For use under an Emergency Use Authorization (EUA) only
For use with anterior nasal swab specimens
For *in vitro* diagnostic use only

CareStart™

COVID-19 Antigen Home Test

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

Healthcare Provider Instructions for Use

Intended Use

The CareStart™ COVID-19 Antigen Home Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigens from SARS-CoV-2.

This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 7 days of symptom onset. This test is also authorized for non-prescription home use with adult-collected nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 7 days of symptom onset.

This test is also authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. The antigen is generally detectable in anterior nasal (nares) swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses and the agent detected may not be the definite cause of disease. Individuals who test positive with the *CareStart*™ COVID-19 Antigen Home Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results should be treated as presumptive and confirmation with a molecular assay for patient management, may be performed if necessary. 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 an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

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.

Individuals who test negative and continue to experience COVID-like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from their healthcare provider.

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

The *CareStart*™ COVID-19 Antigen Home Test is authorized for non-prescription self-use and/or, as applicable for an adult lay user testing another person aged 2 years or older. The *CareStart*™ COVID-19 Antigen Home Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Principles of the Test

The *CareStart*™ COVID-19 Antigen Home Test is a lateral flow immunochromatographic assay for the detection of extracted nucleocapsid protein antigens specific to SARS-CoV-2 in self-collected anterior nasal (nares) swab specimens.

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.

The user should perform the test following the in-app self-paced, step-by-step instructions or Quick Reference Instructions.

Test results are interpreted visually at 10 minutes after sample loading followed by the instructions. 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. Results should not be read after 15 minutes.

Quality Control

- The *CareStart*™ COVID-19 Antigen Home Test contains a built-in internal procedural control that is included in the test device. A purple-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).

- The unique barcode on the test device contains essential device information and captured during the test process using mobile application to ensure test validity. In the event the barcode is not valid for any reason, the user is presented with a final screen indicating the fail reason by one of the below:
  Invalid: Barcode Not Found
  Invalid: Test Expired
  Invalid: Test Barcode Invalid
  Invalid: Test Previously Used

Reagents and Materials

Materials provided

All following required components for single-use are packed and sealed in a tray.

- a test device: foil pouched test device containing one test strip which is encased in plastic device cassette with a desiccant.
- an extraction vial and cap: the extraction vial contains 500 µL of extraction buffer solution.
- a nasal swab: swab for anterior nasal specimen collection.

Quick Reference Instructions and Fact Sheet for Individuals are also included in each box.

CareStart™ COVID-19 Antigen Home Test is available in the following packaging configuration: 1 test (REF: RCPM-00171), 2 tests (REF: RCPM-00271), 4 tests (REF: RCPM-00471), or 20 tests (REF: RCPM-02071)

Materials required but not provided

- Smartphone (supplied by the user): For a list of compatible smartphone OS systems, visit www.accessbio.net/app.
- Mobile application: Prior to testing, the user should download the free mobile application, on/go™ App, for iOS or Android smartphones.
- Timer

Warnings and Precautions

- For *in vitro* diagnostic use only.
- This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA).
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for the detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.
- Children aged 13 years old and younger should be tested by a parent or legal guardian.
- Wear a safety mask or other face-covering when collecting anterior nares swab specimen from a child or another individual.
- Wash hands thoroughly for at least 20 seconds before and after handling nasal swab samples.
- In order to obtain accurate results, the user must follow the instructions for use.
- Immediately use after opening the test device in the pouch.
- Keep the test device on a flat surface during the testing.
- Keep testing kit and kit components away from children and pets before and after use.
- Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false-positive result. Avoid touching any bleeding areas of the nasal cavity when collecting specimens.
- Inadequate or inappropriate sample collection, storage, and transport can result in incorrect results. If specimen storage is necessary, swabs can be placed into the extraction vial for up to four hours. Specimens should not be stored dry.
- When collecting a nasal swab sample, use only the Nasal Swab provided in the kit.
- Keep foreign substances and household cleaning products away from the test during the testing process. Contact with foreign substances and household cleaning products may result in an incorrect test result.
- Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
- Handle all specimens as though they contain infectious agents.
- Do not operate your test outside of storage conditions.
- Do not use on anyone under 2 years of age.
- Do not close the App during processing as it may cause an error and you will need a new test kit.
- Do not interpret the test result before 10 minutes and after 15 minutes starting the test.

