U.S. FOOD & DRUG ADMINISTRATION

April 5, 2021

Donna Hongo, Ph.D.
Co-Founder and Co-CEO
Symbiotica, Inc.
1350 Burton Drive, Ste 210
Vacaville, CA 95687

Device:	COVID-19 Self-Collected Antibody Test System
EUA Number:	EUA201081
Company:	Symbiotica, Inc.
Indication:	Qualitative detection of IgG antibodies to SARS-CoV-2 in human fingerstick blood dried blood spot (DBS) specimens that are self-collected at home by an individual age 18 years or older or collected by an adult from an individual 5 years of age and older using the COVID-19 Self-Collected Antibody Test System Collection Kit when determined to be appropriate 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.
Authorized Laboratories:	Testing is limited to Symbiotica, Inc., located at 1350 Burton Drive, Ste 210, Vacaville, CA 95687 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. Hongo:

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

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Symbiotica, Inc.
[2] For ease of reference, this letter will use the term "your product" to refer to the COVID-19 Self-Collected Antibody Test System for the indication identified above.

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]

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 in the EUA Summary (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. 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 an enzyme-linked immunosorbent assay (ELISA) for the qualitative detection of IgG antibodies to SARS-CoV-2 in human fingerstick dried blood spot (DBS) specimens that are self-collected at home by an individual age 18 years or older or collected by an adult from an individual 5 years of age and older using the COVID-19 Self-Collected Antibody Test System Collection Kit when determined to be appropriate by a healthcare provider. The product is

[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.

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.

Your product is comprised of a collection kit, the COVID-19 Self-Collected Antibody Test System Collection Kit, which is delivered to individuals for home collection, and an ELISA assay, which is performed using the self-collected DBS specimens. The assay, part of the COVID-19 Self-Collected Antibody Test System, is referred to as the COVID-19 eSTAD. The COVID-19 Self-Collected Antibody Test System Collection Kit includes the following materials or other authorized materials: instruction sheet, DBS card, two safety lancets, two sterile gauze pads, two alcohol prep pads, two Band Aids and a return mailer with a prepaid label.

Your assay must be used in combination with the Calibrator (IgG, Human), Positive control and Negative control that are included as part of your product and are run as outlined in the standard operating procedure (SOP).

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).

Your assay is authorized to be accompanied by the EUA Summary (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), as well as the "COVID-19 Self-Collected Antibody Test System (COVID-19 eSTAD) Testing Procedure" standard operating procedure and the following fact sheets pertaining to the emergency use, which are required to be made available to healthcare providers and recipients:

- Fact Sheet for Healthcare Providers: Symbiotica Inc. - COVID-19 Self-Collected Antibody Test System
- Fact Sheet for Recipients: Symbiotica Inc. - COVID-19 Self-Collected Antibody Test System

Your assay, when accompanied by EUA Summary (identified above), the "COVID-19 Self-Collected Antibody Test System (COVID-19 eSTAD) Testing Procedure" standard operating procedure, and the two Fact Sheets, is authorized to be used under this EUA despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

The COVID-19 Self-Collected Antibody Test System Collection Kit with the "COVID-19 Self-Collected Antibody Test System Collection Kit Instructions for Use" is authorized to be distributed and used as part of the above described product as set forth in this EUA.

"Authorized labeling" includes the EUA Summary (identified above), the "COVID-19 Self-Collected Antibody Test System (COVID-19 eSTAD) Testing Procedure" standard operating procedure , two Fact Sheets, and "COVID-19 Self-Collected Antibody Test System Collection Kit Instructions for Use."

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 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:

Symbiotica, 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).

[5] "Authorized distributor(s)" are identified by you, Symbiotica, Inc., in your EUA submission as an entity allowed to distribute the COVID-19 Self-Collected Antibody Test System Collection Kit.

B. You and authorized distributor(s) must 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 and authorized distributor(s) must make available all instructions related to the self-collection of fingerstick blood dried blood spot (DBS) samples using the COVID-19 Self-Collected Antibody Test System Collection Kit, both in the shipped kit and on your website.

D. You and authorized distributors must make available on your website(s), if applicable, the Fact Sheet for Healthcare Providers and the Fact Sheet for Recipients.

E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers and locations to which the COVID-19 Self-Collected Antibody Test System Collection Kit is distributed.

F. You and authorized distributor(s) must maintain customer complaint files on record. You must report to FDA any significant complaints about usability or 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) must ensure that any records associated with this EUA, including test usage, are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

Symbiotica, Inc. (You)

I. You must notify FDA of any authorized distributor(s) of the COVID-19 Self-Collected Antibody Test System Collection Kit, including the name, address, and phone number of any authorized distributor(s).

J. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any authorized revisions that might be made to this EUA and its authorized labeling.

K. You must notify the relevant public health authorities of your intent to run your product.

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

M. You 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.

N. You must use your product as outlined in the authorized labeling. Deviations from the authorized laboratory procedures, including the authorized instruments, authorized sample preparation methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and/or authorized materials required to use your product are not permitted.

O. When testing authorized specimens self-collected using the COVID-19 Self-Collected Antibody Test System Collection Kit, you must follow any specimen accessioning protocols provided in the "COVID-19 Self-Collected Antibody Test System (COVID-19 eSTAD) Testing Procedure" SOP when accepting specimens for testing.

P. 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.

Q. You must submit to FDA a summary report within 30 calendar days of authorization summarizing the results of any testing performed using specimens collected with the COVID-19 Self-Collected Antibody Test System Collection Kit during that timeframe, including how many specimens were received, how many specimens had to be rejected during accession and the main reasons for rejection, and the positivity rate for specimens collected with the authorized self-collection kit.

R. You must collect information on the performance of your product and report to DMD/OHT-7-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.

S. You must evaluate the performance and assess traceability[6] 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.

T. You must have a process in place to track adverse events with the COVID-19 Self-

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

Collected Antibody Test System Collection Kit, including any occurrence of false results with the COVID-19 Self-Collected Antibody Test System and report to FDA in accordance with 21 CFR Part 803. Serious adverse events, including unexpected biosafety concerns and adverse sampling events occurring with the COVID-19 Self-Collected Antibody Test System Collection Kit must be immediately reported to DMD/OHT-7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).

U. 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.

V. You must complete the agreed upon real-time stability for your specimen collection device. 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.

Conditions Related to Printed Materials, Advertising and Promotion

W. 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.

X. 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.

Y. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This test system has not been FDA cleared or approved but has been authorized for emergency use by FDA under an Emergency Use Authorization for use by Symbiotica Inc., located at 1350 Burton Drive, Vacaville, CA 95687;
- This test system has been authorized only for detecting IgG antibodies to SARS-CoV-2, not for any other viruses or pathogens; and
- The emergency use of this test system 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,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure