

March 22, 2021

Abhijit Datta, Ph.D.
VP Operations
Diazyme Laboratories, Inc.
12889 Gregg Court
Poway, CA 92064

Device: Diazyme DZ-Lite SARS-CoV-2 IgG CLIA Kit
EUA Number: EUA200217
Company: Diazyme Laboratories, Inc.
Indication: Qualitative and semi-quantitative detection of IgG antibodies to SARS-CoV-2 in human serum and plasma (potassium EDTA, disodium EDTA and lithium heparin). 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: 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 Dr. Datta:

On July 8, 2020, based on your¹ request, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of the Diazyme DZ-Lite SARS-CoV-2 IgG CLIA Kit, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3), for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum and plasma (potassium EDTA, disodium EDTA and lithium heparin) using the DZ-lite 3000 Plus Chemiluminescence Analyzer; 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.

On December 11, 2020, you requested to amend your EUA. Based on that request, and having concluded that revising the July 8, 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

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

July 8, 2020, letter in its entirety with the revisions incorporated.² 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 product³ is now 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.⁴

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 the “Diazyme DZ-Lite SARS-CoV-2 IgG CLIA Kit” 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 The revisions to the July 8, 2020, letter and authorized labeling include: (1) update the intended use to include semi-quantitative detection, (2) update the healthcare provider (HCP) and recipient fact sheets to include information regarding semi-quantitative results and testing of individuals who have received a COVID-19 vaccine, and update the HCP fact sheet to include information related to performance with circulating variants, (3) edits to the Instructions for Use to update the intended use and to add semi-quantitative result interpretation criteria, limitations related to testing of individuals who have received a COVID-19 vaccine and information related to performance with circulating variants, and other minor edits to reflect language used in more recent authorizations, and (4) revise the Letter of Authorization to remove reference to the instrument in the indication, revisions to reflect language used in more recent authorizations, the addition of Condition of Authorization S. and consolidation of several conditions in new Condition K. below.

³ For ease of reference, this letter will use the term “your product” to refer to the Diazyme DZ-Lite SARS-CoV-2 IgG CLIA Kit for the indication identified above. “CLIA” as used in the device name refers to chemiluminescence immunoassay. The Diazyme DZ-Lite SARS-CoV-2 IgG CLIA Kit is an indirect chemiluminescence immunoassay.

⁴ 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).

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.⁵

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 chemiluminescent immunoassay intended for the qualitative and semi-quantitative detection of IgG antibodies to SARS-CoV-2 in human serum and plasma (potassium EDTA, disodium EDTA and lithium heparin). Your 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 is limited to laboratories certified under CLIA that meet requirements to perform moderate or high complexity tests. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. Semi-quantitative results from your product should not be interpreted as an indication or degree of immunity or protection from reinfection.

Your product is an indirect chemiluminescence immunoassay performed using the DZ-lite 3000 Plus Chemiluminescence Analyzer (includes DZ-Lite 3000Plus Chemiluminescence Analyzer Operating Instructions Manual). Sample, buffer and magnetic microbeads coated with SARS-CoV-2 recombinant antigen are mixed thoroughly and incubated, forming immune-complexes. After precipitation in a magnetic field and decanting of the supernatant, wash cycles are performed. Subsequently, N-(4-aminobutyl)-N-ethylisoluminol (ABEI)-labeled anti-human IgG antibody is added and incubated to form additional complexes. After precipitation in a magnetic field and decanting of the supernatant, wash cycles are performed. Subsequently, the Starter 1+2 are added to initiate a chemiluminescent reaction. The light signal is measured by the DZ-lite 3000 Plus Chemiluminescence Analyzer as a relative light units (RLU), which is proportional to the concentration of SARS-CoV-2 IgG presented in the sample. The product contains a Low and a High Calibrator to execute calibration operation.

Your product also includes external negative and positive controls or other authorized controls (as may be requested under Condition K below) to be run as outlined in the Instructions for Use:

- Negative Control: Phosphate buffered saline with bovine serum albumin and preservative.

⁵ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

- Positive Control: Phosphate buffered saline containing SARS-CoV-2 IgG and bovine serum albumin with preservative.

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 product described above is authorized to be accompanied with the labeling entitled “Diazyme DZ-Lite SARS-CoV-2 IgG CLIA Kit” 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 fact sheets pertaining to the emergency use, which is required to be made available to healthcare providers and recipients (collectively referred to as “authorized labeling”):

- Fact Sheet for Healthcare Providers: Diazyme DZ-Lite SARS-CoV-2 IgG CLIA Kit
- Fact Sheet for Recipients: Diazyme DZ-Lite SARS-CoV-2 IgG CLIA Kit

The above described product, when accompanied by the Instructions for Use (identified above) and the two Fact Sheets 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:

Diazyme Laboratories, Inc. (You) and Authorized Distributor(s)⁶

- 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 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 your product and number they distribute.
- F. You and authorized distributor(s) must collect information on the performance of your product. You must report to FDA any suspected occurrence of false positive (detected) and false negative (non-reactive) 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.

⁶ “Authorized Distributor(s)” are identified by you, Diazyme Laboratories, Inc., in your EUA submission as an entity allowed to distribute your product.

Diazyme Laboratories, Inc. (You)

- H. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).
- I. 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).
- J. You must 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, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).
- K. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) and require appropriate authorization from FDA prior to implementation.
- L. You must evaluate the performance and assess traceability⁷ 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.
- M. 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.
- N. 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.
- O. 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.

⁷ Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

- P. 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.
- Q. 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.
- R. You must complete the Interference Study that you provided in a protocol submitted to FDA dated February 9, 2021. The study includes testing of a sample with an antibody analyte level slightly below the upper limit of the measuring interval and will be completed within 30 calendar days of the date of this letter. 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.
- 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 you (support@diazyme.com; 858-455-4768 Option 2) any suspected occurrence of false positive (detected) or false negative (non-reactive) 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.

Diazyme Laboratories, 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 test 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 test has been authorized only for detecting IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens; and
 - The emergency use of this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the 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