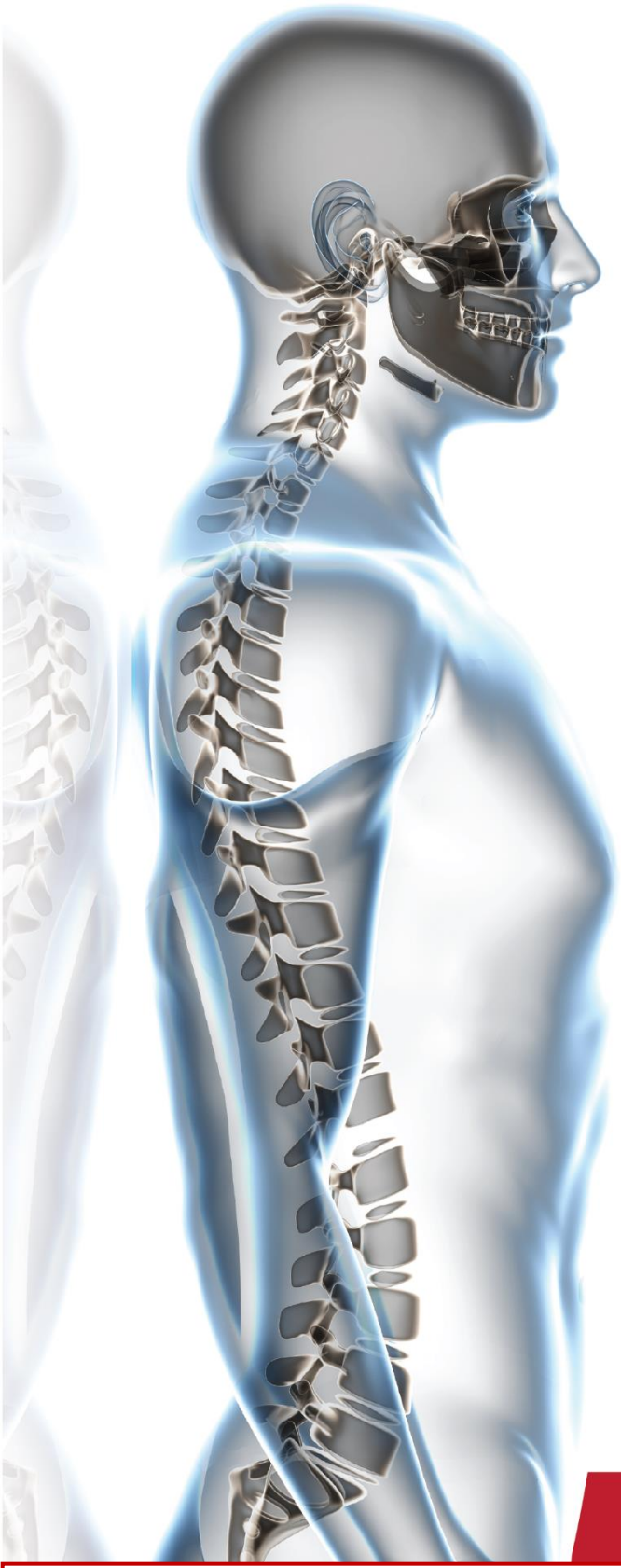

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Inside this Device Packet ...

- ***CareStart by AccessBIO | Rapid Antigen SARS-CoV-19 Test Kit***
- *Information and Billing Information (Back of the Booklet)*

Billing & Coding Guidance

New CPT Code Expands COVID-19 Coding, Billing to Antigen Tests

The AMA's new Category I CPT code will allow for COVID-19 coding and billing of antigen tests performed on patients suspected of being infected by the novel coronavirus.
AMA develops CPT code for COVID-19 antigen tests

87426 is a Category I CPT code approved by the CPT Editorial Panel late last week during a special meeting. The long descriptor is:

Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19])

The new code is meant for "use as the industry standard for accurate reporting and tracking of antigen tests using immunofluorescent or immunochromatographic technique for the detection of biomolecules produced by the SAR-CoV-2 virus," the AMA stated in the release.

