Antigen kit IS INTENDED to be 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

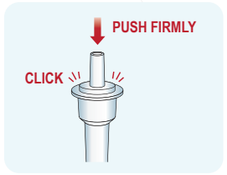
1 Peel off aluminum foil seal from the top of the extraction vial containing the extraction buffer



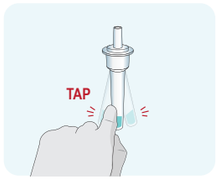
2 Place the swab into the extraction vial. Rotate the swab vigorously at least 5 times.



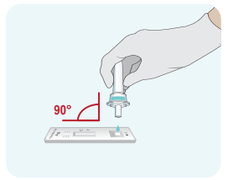
3 Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab. Properly discard the swab.



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

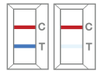
The false positive, false negative, or invalid results may occur if the test is interpreted outside of the interpretation window.

Interpretation of Results

NOTE: The test results should be read and interpreted at 10 minutes after the sample application and the reading and interpretation of the results should not exceed 15 minutes. The test results should not be interpreted using any instruments.

Positive: two distinct colored lines appear.

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



NOTE: The color intensity in the test region will vary depending on the amount of SARS-CoV-2 nucleocapsid protein antigen present in the sample. Any faint colored line(s) in the test region(s) should be considered as positive.

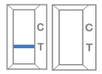
Negative:

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

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

Invalid:

If the red-colored line in the control region "C" is not visible, the result is invalid. Re-run the test one time using the remaining specimen in the extraction vial if an invalid result is obtained during initial testing.



Serial Testing Results Reporting

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19, such as, an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Limitations

1. 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 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests, and performance may differ in these populations. A study to support use for serial testing will be completed.
2. 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.
3. Negative results, should be treated as presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed.
4. Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result.
5. If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
6. Extracted specimens are stable for 4 hours in extraction buffer at room temperature.
7. 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.
8. This test will indicate the presence of SARS-CoV-2 nucleocapsid protein antigen in the specimen from both viable and non-viable SARS-CoV-2 virus. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
9. 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.
10. Results from the device should be correlated with the clinical history, epidemiological data and other data available to the clinician evaluating the patient.
11. This device has been evaluated for use with human specimen material only.
12. False-negative results may occur if the concentration of the target antigen in the clinical specimen is below the detection limits of the device.
13. This device is a qualitative test and does not provide information on the viral concentration present in the specimen.
14. This test cannot rule out diseases caused by other bacterial or viral pathogens.
15. The prevalence of infection will affect the test's predictive values.
16. 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 in 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.
17. 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 FDAwebsite: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/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 be used, which may include mass media.

B. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the 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 (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 Q/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%	43.85%	100.01%
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%

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). 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 to prepare positive samples. 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.

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 10^8 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, Tainan/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 10^8 $TCID_{50}$ /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@accessbio.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. C / Apr. 15, 2021

Quick Reference Instructions for *CareStart*™ COVID-19 Antigen | **Rapid Diagnostic Test for Detection of SARS-CoV-2 Antigen**

For Emergency Use Authorization (EUA) Only

Rx Only IVD 1°C 30°C

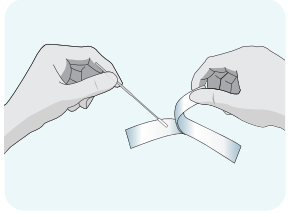
The *CareStart*™ COVID-19 Antigen test is a lateral flow immunochromatographic assay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal or anterior nasal swab specimens directly collected from individuals who are either suspected of COVID-19 by 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!

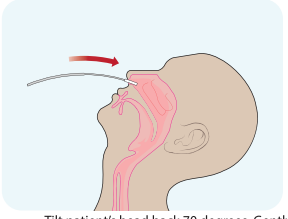
- Refer to the Package Insert for Warnings and Precautions, Specimen Collection Procedures, Storage and Handling Conditions, and Quality Control Recommendations.
- Warning and Precautions - All kit components can be discarded as Biohazard waste according to local guidelines. Refer to the product safety 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.
- 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

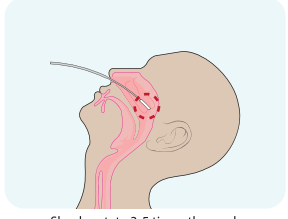
Nasopharyngeal (NP) Swab Collection



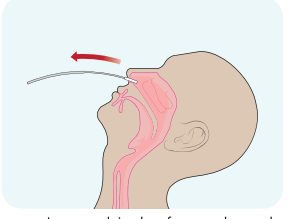
1 Remove a nasopharyngeal swab from the pouch.