- Do not use on anyone who is prone to nosebleeds or has had facial or head injury/surgery in the last 6 months.
- Do not use if the test device package is damaged.
- Do not touch the tip (specimen collection area) of the swab.
- 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.
- Do not interchange kit contents from different lots.
- Do not re-use any contents in the kit as they are single-use only.
- Eye and skin contact with the extraction solution should be avoided.
- Extraction solution should not be ingested.
- The extraction solution in the vial contains potentially harmful chemicals (see table below). If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, seek medical advice: https://www.poison.org/contact-us or 1-800-222-1222.

Chemical Name/CAS	**Harms (GHS Code) for each Ingredient**
Sodium Tetraborate Pentahydrate/12179-04-3	H319 Causes serious eye irritation. H360 May damage fertility or the unborn child.
Ethylenediaminetetraacetic acid (EDTA)/13235-36-4	H302 Harmful if swallowed. H318 Causes serious eye damage.
Sodium Chloride (NaCl)/ 7647-14-5	None
Triton X-100/9002-93-1	H302 Harmful if swallowed. H315 Causes skin irritation. H318 Causes serious eye damage. H410 Very toxic to aquatic life with long-lasting effects.
N-Lauroylsarcosine sodium salt/137-16-6	H315 Causes skin irritation. H318 Causes serious eye damage. H330 Fatal if inhaled.

Storage and Stability

- Store the test kit as packaged between 1 ~ 30°C.
- The test device must remain in the sealed pouch until use.
- Do not freeze any contents of the kit.

Disposal

Dispose of all used test kit components and patient samples in household trash.

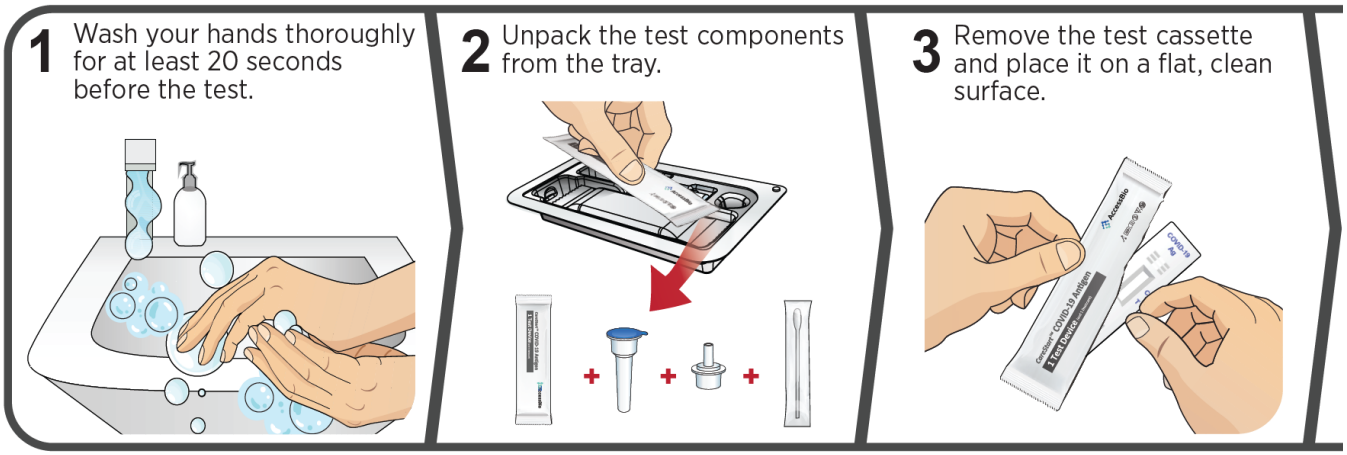
Specimen Collection and Handling

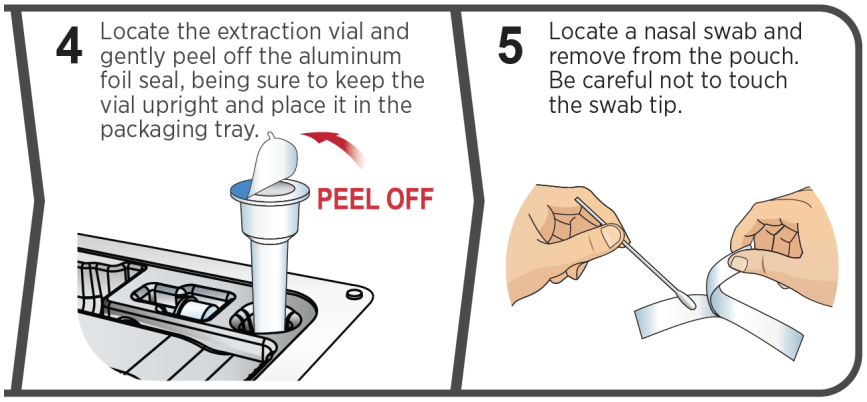
Acceptable specimen type for testing with the *CareStart*™ COVID-19 Antigen is a direct anterior nasal (nares) swab specimen. It is essential that correct specimen collection and preparation methods be followed. Inadequate specimen collection, improper specimen handling and/or transport may yield false results. Process the test swab sample immediately after collection (specimens are stable up to 4 hours in extraction buffer). Refer to the CDC Interim Guidelines

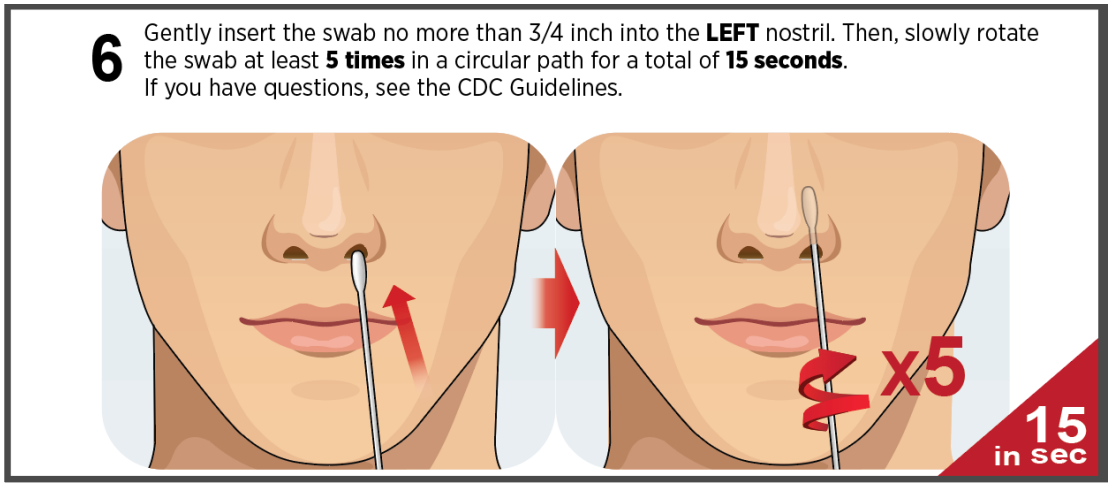
for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19)
https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

Instructions for Running the Test

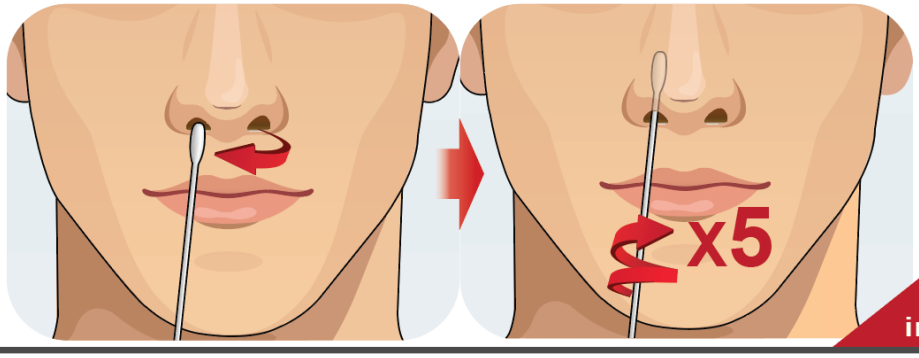
IMPORTANT: Do not open kit components until instructions to do so. Follow the in-app self-paced, step-by-step instructions or paper instructions printed on the QRI as below.



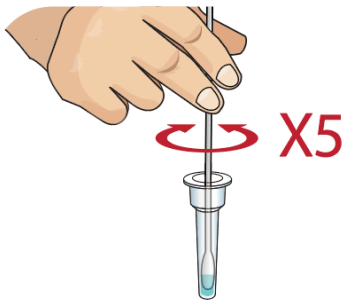




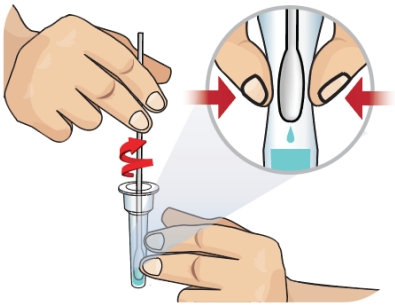
7 Gently remove the swab from the LEFT nostril and place directly into the **RIGHT** nostril, repeating the process of rotating at least **5 times** in a circular path for a total of **15 seconds**. Remove the swab from the RIGHT nostril.



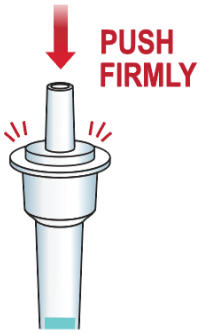
8 Place the swab into the extraction vial. Rotate the swab vigorously at least 5 times.



9 Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab. Discard the swab in trash.

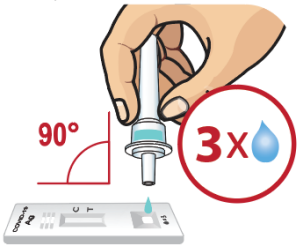


10 Close the vial by pushing the cap firmly onto the vial.



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

12 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.



13 **Start a timer.**
Read the result at **10 minutes**.
The test result should not be read after 15 minutes.

IMPORTANT
Do not move or lift the test cassette during this time. Do not exit the mobile app during this process.

If used for serial testing and the test result is negative, a second test should be obtained two or three days with at least 24 hours and no more than 48 hours between tests.

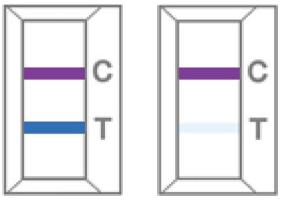
Interpretation of Results

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

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

COVID-19 Detected (Positive):

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



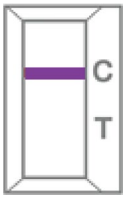
NOTE: The color intensity of the blue-colored test line will vary depending on the amount of SARS-CoV-2 nucleocapsid protein antigen present in the sample. Any faint blue-colored line in the test line should be considered as positive.

A positive test result for COVID-19 indicates that antigens from SARS-CoV-2 were detected, and the patient is very likely to be infected with the virus and presumed to be contagious. 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 follow current CDC guidelines. Additional confirmatory testing with a molecular

test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

COVID-19 Not Detected (Negative):

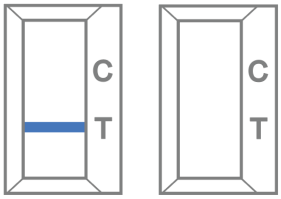
One purple-colored line only next to "C" indicates a negative result.



Negative results do not rule out SARS-CoV-2 infection. Individuals without symptoms that test negative should be tested again with at least 24 hours and no more than 48 hours between tests. All negative results are considered presumptive, and confirmation with a molecular assay, if necessary for patient management, may be performed. The amount of antigen in a sample may decrease as the duration of illness increases. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19 and confirmed with a molecular assay, if necessary, for patient management.

Invalid:

Invalid barcode or absence of a purple-colored line next to "C". Re-test with a COVID-19 test may be needed.
An invalid test result indicates that your test has experienced an error and unable to interpret the result of the test. You will need to retest with a new test or consult a healthcare professional. If you still have symptoms, you should self-isolate at home and avoid contact with others prior to the retest



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).

Limitations

1. 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.

2. 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.
3. False negative results may occur in patients who have indicated or whose clinical status or history would indicate they are currently taking high doses of biotin (> 10 mg per day). Biotin levels of 2.5 µg/mL and greater have been demonstrated to result in false negative test results.
4. Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result.
5. False negative results are more likely after seven days or more of symptoms.
6. Interpretation of any result after 15 minutes may yield inaccurate test results.
7. This test and the results from this test do not establish that the user has acquired immunity to COVID-19.
8. Extracted specimens are stable for 4 hours in extraction buffer at room temperature.
9. 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.
10. Negative results are presumptive in symptomatic individuals, do not rule out COVID-19 and it may be necessary to obtain additional testing with a molecular assay, if needed for patient management.
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. False positive results may occur, particularly in individuals without COVID-19 symptoms and/or individuals who live in areas with low numbers of COVID-19 and without known exposure to COVID-19.
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.
18. Performance of nasal swabs collected from individuals without symptoms or other epidemiological reasons to suspect COVID-19 or for serial screening, when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests has not been determined, a study to support use will be completed.

19. If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
20. The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between March 2021 and May 2021. 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.
21. Testing for asymptomatic individuals should be performed at least twice over three days, with at least twenty-four hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.
22. There is a higher chance of false negative results with home use tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.
23. Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.

Performance Characteristics

Clinical Performance

The clinical performance characteristics of the *CareStart*™ COVID-19 Antigen Home Test using anterior nasal swab specimen were evaluated at seven (7) geographically diverse study sites in the U.S. between March 2021 and May 2021 against an FDA Emergency Use Authorized RT-PCR molecular assay as a comparator method. Subjects self-sampled and self-tested using the *CareStart*™ COVID-19 Antigen Home Test in a simulated home setting utilizing only the labeling provided with the test. A total of 153 subjects were evaluated in this study. The CareStart™ COVID-19 Antigen Home Test when conducted by a lay user correctly identified 87% of positive samples and 98% of negative samples. The overall clinical performance is shown in the following tables.

CareStart™ COVID-19 Antigen Home Test clinical performance against the comparator method

CareStart™ COVID-19 Antigen Home Test	Comparator		
	Positive	Negative	Total
Positive	26	3[a]	29
Negative	4[b]	120	124
Total	30	123	153
Positive Percent Agreement (PPA)	87% (26/30) (95% CI: 70%-95%)		
Negative Percent Agreement (NPA)	98% (120/123) (95% CI: 93%-99%)		

[a]COVID-19 was detected in 0/3 False Positive specimens using the Quidel Lyra SARS-CoV-2 Assay

[b]*COVID-19 was not detected in 2/4 False Negative specimens using the Quidel Lyra SARS-CoV-2 Assay*

Patient Demographics

Age Group	*CareStart*™ COVID-19 Antigen Home Test		
	Female	Male	Positivity Rate % (total positive / total tested)
2-13 Years of Age	6	2	0.0% (0/8)
14-24 Years of Age	16	10	15.4% (4/26)
25-64 Years of Age	69	34	22.3% (23/103)
≥65 Years of Age	9	7	12.5% (2/16)
Total	100	53	13.9% (29/153)

Positive results are broken down by days since onset of symptoms:

Days Since Symptom Onset	PPA (95% CI)	NPA (95% CI)
Asymptomatic	70.0% (7/10) (95% CI: 39.7%-89.2%)	97.6% (123/126) (95% CI: 93.2%-99.2%)
0-1	100% (5/5) (95% CI: 56.6%-100%)	96.8% (30/31) (95% CI: 83.8%-99.4%)
0-2	100% (11/11) (95% CI: 74.1%-100%)	94.8% (55/58) (95% CI: 85.9%-98.2%)
0-3	100% (20/20) (95% CI: 83.9%-100%)	96.3% (78/81) (95% CI: 89.7%-98.7%)
0-4	92.0% (23/25) (95% CI: 75.0%-97.8%)	97.1% (100/103) (95% CI: 91.8%-99.0%)
0-5	92.6% (25/27) (95% CI: 76.6%-97.9%)	97.3% (108/111) (95% CI: 92.4%-99.1%)
0-6	89.7% (26/29) (95% CI: 73.6%-96.4%)	97.3% (109/112) (95% CI: 92.4%-99.1%)
0-7	86.7% (26/30) (95% CI: 70.3%-94.7%)	97.5% (116/119) (95% CI: 92.9%-99.1%)
0-14	86.7% (26/30) (95% CI: 70.3%-94.7%)	97.6% (120/123) (95% CI: 93.1%-99.2%)

Invalid Test Rate: The overall invalid result rate within a total of 172 subjects that performed testing in a clinical study was 2.9% (5/172).

Analytical Sensitivity: Limit of Detection (LoD)

The LoD for direct nasal swab was established using gamma-irradiated SARS-CoV-2 isolate USA-WA1/2020 (NR-52287). The strain was spiked into the pooled human nasal swab matrix obtained from multiple healthy volunteers eluted in PBS 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 2.8 x 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 Home Test. Potential microbial interference was evaluated with samples containing gamma-irradiated SARS-CoV-2 isolate USA-WA1/2020 at approximately 3x LoD. A total of 10 bacteria were tested at a target concentration of approximately 10^7 cfu/ml with the exception of *Mycoplasma pneumoniae*, which was tested at a final concentration of 1.5 x 10^3 cfu/ml. The 18 viruses were tested at

concentrations between $10^{5.2}$ and $10^{7.9}$ $TCID_{50}$/ml. All negative samples gave negative results at the concentrations of the potentially cross-reactive common organisms tested showing no cross-reactivity with *CareStart*™ COVID-19 Antigen Home Test 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 cannot 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 cannot 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 Home Test 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, however cross-reactivity cannot be ruled out.

Endogenous Interfering Substances Effect

To assess substances with the potential to interfere with the performance of the *CareStart*™ COVID-19 Antigen Home Test, 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 Home Test performance was not affected by any of the 35 potentially interfering substances listed in the table below at the concentrations tested.

Potential Interfering Substances	Concentration	Potential Interfering Substances	Concentration
Acetaminophen	10 mg/ml	Oseltamivir Phosphate (Tamiflu)	5mg/ml
Acetyl salicylic acid	15 mg/ml	OTC Nasal Spray (Alkaol)	1:10 dilution
Beclomethasone	0.5 mg/ml	OTC Nasal Spray (Cromolyn Sodium)	15%
Benzocaine	5 mg/ml	OTC Naso GEL (NeilMed)	5%
Budesonide	2 mg/ml	OTC Sore Throat Phenol Spray	5%
Chlorpheniramine maleate	5 mg/ml	OTC Throat drop (Halls)	15%
Dexamethasone	1 mg/ml	OTC Throat drop (Ricola)	15%
Dextromethorphan HBr	2 mg/ml	OTC Nasal spray (Afrin)	15%
Diphenhydramine HCl	5 mg/ml	OTC Nasal spray (VicksSinex)	15%
Ephedrine HCl	10 mg/ml	OTC Nasal spray (Zicam)	15%
Flunisolide	5 mg/ml	Oxymetazoline HCl	10 mg/ml
Fluticasone	1 mg/ml	Phenylephrine HCl	5 mg/ml
Guaiacol Glyceryl Ether	20 mg/ml	Phenylpropanolamine	5 mg/ml
Histamine Dihydrochloride	10 mg/ml	Tobramycin	1 mg/ml
Menthol	10 mg/ml	Triamcinolone	1 mg/ml
Mometasone	1 mg/ml	Whole Blood	4%
Mucin	2%	Zanamivir	1 mg/ml
Mupirocin	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 Home Test.

High-dose Hook Effect

The *CareStart*™ COVID-19 Antigen Home Test was tested up to 10^6 $TCID_{50}$/ml of gamma-irradiated SARS-CoV-2 isolate USA-WA1/2020 strain and no high-dose hook effect was observed.

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).

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.
Rx	Prescription-only

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.
Σ	Contains sufficient for <n> tests Indicates the total number of IVD tests that can be performed with the IVD.

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