April 16, 2021

Michelle Ortiz, Chief Operating Officer
Synergy Diagnostic Laboratory, Inc.
DBA SynergyDx
4081 SW 47th Avenue, Suite 1-4
Davie, FL 33314

Device:	SynergyDx SARS-CoV-2 RNA Test
EUA Number:	EUA210195
Company:	Synergy Diagnostic Laboratory, Inc., DBA SynergyDx
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal swab specimens collected from individuals suspected of COVID-19 by their healthcare provider (HCP), and from individuals without symptoms or other reasons to suspect COVID-19. This test is also authorized for use with anterior nasal swab specimens that are self-collected using the SynergyDx Home Collection Kit for COVID-19 at home or in a healthcare setting by any individuals, 18 years of age and older, including individuals without symptoms or other reasons to suspect COVID-19, when determined to be appropriate by a healthcare provider. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Testing is limited to laboratories designated by Synergy Diagnostic Laboratory, Inc., which are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C.§263, and meet the requirements to perform high-complexity tests.

Dear Michelle Ortiz:

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).

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Synergy Diagnostic Laboratory, Inc., DBA SynergyDx.
[2] For ease of reference, this letter will use the term "your product" to refer to the SynergyDx SARS-CoV-2 RNA

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]

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 contained 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 COVID-19, and that the known and potential benefits of your product when used for diagnosing 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

Test used 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 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.

Your product is a a real-time RT-PCR test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal swab specimens collected from individuals suspected of COVID-19 by their healthcare provider (HCP), and from individuals without symptoms or other reasons to suspect COVID-19. Your product is also authorized for use with anterior nasal swab specimens that are self-collected using the SynergyDx Home Collection Kit for COVID-19 at home or in a healthcare setting by any individuals, 18 years of age and older, including individuals without symptoms or other reasons to suspect COVID-19, when determined to be appropriate by a healthcare provider.

Testing of anterior nasal swab specimens is limited to laboratories designated by Synergy Diagnostic Laboratory, Inc., which are certified under the CLIA, 42 U.S.C.§263, and meet the requirements to perform high-complexity tests.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.
To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from anterior nasal swab specimens. The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection using an authorized real-time (RT) PCR instrument. The SynergyDx SARS-CoV-2 RNA Test uses all commercially sourced materials or other authorized materials and authorized ancillary reagents commonly used in clinical laboratories as described in the authorized procedures submitted as part of the EUA request.

Your product requires the following control materials, or other authorized control materials (as may be requested under Condition L. below), that are to be run as outlined in the authorized procedures submitted as part of the EUA request. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the authorized procedures submitted as part of the EUA request:

- nCoV Internal Control (IC) – bacteriophage MS2 - monitors the integrity of nucleic acid extraction and RT-PCR for each specimen
- nCoV Positive Control - SARS-CoV-2 RNA fragments capsulated in bacteriophage - monitors the integrity of the RT-PCR reagents.
- nCoV Negative Control - TE buffer - monitors for contamination of reagents and carryover during RNA extraction and RT-PCR.
- Extraction Control – targeting human RNase P (RP) mRNA – run on all specimens collected using the SynergyDx Home Collection Kit for COVID-19 - controls for specimen quality and demonstrates that nucleic acid was generated by the extraction process.

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 authorized labeling.

When using the SynergyDx Home Collection Kit for COVID-19, individuals must follow all specimen collection and mailing instructions provided with the kit, as described in the "SynergyDx Home Collection Kit for COVID-19 Kit Components," and "SynergyDx Home Collection Kit for COVID-19 Shipping Instructions."

The labeling entitled "SynergyDx Home Collection Kit for COVID-19 Kit Components", "SynergyDx Home Collection Kit for COVID-19 Shipping Instructions","SynergyDx Home Collection Kit for COVID-19" mailer box label and 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), the "Standard Operating Procedure: - SynergyDx SARS-CoV-2 RNA Test and SynergyDx Home Collection Kit for COVID-19 (Rx only) and - SynergyDx SARS-CoV-2 RNA Test DTC and SynergyDx Home Collection Kit for COVID-19 DTC" (only for the Rx only information), and the following fact sheets pertaining to the emergency use, is required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling":

- Fact Sheet for Healthcare Providers: Synergy Diagnostic Laboratory, Inc. (DBA SynergyDx)- SynergyDx SARS-CoV-2 RNA Test
- Fact Sheet for Patients: Synergy Diagnostic Laboratory, Inc. (DBA SynergyDx) - SynergyDx SARS-CoV-2 RNA Test

The above described product, with the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), 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.

The SynergyDx Home Collection Kit for COVID-19, with the "SynergyDx Home Collection Kit for COVID-19 Kit Components," "SynergyDx Home Collection Kit for COVID-19 Shipping Instructions" and "SynergyDx Home Collection Kit for COVID-19" mailer box label is authorized to be distributed and used as set forth in this EUA.

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 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.

IV. Conditions of Authorization

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

Synergy Diagnostic Laboratory, Inc. (You) and Authorized Distributor(s) [5]

A. Your product must comply with the following labeling requirements pursuant to 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 available all instructions related to the self-collection and shipping of nasal swab specimens using the SynergyDx Home Collection Kit for COVID-19 and the Fact Sheet for Individuals both in the shipped kit and on your website.

C. You and authorized distributor(s) must make available on your website(s), if applicable, the authorized Fact Sheet for Healthcare Providers and the Fact Sheet for Patients.

D. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers and locations to which the SynergyDx Home Collection Kit for COVID-19 is distributed.

E. You and authorized distributor(s) must maintain customer complaint files on record. You will report to FDA any significant complaints about usability or deviations from the established performance characteristics of the product of which you become aware.

[5] "Authorized Distributor(s)" are identified by you, Synergy Diagnostic Laboratory, Inc., in your EUA submission as an entity allowed to distribute the SynergyDx Home Collection Kit for COVID-19.

F. 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.

Synergy Diagnostic Laboratory, Inc. (You)

G. You must make your product available with the authorized labeling to authorized laboratories.

H. You 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.

I. You must ensure that authorized laboratories using your product have a process in place for reporting test results to relevant public health authorities, as appropriate.

J. You must maintain records of the authorized laboratories to which your distribute your product and test usage.

K. You must collect information on the performance of your product. You will report to to 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) (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.

L. 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. Any request for changes to this EUA should be submitted to DMD/OHT7- OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

M. You must evaluate the analytical limit of detection and assess traceability[6] of your product with any FDA-recommended reference material(s). 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.

N. You must submit to FDA a summary report within 30 calendar days of authorization summarizing the results of any testing performed using anterior nasal swab specimens collected with the SynergyDx Home Collection Kit for COVID-19 for use with your product 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.

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

O. You must further evaluate the performance of your product with specimens collected from asymptomatic individuals (to detect positive samples) in an FDA agreed upon post authorization study within four months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and FDA's concurrence with the data, you must update authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

P. You must have a process in place to track adverse events, including any occurrence of false results with your product, including with the SynergyDx Home Collection Kit for COVID-19, and report to FDA in accordance with 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, must immediately be reported to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).

Authorized Laboratories

Q. 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.

R. Authorized laboratories using your product must perform the test as outlined in the authorized labeling. Deviations from the authorized labeling, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

S. Authorized laboratories when testing anterior nasal swab specimens self-collected using the SynergyDx Home Collection Kit for COVID-19 authorized for use with your product you must follow your specimen accessioning protocol when accepting specimens for testing.

T. Authorized laboratories must notify the relevant public health authorities of your intent to run your product.

U. 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.

V. Authorized laboratories using your product 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 (CovidSupport@synergydx.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which they become aware.

W. All laboratory personnel using your product must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit and use the test in accordance with the authorized labeling.

Synergy Diagnostic Laboratory, Inc. (You), Authorized Distributor(s) and Authorized Laboratories

X. 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

Y. 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.

Z. 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.

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

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA;
- This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- The emergency use of this product 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