



March 14, 2023

Sung A. Jang
Manager, Regulatory Affairs Division
Access Bio, Inc.
65 Clyde Road, Suite A
Somerset, NJ 08873

Device: *CareStart* COVID-19 Antigen Home Test
EUA Number: EUA210314
Company: Access Bio, Inc.
Indication: Non-prescription home use for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus 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. This test is authorized for individuals with symptoms of COVID-19 within the first 7 days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests..

Dear Sung A. Jang:

On August 2, 2021, based on your¹ request the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the *CareStart* COVID-19 Antigen Home Test pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) for the indication stated in the letter.² Based on your request, FDA reissued the letter in its entirety with revisions incorporated on November 22, 2021.³ In addition, based on

¹ For ease of reference, this letter will use the term “you” and related terms to refer to Access Bio, Inc.

² The August 2, 2021, letter authorized the *CareStart* COVID-19 Antigen Home Test for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigens from individuals with or without symptoms or other epidemiological reasons to suspect a COVID-19 infection when tested twice over two or three days with at least 24 hours and not more than 48 hours between tests. This test is authorized for non-prescription home use with self-collected direct anterior nasal (nares) swab samples from individuals aged 14 years or older or adult collected anterior nasal swab samples from individuals aged 2 years or older.

³ On November 22, 2021, the revisions to the August 2, 2021, letter and authorized labeling included: (1) updates to the intended use to include use of your product with “*self-collected anterior nasal (nares) swab samples from*

your requests, FDA granted updates to the authorized labeling on August 23, 2021,⁴ January 22, 2022,⁵ May 12, 2022,⁶ June 7, 2022,⁷ August 29, 2022,⁸ and February 1, 2023.⁹ Further, FDA revised the authorized uses and established one additional Condition of Authorization requiring updates to product labeling regarding repeat, or serial, testing, for all currently authorized SARS-CoV-2 antigen tests on November 1, 2022.¹⁰

On August 22, 2022 and November 15, 2022, you requested to amend this EUA. Based on these requests, and having concluded that revising the November 22, 2021, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the November 22, 2021, letter in its entirety with the revisions

individuals aged 14 years or older with symptoms of COVID-19 within the first 7 days of symptom onset,” “adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 7 days of symptom onset,” and “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,” (2) update the outer box labels and Instructions for Use (IFU) limitations section to reflect the updates to the intended use, (3) offer the test kit with 1-test option, in addition to the 2-test, 4-test and 20-test options currently offered, (4) Update Condition of Authorization Q. and S. (in the November 22, 2021 letter) to give a 1 month extension and Condition of Authorization R. (in the November 22, 2021 letter) to give a 6 month extension, and (5) updates to the letter and fact sheets to reflect the updated intended use and for consistency with language used in more recent authorizations.

⁴ On August 23, 2021, your request was granted to update the authorized labeling for the *CareStart* COVID-19 Antigen Home Test with various edits and clarifications, including a new QR code used to access the mobile application and to make those same edits to the authorized brand name labeling.

⁵ On January 22, 2022, your request was granted to update the shelf-life expiration date of the *CareStart* COVID-19 Antigen Home Test to 9 months when stored at 1–30°C based on the results of your ongoing stability studies.

⁶ On May 12, 2022, your request was granted to update the *CareStart* COVID-19 Antigen Home Test to extend the shelf-life expiration date to 12 months when stored at 1°C – 30°C, based on the results of your ongoing stability studies.

⁷ On June 7, 2022, your request was granted to; (1) fulfil Condition of Authorization S. in the November 22, 2021 Letter of Authorization, and (2) modify the dimensions of the 2-tests outer box for the *CareStart* COVID-19 Antigen Home Test and update some of the statements on the outer box. During interactive review, updates to the Instructions for Use and Quick Reference Instructions were made to harmonize with other authorized over the counter (OTC) antigen tests.

⁸ On August 29, 2022, your request was granted to update the *CareStart* COVID-19 Antigen Home Test to extend the shelf-life expiration date to 15 months when stored at 1°C – 30°C, based on the results of your ongoing stability studies.

⁹ On February 1, 2023, your request was granted to update the *CareStart* COVID-19 Antigen Home Test to extend the shelf-life expiration date to 21 months when stored at 1°C – 30°C, based on the results of your on-going stability studies.

¹⁰ The Repeat Testing Revision Letter - November 1, 2022, can be accessed at: <https://www.fda.gov/media/162799/download>.

incorporated.¹¹ Accordingly, your product¹² is hereby authorized pursuant to section 564 of the Act when used pursuant to the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter.

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 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.¹³

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 included in the “*CareStart* COVID-19 Antigen Home Test Healthcare Provider 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:

¹¹ The revisions to the November 22, 2021, letter and authorized labeling include: (1) incorporating your response to Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022 to revise the authorized use(s) as required and described in Appendix A, and make various updates to the authorized labeling as required and described in Appendix B of the letter for both the *CareStart* COVID-19 Antigen Home Test and the on/go COVID-19 Antigen Self-Test (alternate brand name/trade name – updates made to the authorized labeling with the exception of the box label), (2) discontinue the Fact Sheet for Individuals as the necessary information is contained in the authorized “*CareStart* COVID-19 Antigen Home Test Quick Reference Instructions,” (3) deleting Condition of Authorization R. in the November 22, 2021, letter in accordance with the Repeat Testing Revision Letter dated November 1, 2022, (4) deleting Conditions of Authorization Q. and S. in the November 22, 2021, letter as fulfilled through data and information submitted to the agency, (5) replacing use of the “on/go App” software application with the new “Othena App” mobile application downloaded onto a compatible smartphone to facilitate the end user option to use step-by-step “*CareStart* COVID-19 Antigen Home Test” instructions, (6) addition of the option to facilitate test result reporting via reference to the the [MakeMyTestCount.Org](https://makemytestcount.org) (<https://makemytestcount.org>) website, (7) include results of additional reactivity studies, (8) addition of Condition of Authorization M. (below) to facilitate additional box labels and update the letter with additional box label options offered for 2 (version 2)-, 5-, 25-, and 30-tests per kit, and (9) updating the Letter of Authorization and Fact Sheet for Healthcare Professionals to reflect the revised intended use, and for consistency with language used in more recent authorizations.

¹² For ease of reference, this letter will use the term “your product” to refer to the *CareStart* COVID-19 Antigen Home Test used for the indication identified above.

¹³ 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).

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 diagnosing COVID-19, 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.¹⁴

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 lateral flow immunoassay device intended for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus. This test is 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. This test is authorized for individuals with symptoms of COVID-19 within the first 7 days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests. Your product does not differentiate between SARS-CoV or SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which 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 patient 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 definitive cause of disease. Individuals who test positive with your product should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

All 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 measures such as isolating from others and wearing masks. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Individuals who test negative and continue to experience COVID-19-like symptoms of fever,

¹⁴ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

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 and to receive appropriate medical care. 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 (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by the Centers for Disease Control and Prevention (CDC).

Your product is performed using anterior nasal (nares) swab samples from individuals aged 2 years or older. When using your product, the individual performing the test has the option to follow the “*CareStart* COVID-19 Antigen Home Test Quick Reference Instructions” provided with the kit or follow step-by-step mobile application-based instructions by downloading the “Othena App” onto a compatible smartphone.¹⁵

The *CareStart* COVID-19 Antigen Home Test kit includes the materials or other authorized materials (as may be requested under Condition L. and M. below), required to collect the anterior nasal (nares) swab sample and perform the test procedure, as described in the “*CareStart* COVID-19 Antigen Home Test Healthcare Provider Instructions for Use” and the “*CareStart* COVID-19 Antigen Home Test Quick Reference Instructions.”.

Your product includes an internal control test line that must generate the expected result for a test to be considered valid, as outlined in the “*CareStart* COVID-19 Antigen Home Test Healthcare Provider Instructions for Use” and the “*CareStart* COVID-19 Antigen Home Test Quick Reference Instructions.”

The labeling entitled “*CareStart* COVID-19 Antigen Home Test Healthcare Provider Instructions for Use,” the “*CareStart* COVID-19 Antigen Home Test Quick Reference Instructions”) and the “*CareStart* COVID-19 Antigen Home Test” box labels¹⁶ (available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>), the “Othena App” mobile application, and the following fact sheet pertaining to the emergency use, is required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as “authorized labeling”:

- Fact Sheet for Healthcare Professionals¹⁷: Access Bio, Inc. - *CareStart* COVID-19

¹⁵ Compatible smart phone includes Apple iPhone running Operation System (iOS) 13 or later versions of the OS, and Android Phones running Android10 or later versions. Additional smart phone models as may be requested, and for which you receive appropriate authorization, in accordance with Condition L. below.