Although the code is not specific to the novel coronavirus, the association points out in official CPT coding guidance. The code can be used for an immunoassay that detects antigenic proteins for either SARS-CoV or SARS-CoV-2.

The healthcare industry is increasingly using antigen tests as a quicker and simpler means to test patients for COVID-19.

Antigen tests notably differ from other diagnostic tests by determining whether a patient had COVID-19 in the past and antibodies against the novel coronavirus. They are another type of serology test, which has become popular in the fight against COVID-19 amid diagnostic test shortages.

New CPT codes approved during the special meetings have enabled providers, clinical laboratories, and other healthcare stakeholders to more accurately report and track cases of COVID-19. The codes have also allowed CMS and other payers to reimburse providers for performing COVID-19 tests.

ACCESSBIO

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

CareStart™

COVID-19 Antigen

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

Package Insert

(Instructions for Use)

Table of Contents

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

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 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. 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 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 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.

The *CareStart*™ COVID-19 Antigen is intended for use by medical professionals or trained operators who are proficient in performing tests and trained clinical laboratory personnel or individuals trained in point of care settings. 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. To effectively end the SARS-CoV-2 pandemic, systematic screening and detection of both clinical and asymptomatic COVID-19 cases is critical. Particularly, the identification of subclinical or asymptomatic cases is important to reduce or stop the infection because these individuals may transmit the virus. As a point-of-care test with a 10 min testing time, *CareStart*™ COVID-19 Antigen test allows effective screening of COVID-19 infection on a large scale.

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 swab specimens either directly collected or collected in BD universal transport media from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of symptom onset.

Nasopharyngeal 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 lines 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 400 μl extraction buffer solution.
Nasopharyngeal swab	20 each	swabs for nasopharyngeal 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 Universal Viral Transport media (BD UVT) is dried on the foam-tipped head.
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 test has not been FDA cleared or approved.
- This test has not been FDA cleared or approved; the test 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 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.
- This test 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 authorization is terminated or revoked sooner.
- This test 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.
- 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 nasopharyngeal 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.

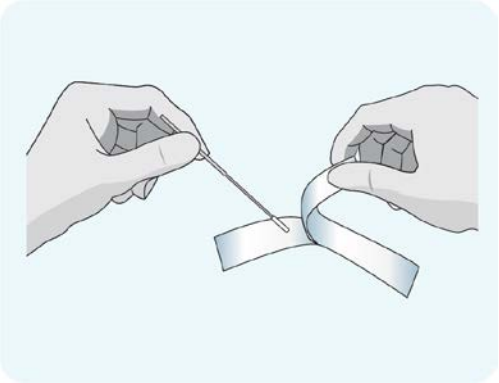
Specimen Collection and Handling

Acceptable specimen type for testing with the *CareStart*™ COVID-19 Antigen is a direct nasopharyngeal swab specimen or a swab in BD universal transport media. 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 may be frozen at -80C and used up to 5 days and 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

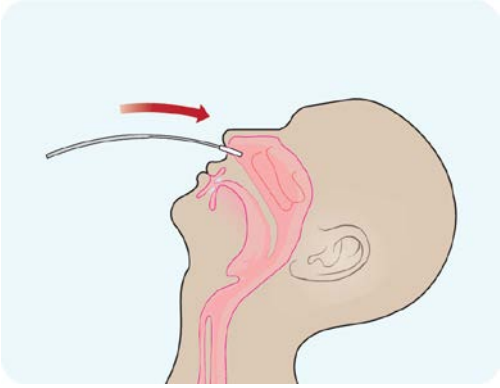
Nasopharyngeal Swab Sample Collection Procedure

Procedural Notes

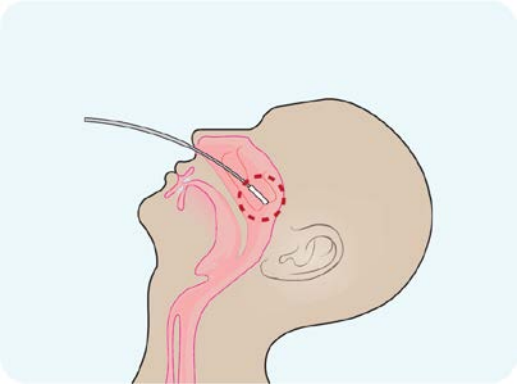
- Process the test sample immediately after collection.
- Use only provided or recommended nasopharyngeal swab for specimen collection.
- Collect the specimen wearing safety gloves to avoid contamination.
- Do not touch the tip (specimen collection area) of the swab.
- Collect samples as soon as possible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



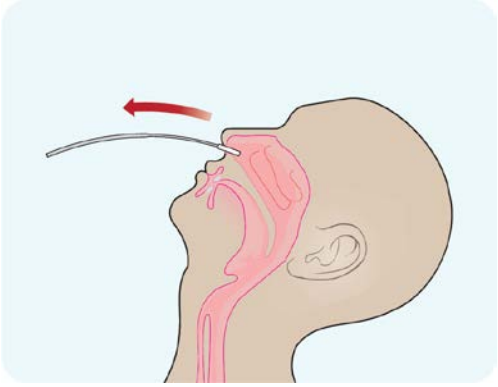
1. Remove a nasopharyngeal swab from the pouch.



2. Place 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. Slowly remove the swab from the nostril while rotating it.

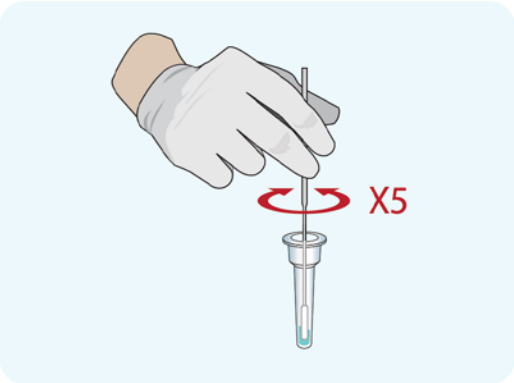
Test Procedures

Procedural Notes

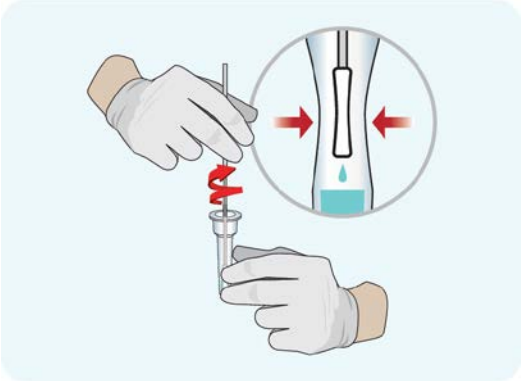
- Allow test devices, reagents, specimens, and/or controls to equilibrate to room temperature (15~30°C) prior to testing.
- Remove the *CareStart*™ COVID-19 Antigen test device and extraction vial from its foil pouch immediately before testing.
- The *CareStart*™ COVID-19 Antigen kit IS INTENDED to be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

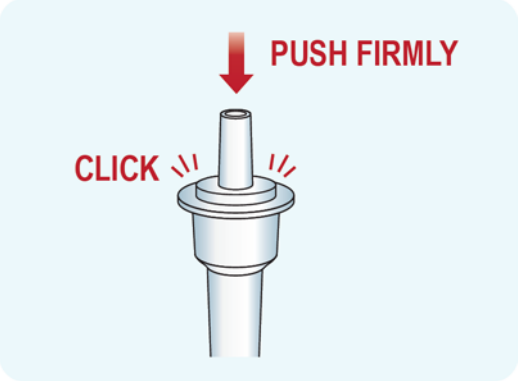
Direct Nasopharyngeal Swab Test Procedure

