



June 24, 2021

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Device: *CareStart* COVID-19 IgM/IgG
EUA Number: EUA201309
Company: Access Bio, Inc.
Indication: This test is indicated for the following indications for use:

For certain authorized laboratories (see below) – Qualitative detection and differentiation of Immunoglobulin M (IgM) and Immunoglobulin G (IgG) antibodies to SARS-CoV-2 in human serum, plasma (sodium citrate, sodium heparin, or dipotassium EDTA), and venous whole blood (sodium citrate, sodium heparin, or dipotassium EDTA). Intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

For certain authorized laboratories (see below) – Qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in fingerstick whole blood. Intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

Emergency use of this test is limited to authorized laboratories.

Authorized Laboratories: Testing of serum, plasma and venous whole blood is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform moderate or high complexity tests.

Testing of fingerstick whole blood specimens 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 high, moderate or waived complexity tests. Testing of fingerstick whole blood specimens 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 Dr. Ha:

On July 24, 2020 based on your¹ request, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of the *CareStart* COVID-19 IgM/IgG pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human serum, plasma (sodium citrate, sodium heparin, or dipotassium EDTA), and venous whole blood (sodium citrate, sodium heparin, or dipotassium EDTA). Your product was intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. Testing was limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform moderate or high complexity tests. Based on your request, FDA granted updates to the authorized labeling on October 31, 2020² and March 19, 2021³.

On June 24, 2021 based on your request, and having concluded that revising the July 24, 2020, 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 July 24, 2020, letter in its entirety with the revisions incorporated.⁴ Pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, your product⁵ is

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

² The October 31, 2020 request was granted (1) to revise the name of your assay for one distributor, and (2) to revise the assay labeling to reflect the availability of external controls with separate labeling per Condition “T” of the July 24, 2020 Letter of Authorization.

³ The March 19, 2021 request was granted (1) to add an additional authorized distributor of the *CareStart* COVID-19 IgM/IgG test, and (2) to extend the *CareStart* COVID-19 IgM/IgG Kit shelf-life stability to 8 months when stored at 1 – 30 °C.

⁴ The revisions to the July 24, 2020, letter and authorized labeling include: (1) update the intended use to include the addition of fingerstick whole blood as an authorized specimen type for all laboratories certified under CLIA that meet requirements to perform high, moderate or waived complexity tests and to include the testing of fingerstick whole blood 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, and additional updates to the intended use to reflect language used in more recent authorizations, (2) modification of the device design to include a detached lancet for obtaining fingerstick whole blood (3) update the Instructions for Use (IFU) to update kit stability to 12 months, to add additional limitations (related to performance in individuals who have received a COVID-19 vaccine and performance with circulating variants), revised test instructions and other minor edits to reflect language used in more recent authorizations, (4) clarifying revisions to the Letter of Authorization to include italicization of the name of the assay (*CareStart* COVID-19 IgM/IgG), update of the indication and Conditions of Authorization, consolidation of several conditions in new Condition L below and other clarifying modifications to reflect language used in more recent authorizations, (5) addition of a quick reference guide for use with fingerstick specimens “User Quick Reference Instructions for *CareStart* COVID-19 IgM/IgG”, (6) update the healthcare provider (HCP) and recipient fact sheets to include information regarding testing of individuals who have received a COVID-19 vaccine and other updates to reflect language used in more recent authorizations, and update the HCP fact sheet to include information related to performance with circulating variants, and (7) remove AQSIGN COVID-19 IgM/IgG, Easy Check COVID-19 IgM/IgG and *KarmaCare* COVID-19 IgM/IgG as distributed tests under this EUA.

⁵ For ease of reference, this letter will use the term “your product” to refer to the *CareStart* COVID-19 IgM/IgG for the indication identified above. (Also distributed as Rapid Response Liberty COVID-19 IgG/IgM).

hereby authorized for use consistent with the indication described above.

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.⁶

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 IgM/IgG” 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 recent or prior infection with SARS-CoV-2 by identifying individuals with an adaptive immune response to the virus that causes COVID-19, and that the known and potential benefits of your product when used for such 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.⁷

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.

⁶ 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).

⁷ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

Authorized Product Details

Your product is an immunochromatographic lateral flow immunoassay intended for the qualitative detection and differentiation of Immunoglobulin M (IgM) and Immunoglobulin G (IgG) antibodies to SARS-CoV-2 in human serum, plasma (sodium citrate, sodium heparin, or dipotassium EDTA), venous whole blood (sodium citrate, sodium heparin, or dipotassium EDTA), and fingerstick whole blood. The product is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

Testing of serum, plasma and venous whole blood specimens is limited to laboratories certified under CLIA, that meet requirements to perform moderate or high complexity tests.

Testing of fingerstick whole blood specimens is limited to laboratories certified under CLIA, that meet the requirements to perform high, moderate or waived complexity tests. Testing of fingerstick whole blood specimens 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.

At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity.

The product is an immunochromatographic lateral flow assay in which anti-human IgG, streptavidin, and control antibody are immobilized onto a membrane to form three distinct lines – IgG test line, IgM test line, and control line, respectively. A conjugate pad, located upstream of the immobilized test and control lines, contains recombinant SARS-CoV-2 antigen that is conjugated to colloidal gold and biotinylated anti-human IgM. Specimen (10 µL) followed by one drop of assay buffer is added to the sample well. If present in the specimen, IgM binds to the SARS-CoV-2 antigen colloidal gold conjugate and the biotinylated anti-human IgM and the complex is captured by streptavidin at the IgM test line generating a purple line. If present in the specimen, IgG binds to the SARS-CoV-2 antigen colloidal gold conjugate and the complex is captured by anti-human IgG at the IgG test line generating a purple line. Colloidal gold is captured at the control line generating a purple line and indicating a valid test result. The absence of purple lines at the IgM and IgG test lines but the appearance of a purple control line indicates that IgM and IgG were absent from the specimen. Results are visually read 10 minutes after starting the test and should not be read after 15 minutes. The *CareStart* COVID-19 IgM/IgG includes the following materials or other authorized materials: Test device, Assay buffer, blood transfer pipette, alcohol swab, and sterile safety lancet.

Your product requires the following internal control, that is processed along with the specimen on the device cassette. The internal control listed below must generate expected results in order for a test to be considered valid, as outlined in the “*CareStart* COVID-19 IgM/IgG Instructions for Use”:

- Internal Control – The control line should appear on each strip for every test and checks that flow of reagents is satisfactory. The absence of a control line indicates an

invalid test result.

Your product requires the following authorized external positive and negative controls (*CareStart* COVID-19 Antibody External Controls) which are not included with the kit but are available from you with the “*CareStart* COVID-19 Antibody External Controls Instructions for Use”, or other authorized control materials (as may be requested under Condition L below). Controls are run as outlined in the “*CareStart* COVID-19 IgM/IgG” Instructions for Use and the “*CareStart* COVID-19 Antibody External Controls” Instructions for Use:

- Positive External Control: Mixture of human chimeric SARS-CoV-2 IgM and recombinant IgG antibodies in heat-inactivated SARS-CoV-2 antibody-negative confirmed serum
- Negative External Control: Heat inactivated SARS-CoV-2 antibody-negative confirmed serum.

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 “*CareStart* COVID-19 IgM/IgG” Instructions for Use.

Your above described product is authorized to be accompanied with the labeling entitled “*CareStart* COVID-19 IgM/IgG Instructions for Use” (available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>), the “Quick Reference Instructions for *CareStart* COVID-19 IgM/IgG” and the following product-specific information pertaining to the emergency use (collectively referenced as “authorized labeling”), which is required to be made available to healthcare providers and recipients:

- Fact Sheet for Healthcare Providers: Access Bio, Inc. - *CareStart* COVID-19 IgM/IgG
- Fact Sheet for Recipients: Access Bio, Inc. - *CareStart* COVID-19 IgM/IgG

The above described product, when accompanied by the authorized labeling, 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 recent or prior infection with SARS-CoV-2 by identifying individuals with an adaptive immune response to the virus that causes 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)⁸

- 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) must make your product available with the authorized labeling to authorized laboratories.
- C. You and authorized distributor(s) must make available on your website(s) the Fact Sheet for Healthcare Providers and the Fact Sheet for Recipients.
- D. You and authorized distributor(s) must inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and

⁸ “Authorized Distributor(s)” are identified by you, Access Bio, Inc., in your EUA submission as an entity allowed to distribute your product.

any updates made to your product, and authorized labeling.

- E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the authorized laboratories to which they distribute the test and number of tests they distribute.
- F. You and authorized distributor(s) must collect information on the performance of your product. You must report 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) (via email: CDRH-EUA-Reporting@fda.hhs.gov) any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the product of which you become aware.
- 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) must make available the control material (*CareStart* COVID-19 Antibody External Controls with the “*CareStart* COVID-19 Antibody External Controls” Instructions for Use or other authorized control materials (as may be requested under Condition L below), at the same time as your product.

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 amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).
- K. 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).
- 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 not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to the DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

- M. You must evaluate the performance and assess traceability⁹ of your product with any FDA-recommended reference material(s) or established panel(s) of characterized clinical specimens. After submission to and concurrence with the data by FDA, you must 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.
- N. You must have a process in place to track adverse events, including any occurrence of false results and report to FDA pursuant to 21 CFR Part 803.
- O. 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.
- P. 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.
- Q. If requested by FDA, you must periodically submit new lots for testing at the National Cancer Institute, or by another government agency designated by FDA, to confirm continued performance characteristics across lots. In addition, FDA may request records regarding lot release data for tests to be distributed or already distributed. If such lot release data are requested by FDA, you must provide it within 48 hours of the request.
- R. You must complete the agreed upon real-time stability study for your product. 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.

Authorized Laboratories

- S. Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- T. Authorized laboratories must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

⁹ Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material. FDA may request, for example, that you perform this study in the event that we receive reports of adverse events concerning your product.

- U. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- V. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- W. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and to you (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.
- X. All laboratory personnel using your product must be appropriately trained in immunochromatographic techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product.

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

- Y. You, authorized distributor(s), and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Conditions Related to Printed Materials, Advertising and Promotion

- Z. 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 and FDA implementing regulations.
- AA. 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.
- BB. 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 for emergency use by FDA under an EUA for use by authorized laboratories;
 - This product has been authorized only for detecting the presence of IgM and IgG antibodies to SARS-CoV-2, not for any other viruses or pathogens; and
 - The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use

of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

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