¹⁶ “*CareStart* COVID-19 Antigen Home Test” box labels include boxes for 1-, 2 (version 1)-, 2 (version 2)-, 4-, 5-, 20-, 25-, and 30-tests per kit and “*CareStart* COVID-19 Antigen Home Test” box labels for additional test kit numbers/options as may be requested, and for which you receive appropriate authorization, in accordance with Condition M. below. *CareStart* COVID-19 Antigen Home Test numbers/options are described in the “*CareStart* COVID-19 Antigen Home Test Healthcare Provider Instructions for Use.”

¹⁷ Note that the information typically found in a Fact Sheet for Individuals is contained in the authorized “*CareStart*

Antigen Home Test

The above described product, when accompanied by authorized labeling as set forth in the Conditions of Authorization (Section IV) is authorized to be distributed and used 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:

COVID-19 Antigen Home Test Quick Reference Instructions” that will be available to end users as set forth in the Conditions of Authorization (Section IV).

Access Bio, Inc. (You) and Authorized Distributor(s)¹⁸

- A. Your product must comply with the following labeling requirements pursuant to FDA regulations: the intended use statement in 21 CFR 809.10(a)(2), (b)(2); adequate directions for use in 21 U.S.C. 352(f) and 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) must make available the “*CareStart COVID-19 Antigen Home Test Quick Reference Instructions*” hard copy format for your product in the shipped kit using the authorized box labels (refer to footnote 16) and make these documents electronically available on your website.
- C. You and authorized distributor(s) must maintain records of customer complaint files and report to FDA any significant complaints about usability or deviations from the established performance characteristics of which you and authorized distributor(s) become aware.
- D. You and authorized distributor(s) must inform relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and/or the authorized labeling.
- E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the locations (e.g., pharmacies, doctor’s offices, etc.) to which your product is distributed and the number of tests distributed to each location.
- F. You and authorized distributor(s) must collect information on the performance of your product and have a process in place to track adverse events, including any occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware and report any such events to FDA in accordance with 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) (via email: CDRH-EUAREporting@fda.hhs.gov).
- G. 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.
- H. You and authorized distributor(s) using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records

¹⁸ “Authorized Distributor(s)” are identified by you, Access Bio, Inc., in your EUA submission as an entity allowed to distribute your product.

will be made available to FDA for inspection upon request.

Access Bio, Inc. (You)

- I. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).
- J. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent revisions that might be made to this EUA and its authorized accompanying materials, including the authorized labeling.
- K. You must make the authorized “*CareStart* COVID-19 Antigen Home Test Healthcare Provider Instructions for Use” and the “Fact Sheet for Healthcare Professionals” electronically available on your website. Additionally, you must provide the opportunity to request a copy of the “*CareStart* COVID-19 Antigen Home Test Healthcare Provider Instructions for Use” and “Fact Sheet for Healthcare Professionals” in paper form, and after such request, promptly provide the requested labeling at no additional cost.
- L. 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 shall not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to DMD/OHT7/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.
- M. You may request new box labels to allow additional test kits numbers/options for your product. Such additional labeling requests to this EUA should be submitted to and require concurrence of DMD/OHT7/OPEQ/CDRH prior to implementation.
- N. You must comply with the following requirements pursuant to FDA regulations: 21 CFR 820 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).
- O. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the product released for distribution meet the clinical and analytical performance claimed in the authorized labeling.
- P. If requested by FDA, you must submit your 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 them within 48 hours of the request.

- Q. You must evaluate the analytical limit of detection and assess traceability¹⁹ 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 if requested by FDA. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.
- R. You must complete the agreed upon real-time stability study for your product and notify DMD/OHT7/OPEQ/CDRH of the testing results as they become available until completion of the study. After submission of the study data, and review and concurrence with the data by FDA, you must update your product labeling accordingly if requested by FDA. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.
- S. You must evaluate the impact of SARS-CoV-2 viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately (via email: CDRH-EUA-Reporting@fda.hhs.gov).
- T. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA, such as those related to the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

Conditions Related to Printed Materials, Advertising and Promotion

- U. All descriptive printed matter, 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 meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.
- V. No descriptive printed matter, 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 of SARS-CoV-2.
- W. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall clearly and conspicuously state that:
- This product has not been FDA cleared or approved; but has been authorized by FDA under an EUA;

¹⁹ Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

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

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,

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

Enclosure