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.

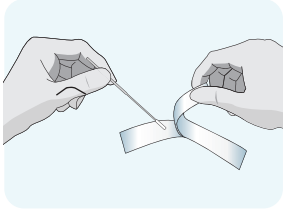


3 Slowly rotate 3-5 times the swab over the surface of the posterior nasopharynx.

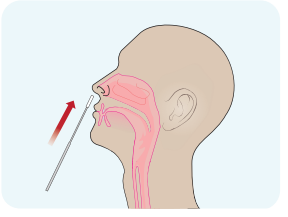


4 Leave swab in place for several seconds to absorb secretions. Slowly remove the swab from the nostril while rotating it.

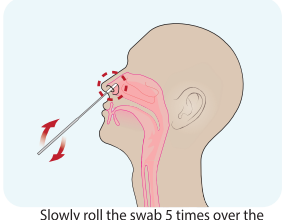
Anterior Nasal Swab Collection



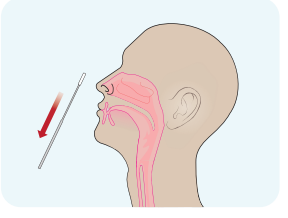
1 Remove a nasal swab from the pouch.



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 EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, 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 of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 under Section 564(b)(1) of the FederalFood, 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

Tel: 732-873-4040
Fax: 732-873-4043
Email: info@accessbio.net
Website: www.accessbio.net

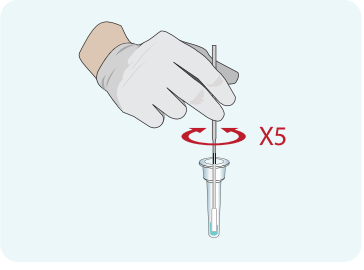
Technical Support
Tel: 888-898-1270 (Toll Free)
Email: TShelp@accessbio.net

REF RCHM-02071

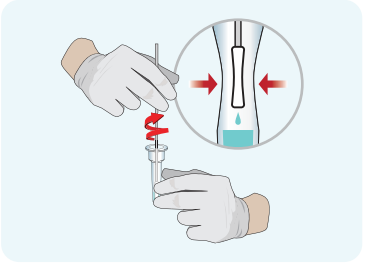
Quick Reference Instructions for *CareStart*™ COVID-19 Antigen | **Rapid Diagnostic Test for Detection of SARS-CoV-2 Antigen**

TEST PROCEDURES

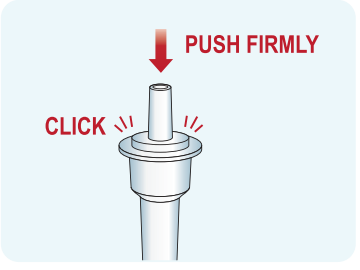
1 Peel off aluminum foil seal from the top of the extraction vial containing the extraction buffer.



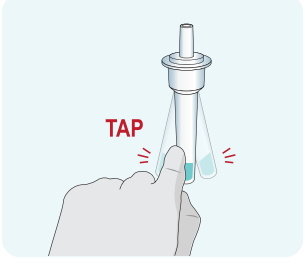
2 Place the swab into the extraction vial. Rotate the swab vigorously at least 5 times.



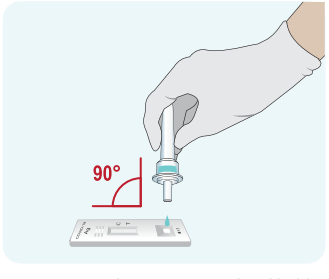
3 Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab. Properly discard the swab.



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



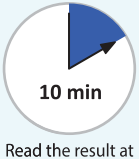
5 Mix thoroughly by flicking the bottom of the tube.



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.

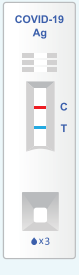
Start the timer



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.



Result Interpretation

Positive

SARS-CoV-2 antigen present; does not rule out co-infection with other pathogens. The color intensity in the test region will vary depending on the amount of SARS-CoV-2 antigen present in the sample. Any faint colored line(s) in the test region(s) should be considered as positive.

Negative

Negative results are presumptive. Negative test results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions, including infection control decisions,particularly in the presence of clinical signs and symptoms consistent with COVID-19, or in those who have been in contact with the virus. It is recommended that these results be confirmed by a molecular testing method, if necessary for patient management.

Invalid

If the red-colored line in the control region "C" is not visible, the result is invalid. Re-run the test one time using the remaining specimen in the extraction vial if an invalid result is obtained during initial testing.

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.

Access Bio, Inc.

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.