



October 8, 2020

David Ikeda
Senior Staff Regulatory Affairs
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318

Device: Access SARS-CoV-2 IgM

Company: Beckman Coulter, Inc.

Indication: Qualitative detection of immunoglobulin M (IgM) antibodies to SARS-CoV-2 in human serum, serum separator tubes, and plasma (lithium heparin, dipotassium EDTA, tripotassium EDTA, and sodium citrate). Intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. Samples should only be tested from individuals that are 8 days to 30 days post symptom onset. SARS-CoV-2 antibody negative samples collected 8 days or more post symptom onset should be reflexed to a test that detects and reports SARS-CoV-2 IgG. 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 requirements to perform moderate or high complexity tests.

Dear Mr. Ikeda:

This letter is in response to your¹ 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 Beckman Coulter, Inc.

² For ease of reference, this letter will use the term “your product” to refer to the Access SARS-CoV-2 IgM 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 “Access SARS-CoV-2 IgM Instructions for Use.”

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.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 qualitative test intended for the detection of IgM antibodies to SARS-CoV-2 in human serum, serum separator tubes, and plasma (lithium heparin, dipotassium EDTA, tripotassium EDTA, and sodium citrate). 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. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. Samples should only be tested from individuals that are 8 days to 30 days post symptom onset. SARS-CoV-2 antibody negative

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.

samples collected 8 days or more post symptom onset should be reflexed to a test that detects and reports SARS-CoV-2 IgG.

The Access SARS-CoV-2 IgM assay is a two-step enzyme immunoassay that can be run using one of the fully automated Access Family of Immunoassay Analyzers, including the standalone Access 2, UniCel DxI 600, and UniCel DxI 800 analyzers and the integrated chemistry/immunoassay platforms; UniCel DxC 600i, UniCel DxC 680i, UniCel DxC 880i, UniCel DxC 660i and UniCel DxC 860i. A prediluted patient sample is added to a reaction vessel along with paramagnetic particles coated with a mouse monoclonal anti human IgM antibody. Human IgM present in the patient specimen is captured by the anti-human IgM antibody on the paramagnetic particles. After incubation, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. Diluent buffer and recombinant SARS-CoV-2 protein alkaline phosphatase conjugate are added to the vessel. The recombinant SARS-CoV-2 protein contains the receptor binding domain (RBD) of the viral S1 protein. This conjugate will bind to any anti-SARS-CoV-2 IgM that was captured by the paramagnetic particle solid phase in the first step. Following a second incubation and wash step, a chemiluminescent substrate is added to the vessel and light generated by the reaction of the chemiluminescent substrate and alkaline phosphatase (conjugated to the recombinant SARS-CoV-2 protein) is measured with a luminometer. By comparison of the light intensity with the cut-off value determined during calibration on the instrument, the presence or absence of anti-SARS-CoV-2 IgM in the patient sample is determined.

Your product requires the use of external controls and calibrators which are available separately, such as Access SARS-CoV-2 IgM QC with the “Access SARS-CoV-2 IgM QC Instructions for Use,” or other authorized controls (as may be requested under Condition L below) and the Access SARS-CoV-2 IgM Calibrator with the “Access SARS-CoV-2 IgM CALIBRATOR Instructions for Use” or other authorized calibrator (as may be requested under Condition L below):

- Access SARS-CoV-2 IgM QC (Quality Control): QC1 – Negative Control consisting of TRIS buffer, defibrinated human plasma negative for anti-SARS-CoV-2 plus additives;
- Access SARS-CoV-2 IgM QC2 – Positive Control consisting of TRIS buffer, defibrinated human plasma, human IgM conjugated to anti-SARS-CoV-2 antibody, plus additives; 1 QC Card.
- Access SARS-CoV-2 IgM Calibrator: C0 – contains TRIS buffer, surfactant and protein (bovine), < 0.1% sodium azide and 0.5% ProClin300; C1 - TRIS buffer containing anti-SARS-CoV-2 plasma, surfactant and protein (bovine), < 0.1% sodium azide and 0.5% ProClin 300; 1 Calibrator Card.

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.

Your above described product is authorized to be accompanied with labeling entitled “Access SARS-CoV-2 IgM Instructions for Use,” (available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>), and the following product-specific information pertaining to the

emergency use, which is required to be made available to healthcare providers and recipients:

- Fact Sheet for Healthcare Providers: Beckman Coulter, Inc. – Access SARS-CoV-2 IgM
- Fact Sheet for Recipients: Beckman Coulter, Inc. – Access SARS-CoV-2 IgM

The above described product, when accompanied by the “Access SARS-CoV-2 IgM Instructions for Use,” and the two Fact Sheets (collectively referenced as “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:

Beckman Coulter, Inc. (You) and Authorized Distributor(s)⁵

- 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 Fact Sheet for Healthcare Providers and the Fact Sheet for Recipients.
- D. 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, and authorized labeling.
- E. 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.
- F. 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 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) will make available the control and calibrator materials (Access SARS-CoV-2 IgM QC and Access SARS-CoV-2 IgM Calibrator), or other authorized control and calibrator materials, at the same time as your product.

Beckman Coulter, 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).

⁵ “Authorized Distributor(s)” are identified by you, Beckman Coulter, Inc., in your EUA submission as an entity allowed to distribute your product.

- J. You will provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent amendments made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).
- K. You will comply with the following requirements pursuant to FDA regulations: Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 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 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.
- M. You will evaluate the performance and assess traceability⁶ 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 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.
- N. You will 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 will 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.

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

- R. You will 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 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.
- T. Authorized laboratories will 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.
- U. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- V. 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.
- W. 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 to you (Customer Technical Support: 1-800-854-3633; Customer portal: www.beckmancoulter.com) 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 automated immunoassay 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.

Beckman Coulter, Inc. (You), Authorized Distributors and Authorized Laboratories

- Y. 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

- Z. 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.

- AA. 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 of SARS-CoV-2.
- BB. 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 presence of IgM antibodies against 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 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

Enclosures