U.S. FOOD & DRUG ADMINISTRATION

April 15, 2020

Carlos Cordon-Cardo, MD, Ph.D.
Mount Sinai Laboratory
Center for Clinical Laboratories
Annenberg Building Floor 15 Room 15-60A
1468 Madison Ave
New York, NY 10029

Device:	COVID-19 ELISA IgG Antibody Test
Company:	Mount Sinai Laboratory
Indication:	Qualitative detection of human IgG antibodies in serum and plasma specimens collected from individuals suspected of prior infection with the virus that causes COVID-19 by their healthcare provider. Emergency use of this test is limited to the Mount Sinai Laboratory (MSL), Center for Clinical Laboratories, a division of the Department of Pathology, Molecular, and Cell-Based Medicine, New York, NY, that is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a to perform high complexity tests ("authorized laboratory").

Dear Dr. Carlos Cordon-Cardo:

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 the Mount Sinai Laboratory.
[2] For ease of reference, this letter will use the term "your product" to refer to the COVID-19 ELISA IgG Antibody Test used 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 prior infection with the virus that causes COVID-19, and that the known and potential benefits of your product when used for diagnosing prior infection with the virus that causes COVID-19, 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 of IgG antibodies against SARS-CoV-2 in serum and plasma specimens collected from individuals suspected of prior infection with the virus that causes COVID-19 by their healthcare provider. Results are for the detection of SARS-CoV-2 IgG antibodies that are generated as part of the human immune response to the virus. IgG antibodies to SARS-CoV-2 generally become detectable 10 – 14 days after infection although may be detected earlier. Positive results for IgG antibodies can be indicative of an immune response to acute or previous infection; however, testing for IgG antibodies should not be used for the diagnosis of acute infection.

Your product has been developed for the qualitative detection of human SARS-CoV-2 antibody in serum and plasma via serial Enzyme-Linked ImmunoSorbent Assays (ELISA). The initial ELISA test assay controls and patient samples diluted 1:50 with PBS are added to a Thermo

[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.

Scientific Immulon 96 well microtiter plate that was coated with SARS-CoV-2 recombinant Receptor Binding Domain protein (RBD). The coated RBD protein combines with patient's SARS-CoV-2 IgG antibodies and the plate is then washed. Secondary anti-human IgG HRP labeled antibody is then added, washed, and substrate for HRP is added. When the value of color is greater than the cut-off value (OD490 = 0.15) the specimen is a presumptive positive. Presumptive positive specimens (OD490 > 0.15) are then confirmed by an ELISA using dilutions of specimen in a Thermo Scientific Immulon 96 well microtiter plate coated with full length SARS-CoV-2 Spike protein. A confirmed positive has a result greater than the cut-off value (OD490 = 0.15) at a titer of 1:80 or above, while a negative is OD490 ≤ 0.15 at a titer of 1:80.

Your product also includes external positive and negative controls, or other authorized controls, to be run as outlined in the Instructions for Use, including:

- Positive Controls are prepared using remnant pooled serum that was tested positive for SARS-CoV-2 antibodies by direct ELISA. The positive control absorbance at 490 nm must be > 0.15.
- Negative Controls are prepared using remnant pooled serum that was tested negative for SARS-CoV-2 antibodies by direct ELISA. The negative control absorbance at 490 nm must be less than 0.15.

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.

The above described product, when labeled consistently with the authorized procedures submitted as part of the EUA request, and as described in the EUA summary (available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations), which may be revised in consultation with, and with concurrence of, the Division of Microbiology Devices (DMD)/Office of Health Technology 7 Office of In Vitro Diagnostics and Radiological Health (OHT7-OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH), is authorized to be distributed to and used by the authorized laboratory under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

Your product is authorized to be accompanied by the following product-specific information pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: COVID-19 ELISA IgG Antibody Test
- Fact Sheet for Patients: COVID-19 ELISA IgG Antibody Test

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 for diagnosing prior infection with the virus that causes COVID-19 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 for the indication above, 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.

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under Section 564(b)(2) of the Act or when the EUA is revoked under Section 564(g) of the Act.

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.

IV. Conditions of Authorization

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

Mount Sinai Laboratory (MSL), Center for Clinical Laboratories

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)); any 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 and

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 Patients.

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 test procedures submitted as part of the EUA request. 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. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

K. You may request changes to the authorized Fact Sheets. 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 instruments 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 ancillary methods 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 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.

O. 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.

P. 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.

Q. 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/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.

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

S. 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.

T. 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 Advertising and Promotion

U. All advertising and promotional descriptive printed matter 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.

V. All advertising and promotional descriptive printed matter relating to the use of your

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

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 detection of IgG 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 diagnostic tests 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.

No advertising or promotional descriptive printed matter 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.

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