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

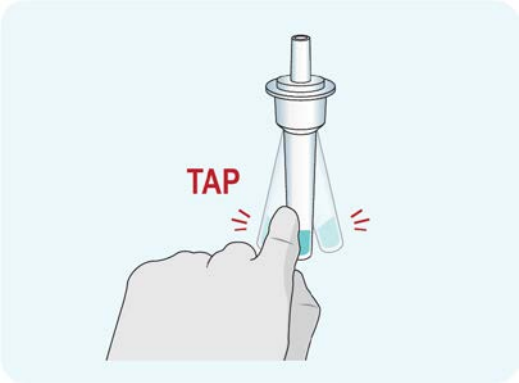


2. Place the swab into the extraction vial. Rotate the swab vigorously at least 5 times.

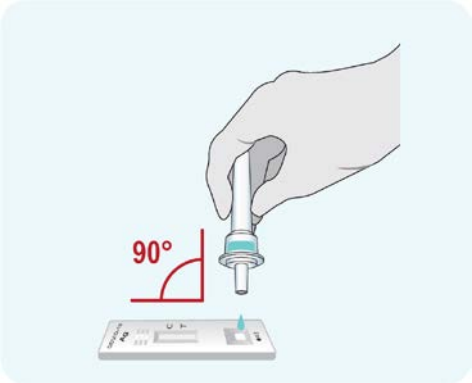




3. Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab. Properly discard the swab.

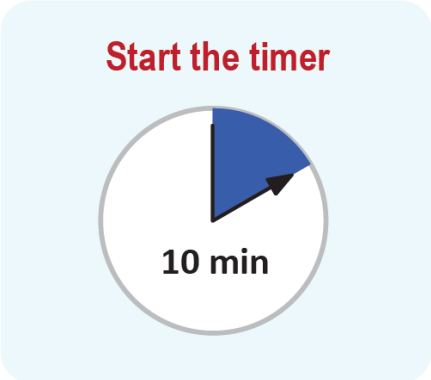


4. Close the vial with the provided cap and push firmly onto the vial.



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.

Nasopharyngeal Swab in Viral Transport Media (VTM) Test Procedure

NOTE: Only BD universal transport media have been validated with the assay.

1. Mix the specimen stored in VTM by vortexing.
2. Collect 400 µl of swab specimen with a calibrated micropipette from the VTM tube.

NOTE: Avoid mucoid substances when collecting from the VTM tube.

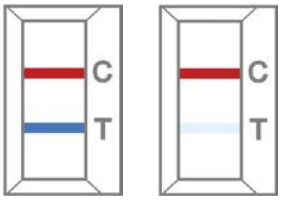
3. Add all 400 µl of collected swab specimen from the micropipette into the extraction vial after peel off the aluminum foil seal.
4. Follow Steps 4 – 7 of the **Direct Nasopharyngeal Swab Test Procedure** above.

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" indicates COVID-19 positive result.



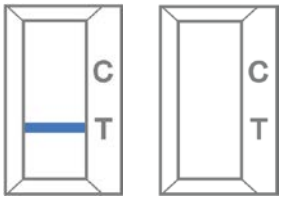
NOTE: The color intensity in the test region will vary depending on the amount of SARS-CoV-2 nucleocapsid protein antigen present in the sample. Any faint colored line(s) in the test region(s) should be considered as positive.

Negative:

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

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.



Limitations

1. 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.
2. Negative results, should be treated as presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed.

3. Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result.
4. If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
5. Clinical performance using VTM was established on frozen specimens and performance may be different with fresh clinical specimens.
6. Extracted specimens may be frozen at -80°C and used up to 5 days after freezing and it 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. Positive and negative predictive values are highly dependent on prevalence. False-negative test results are more likely during peak activity when the prevalence of the disease is high. False-positive test results are more likely during the periods of low SARS-CoV-2 activity when prevalence is moderate to low.

CONDITIONS of AUTHORIZATION for LABORATORY

The *CareStart*™ COVID-19 Antigen test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/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 will 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 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.

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

D. 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.

E. 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 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 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.

[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

To initially evaluate the clinical performance of the *CareStart*™ COVID-19 Antigen test, a total of 126 blinded frozen swab samples, including 106 retrospective clinical specimens and 20 contrived specimens, were tested in one (1) CLIA waived investigational site by five (5) minimally trained operators in the U.S during the 2020 COVID-19 season.

A total of 126 frozen samples consisting of 43 positive nasopharyngeal (NP) swabs, 63 negative NP swab specimens, and 20 contrived near the cut-off samples (10 positives and 10 negatives). NP swab specimens collected from the patients with COVID-19 like symptoms in the U.S during the 2020 COVID-19 season and stored in BD universal transport media tube were provided by multiple vendors in the U.S. All the NP swab specimens were confirmed as positive or negative and validated with Ct value by the FDA EUA RT-PCR as a comparator method prior to the study. The specimens were aliquoted, randomized, and blinded into sample panels that was tested by each operator, using the instructions provided by the Quick Reference Instructions (QRI).

In addition to the clinical population, a total of 20 contrived near the cut-off samples, 10 low positives near the Limit of Detection (LoD) (2x LoD), and 10 negatives (zero analytes) samples, were prepared using the inactivated SARS-CoV-2 strain spiked into the simulated nasal swab matrix, BD universal transport media. The heat-inactivated SARS-CoV-2 isolate USA-WA1/2020 was used to prepare the positive samples. The contrived near the cut-off samples were added to the clinical population and tested at the same study site by the same operators. All the study samples were randomized and assigned with unique study subject ID by the sponsor prior to testing at the study site. The expected results of the samples were completely blinded to the operators. All the samples were tested by five (5) operators according to the Quick Reference Instructions only.

A total of 126 frozen swab samples were considered evaluable in this study. The performance of the *CareStart*™ COVID-19 Antigen as compared to the RT-PCR comparator method are presented in the table below:

CareStart™ COVID-19 Antigen (retrospective samples) Performance against the Comparator Method

CareStart™ COVID-19 Antigen	Comparator		
	Positive	Negative	Total
Positive	38	0	38
Negative	5	63	68
Total	43	63	106
Positive Percent Agreement (PPA)	88.37% (95% CI: 75.52% – 94.93%)		
Negative Percent Agreement (NPA)	100% (95% CI: 94.25% – 100%)		

Patient Demographics

Age Group	*CareStart*™ COVID-19 Antigen		
	Total #	Positive	Prevalence
≤5 Years of Age	1	1	100%
6-21 Years of Age	9	6	66.67%
22-59 Years of Age	58	25	43.10%
≥60 Years of Age	37	10	27.03%
Unknown	1	1	100%

CareStart™ COVID-19 Antigen (near the cut-off samples) Performance

Sample category	Overall % Agreement (result count)
True negative (zero analytes)	100.0% (10/10)
Low positive (2x LoD)	100.0% (10/10)

Prospective Clinical Study

The clinical performance characteristics of *CareStart*™ COVID-19 Antigen test is currently being evaluated in a multi-site prospective study in the U.S in which NP swabs from patients are sequentially enrolled and tested. A total of five (5) investigational sites throughout the U.S are participating in the study. Testing is performed by operators with no laboratory experience and who are representative of the intended users. Operators are only using the QRI for the test without any training provided. The patients presenting the COVID-19 like symptoms within five (5) days of symptom onset at the study sites are enrolled. An FDA EUA RT-PCR assay for the detection of SARS-CoV-2 from a NP or nasal swab is utilized as the comparator method for the study. The initial six (6) positive patient results are presented as below.

CareStart™ COVID-19 Antigen Initial Performance against the Comparator Method

CareStart™ COVID-19 Antigen	Comparator		
	Positive	Negative	Total
Positive	5	0	5
Negative	1	17	18
Total	6	17	23
Positive Percent Agreement (PPA)	83.33% (95% CI: 43.65% – 97.00%)		
Negative Percent Agreement (NPA)	100% (95% CI: 81.57% – 100%)		

Patient Demographics

Age Group	*CareStart*™ COVID-19 Antigen		
	Total #	Positive	Prevalence
≤5 Years of Age	0	0	N/A
6-21 Years of Age	6	3	50.00%

22-59 Years of Age	12	2	16.67%
≥60 Years of Age	5	1	20.00%

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 8×10^2 $TCID_{50}$/ml.

The LoD for swab in VTM (BD universal transport media) was established using heat-inactivated SARS-CoV-2 isolate USA-WA1/2020 (NR-52286). The two-fold serial diluted strain stocks were spiked into each of 3 ml human nasal swab matrix obtained from multiple healthy volunteers eluted in 3 ml VTM tube. The estimated LoD found from the initial two-fold serial dilution test was confirmed by testing 20 replicates. The confirmed LoD for swab in VTM was 6.4×10^3 $TCID_{50}$/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 1.5×10^3 cfu/ml. The 18 viruses were tested at concentrations between $10^{5.2}$ and $10^{7.9}$ $TCID_{50}$/ml. All negative samples gave negative results at the concentrations of the potentially cross-reactive common organisms tested showing no cross-reactivity with *CareStart*™ COVID-19 Antigen assay. All samples with SARS-CoV-2 strain tested positive showing no microbial interference at the concentrations of the potentially interfering common organisms tested.

Potential Cross-Reactant		
Adenovirus 1	MERS-Coronavirus, Irradiated Lysate	*Bodetella pertussis*
Adenovirus 7	Parainfluenza virus type 1	*Candida albicans*
Enterovirus 71, 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*

Potential Cross-Reactant
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. So, cross-reactivity of CareStart™ COVID-19 Antigen against Mycoplasma pneumoniae can be ruled out.

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

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

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

High-dose Hook Effect

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

Point of Care Use

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

Technical Support

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

Description of Symbols

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

Symbol	Descriptions
REF	Catalog number Indicates the manufacturer's catalog number so that the medical device can be identified.
	Caution Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Date of manufacture Indicates the date when the medical device was manufactured.
	Temperature limit Indicates the temperature limits to which the medical device can be safely exposed.
	Do not use if the package is damaged Indicates a medical device that should not be used if the package has been damaged or opened.
	Contains sufficient for <n> tests Indicates the total number of IVD tests that can be performed with the IVD.
	Prescription-only

Manufactured by:
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Website: www.intrivo.com

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

Document number: IFU-RCHM71-E
Revision number: A (Effective date: 2020-10-07)

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

For Emergency Use Authorization (EUA) Only

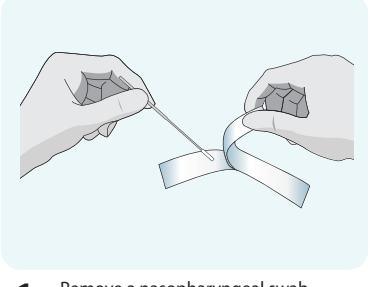
Rx Only IVD 1°C 30°C

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 swab specimens directly collected from individuals who are suspected of COVID-19 by their healthcare provider within five days of symptom onset.

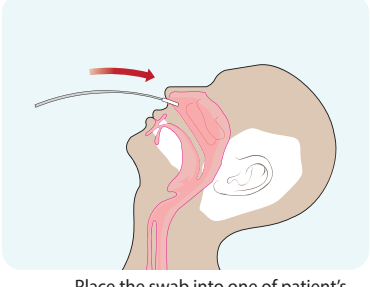
IMPORTANT!

- 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

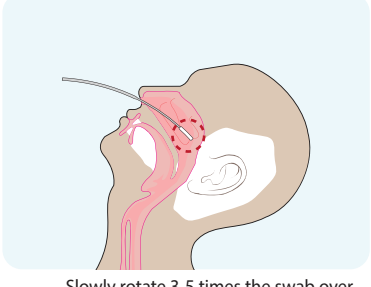
SPECIMEN COLLECTION AND HANDLING



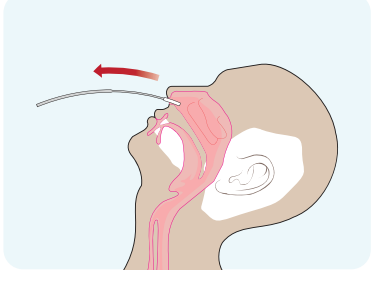
1 Remove a nasopharyngeal swab from the pouch.



2 Place 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 Slowly remove the swab from the nostril while rotating it.

In the USA, this test has not been FDA cleared or approved; this test 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 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. This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. In the USA, - 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 the virus that causes COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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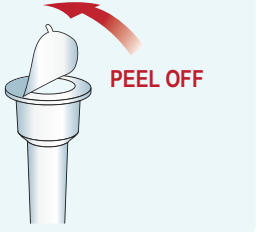
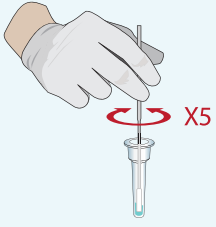
Technical Support
Tel: 888-898-1270 (Toll Free)
Email: TShelp@accessbio.net

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

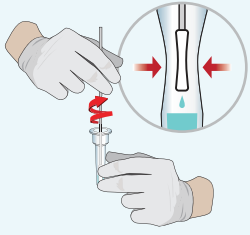
TEST PROCEDURES



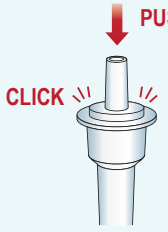
1 Peel off aluminum foil seal from the top of the extraction vial containing the extraction buffer.



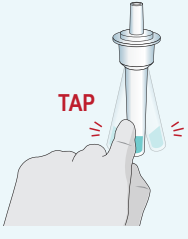
2 Place the swab into the extraction vial. Rotate the swab vigorously at least 5 times.



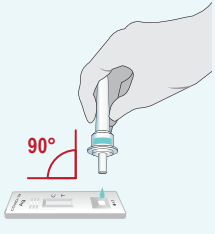
3 Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab. Properly discard the swab.



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

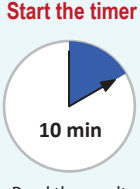


5 Mix thoroughly by flicking the bottom of the tube.

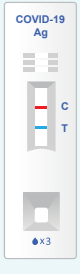


6 Invert the extraction vial and hold the sample vertically above the sample well. Squeeze the vial gently. Allow three (3) drops of sample to fall into the sample well.

NOTE: Refer to the Package Insert for the cautions.



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



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.

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.

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[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).

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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

2019-nCoV IgG/IgM Rapid Test Cassette
Order Form

Hensler Surgical Technologies
2420 South 17th Street
Suite C
Wilmington, NC 28401
Submit Orders to: **sales@henslersurgical.com**

Date of Order:

Order Number:

Customer Info:

Account Name: _____

Contact Name: _____

Contact e-mail: _____

Contact Number: _____

Distributor: Hensler Surgical Technologies

Distributor Contact: 910.399.7380

Distributor Number: 910.599.4885

Sales Rep: _____

Quantity	Description	Unit Price	Amount
	CareStart Antigen Testing Kits (25.00 each) 25 test kits per Bx)	$ 625.00 per BX	
		Total:	

Shipping Method

☐ **FedEx:**

Date to Receive: _____

Ship to Address: _____

Address 2: _____

City: _____ **Zip:** _____

State: _____

☐ **Pick Up**

Date of Pick Up: _____

Time of Pick Up: _____

By: _____

(Must Fill in the CLIA-Waived number Below)

_____

Shipping:

☐ **FedEx Next Day 10:30**

☐ **FedEx Ground**

ACH Authorization Form

- Your account will be debited automatically when your payment is due
- Complete authorization form and attach a voided check
- Fax form to +1 910 399 7381

Company Name: _____

Address: _____

Suite / Building #: _____

City: _____ State: _____ Zip: _____

Financial Institution: _____

Address: _____

Suite / Building #: _____

City: _____ State: _____ Zip: _____

Bank Routing #: _____

Bank Account #: _____

I hereby authorize Hensler Surgical to debit my checking or savings account to collect my payments:

Signature: _____

Name: _____

Title: _____

Date: _____

HENSLER SURGICAL™

TECHNOLOGIES

HENSLER SURGICAL TECHNOLOGIES 2420 SOUTH 17TH STREET. STE C WILMINGTON, NC 28401
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