August 31, 2020

Taylor Edwards, MSc, Ph.D.
Associate Staff Scientist, Clinical Laboratory Manager
University of Arizona Genetics Core for Clinical Services
Keating Bioresearch Building
1657 E. Helen Street Room 111H
Tucson, AZ 85721

Device:	COVID-19 ELISA pan-Ig Antibody Test
Company:	University of Arizona Genetics Core for Clinical Services
Indication:	Qualitative detection of total antibodies to SARS-CoV-2 in human serum. Testing is performed on the Beckman FX Liquid Handler Workstation with BMG CLARIOstar Plus plate reader. 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 University of Arizona Genetics Core for Clinical Services, located at the Keating Bioresearch Building, 1657 E. Helen Street, Tucson, AZ 85721, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, and meets requirements to perform high complexity tests.

Dear Dr. Edwards:

This letter is in response to your[1] 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 University of Arizona Genetics Core for Clinical Services.
[2] For ease of reference, this letter will use the term "your product" to refer to the COVID-19 ELISA pan-Ig Antibody Test 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]

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 for the of detection of total antibodies (including IgA, IgG, and IgM) against SARS-CoV-2 in human serum. 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 how long antibodies persist following infection and if the presence of antibodies confers protective immunity.

The product is an immunoassay using 384 well plates carried out on the Beckman FX Liquid Handler Workstation with BMG CLARIOstar Plus plate reader. The solid phase in the first ELISA contains SARS-CoV-2 spike receptor-binding domain (RBD) and in the confirmatory ELISA the solid phase is coated with spike S2 protein. The coated plates are incubated consecutively with serum and then goat anti-human IgA+IgG+IgM (Heavy+Light)/Horse

[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.

Radish Peroxidase (HRP). Color is developed by addition of tetramethylbenzidine as the substrate for HRP and measured as optical density (OD) at 450 nm. Samples that are Negative in the first assay do not need to be confirmed in the second assay. Samples that are Indeterminate or Positive in the first assay are subjected to the second assay which gives a Final Report of Positive, Negative, or Indeterminate.

Assay	OD_{450} Value	Result	Assay	OD_{450} Value	Result	Final Report
RBD	≥ 0.389	Positive	S2	> 0.350	Positive	Positive
RBD	≥ 0.389	Positive	S2	≤ 0.350	Negative	Negative
RBD	> 0.120 < 0.389	Indeterminate	S2	> 0.350	Positive	Indeterminate
RBD	> 0.120 < 0.389	Indeterminate	S2	≤ 0.350	Negative	Negative
RBD	≤ 0.120	Negative	N/A	N/A	N/A	Negative

The COVID-19 ELISA pan-Ig Antibody Test contains the following controls that must be run as outlined in your laboratory's standard operating procedure (SOP):

- Negative Control – Derived from previously tested serum RBD and S2 negative samples.
- Positive Control – Derived from previously tested, pooled serum RBD and S2 positive samples. These consist of both a high absorbance pool (> 1.0 OD_{450} for both RBD and S2) and a medium absorbance pool (between 0.7-0.8 OD_{450} for both RBD and S2).
- Positive Control for RBD assay only – Human monoclonal antibody against SARS-CoV-2 spike protein S1.
- Negative Template Control – HPLC water.

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 your laboratory's SOP (described below).

The above described product is authorized to be accompanied with the labeling submitted as part of the EUA request (described below), and the EUA Summary (available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations), 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: University of Arizona Genetics Core for Clinical Services-COVID-19 ELISA pan-Ig Antibody Test
- Fact Sheet for Recipients: University of Arizona Genetics Core for Clinical Services-COVID-19 ELISA pan-Ig Antibody Test

Your above described product, when accompanied by the "COVID-19 ELISA pan-Ig Antibody Test Client ordering Information," the COVID-19 ELISA pan-Ig Antibody Test SOP bundle, the EUA Summary (identified above), and the two Fact Sheets (collectively referenced as

"authorized labeling") is authorized to be used by University of Arizona Genetics Core for Clinical Services, Keating Bioresearch Building at 1657 E. Helen Street, Tucson, AZ 85721 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 authorized 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 and storage of your product.

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

University of Arizona Genetics Core for Clinical Services (You)

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 will inform relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.

C. You will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

D. You 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.

E. You will make available on your website(s) the Fact Sheet for Healthcare Providers and the Fact Sheet for Recipients.

F. You 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.

G. You will use your authorized test as outlined in the authorized labeling. Deviations from the authorized test procedures, will be made in consultation with, and require concurrence of, Division of Microbiology Devices/Office of Health Technology-7 – Office of In Vitro Diagnostics and Radiological Health/ Office of Product Evaluation and Quality/ Center for Devices and Radiological Health (DMD/OHT7-OIR/OPEQ/CDRH).

H. You will collect information on the performance of your product. You will report to FDA to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware.

I. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II of this letter) or to the authorized labeling. Such requests should be submitted to the DMD/OHT7-OIR/OPEQ/CDRH, and require appropriate authorization from FDA prior to implementation.

J. You will evaluate the performance and assess traceability[5] of your product with any FDA-recommended reference material(s) or established panel(s) of characterized clinical specimens. After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence with the data, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require

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

concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

K. If requested by FDA, you will participate in a National Cancer Institute study on the evaluation of your product. After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence with the data, you will update your product labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

L. You will track adverse events, including any occurrence of false results and report to FDA pursuant to 21 CFR Part 803.

M. All laboratory personnel using your product must be appropriately trained in 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.

N. You 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

O. 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.

P. 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.

Q. 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 only for use by the authorized laboratory, University of Arizona Genetics Core for Clinical Services, located at the Keating Bioresearch Building, 1657 E. Helen Street, Tucson, AZ 85721.
- This test has been authorized only for the detection of 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 Federal

Food, Drug and Cosmetic 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,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure