June 4, 2020

Vasanth Jayaraman
Chief Operating Officer
Vibrant America Clinical Labs
1360 Bayport Avenue
San Carlos, CA 94070

Device:	Vibrant COVID-19 Ab Assay
Company:	Vibrant America Clinical Labs
Indication:	Qualitative detection and differentiation of human IgG and IgM antibodies to SARS-CoV-2 in human serum and dried blood spot (DBS) collected by a healthcare provider. 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 the Vibrant America Clinical Labs at 1360 Bayport Avenue, San Carlos, CA, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a to perform high complexity tests.

Dear Mr. Jayaraman:

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 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]

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Vibrant America Clinical Labs.
[2] For ease of reference, this letter will use the term "your product" to refer to the Vibrant COVID-19 Ab Assay, for the indication identified above.
[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*

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 Section 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 detection and differentiation of IgG and IgM antibodies against SARS-CoV-2 in human serum and dried blood spot collected by a healthcare provider. 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 convers protective immunity.

Your product has been developed for the qualitative detection of human SARS-CoV-2 antibodies in serum or dry blood spot specimen by chemiluminescence assay. Diluted patient serum or dried bood spot eluate and controls (including positive and negative controls) are added to individual wells allowing the SARS-CoV-2 specific antibodies, if present, to bind to the immobilized antigen. Unbound sample is washed away and an enzyme labeled anti-human IgG conjugate is added to each well in one plate and enzyme labeled anti-human IgM conjugate is added to another plate. After washing away the unbound enzyme labeled conjugate, the remaining enzyme activity is measured by adding a chemiluminescent substrate and measuring

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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.

the intensity of the signal from each well scanned. Two 96 pillar plates are used for each assay (one for IgG antibody detection, and one for IgM antibody detection). The sample results are interpreted and quantitated by comparison with controls and cut-off values. The sample is considered to be negative if the sample intensity is equal to or less than the cut-off value chosen and positive if it is greater than the cut-off value chosen. There are four SARS-CoV-2 antigens tested and the sample is positive if the antibody response to any one of the four antigens is positive. The assay is performed using an automated liquid handling workstation (Hamilton Microlab STAR) employing assay specific software developed for this purpose.

Your product also includes external positive and negative controls, to be run as outlined in your laboratory's standard operating procedure (SOP) including:

- IgG Low Positive Control
- IgG High Positive Control
- IgG Negative Control
- IgM Low Positive Control
- IgM High Positive Control
- IgM Negative Control

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.

The above described product is authorized to be accompanied with labeling submitted as part of the EUA request, and as described in the "Vibrant COVID-19 Ab Assay 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: Vibrant COVID-19 Ab Assay
- Fact Sheet for Recipients: Vibrant COVID-19 Ab Assay

The above described product, when accompanied by the EUA Summary (identified above), the two Fact Sheets, and the Vibrant COVID-19 Test Standard Operating Procedure (SOP) (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 authorized product, when used to diagnose recent or prior infection with SARS-CoV-2 by identifying individuals with an adaptive immune response to the virus and used consistently 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 dignosing 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 consistently 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) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), 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:

Vibrant America Clinical Labs (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, authorized labeling including the authorized Fact Sheets.

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, 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 and 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 the Scope of Authorization (Section II in this letter) of your product. Such requests will be made in consultation with DMD/OHT7-OIR/OPEQ/CDRH, and require concurrence of, Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC) and DMD/OHT7-OIR/OPEQ/CDRH.

J. You may request changes to the authorized labeling, including the authorized Fact Sheets. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

K. You may request the addition of other instruments for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

L. You may request the addition of other ancillary methods for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

M. You may request the addition of other specimen types for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

N. You may request the addition and/or substitution of control materials for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

O. You may request substitution for or changes to the authorized materials used in the detection process of human antibodies against SARS-CoV-2. Such requests will be

made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

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

Q. If requested by FDA, you will participate in the 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.

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

S. You will complete the class specificity study for your product usig DTT and submit to FDA for review by DMD/OHT7-OIR/OPEQ/CDRH by 6/30/2020. 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.

T. 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.

U. You will maintain records of test usage and 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

V. All descriptive printed matter, including advertising and promotional materials, relating to the use of your product, shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

W. 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

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

detection of SARS-CoV-2.

X. 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, Vibrant America Clinical Labs;
- This test has been authorized only for the detection of IgG and 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,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures