

October 15, 2020

Randee K. Lunn, MT (ASCP)
Quality Management & Safety Officer
Clinical Enterprise, Inc.
175 Crossing Blvd., Suite 400
Framingham, MA 01702

Device: EmpowerDX At-Home COVID-19 PCR Test Kit

Company: Clinical Enterprise, Inc.

Indication: For use by individuals to self-collect nasal swabs at home, when determined by a healthcare provider to be appropriate based on the results of an online COVID-19 questionnaire, and for use only with in vitro diagnostic (IVD) molecular tests for the detection of SARS-CoV-2 RNA that are indicated for use with the EmpowerDX At-Home COVID-19 PCR Test Kit.

Authorized Laboratories: Testing is limited to laboratories designated by Clinical Enterprise, Inc. that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests and that run the specimens collected from the EmpowerDX At-Home COVID-19 PCR Test Kit on an IVD molecular test that is indicated for use with the EmpowerDX At-Home COVID-19 PCR Test Kit.

Dear Ms. Lunn,

This letter is in response to your¹ 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-19.³

¹ For ease of reference, this letter will use the term “you” and related terms to refer to Clinical Enterprise, Inc.

² For ease of reference, this letter will use the term “your product” to refer to the EmpowerDX At-Home COVID-19 PCR Test Kit 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).

Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices during the COVID-19 outbreak, subject to the terms of any authorization issued under Section 564(a) of the Act.⁴

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 by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS-CoV-2 RNA from the self-collected human specimen, 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.⁵

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 collection kit intended for use by individuals to self-collect nasal swabs (unsupervised) at home, when determined by a healthcare provider to be appropriate based on the results of an online COVID-19 questionnaire. Once collected, the nasal swab specimen, which may include SARS-CoV-2 RNA, is maintained in the authorized product packaging and transported at ambient temperature to an authorized laboratory. The authorized laboratory then

⁴ U.S. Department of Health and Human Services, *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 17335 (March 27, 2020)

⁵ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

runs the specimen using an IVD molecular test that is indicated for use with nasal swab specimens collected with the EmpowerDX At-Home COVID-19 PCR Test Kit. When using your product, individuals must follow all specimen collection and mailing instructions provided with the kit. The EmpowerDX At-Home COVID-19 PCR Test Kit includes the following materials or other authorized materials: user sample collection instructions (described below), polyester nasal swab, collection tube containing 0.9% buffered saline, tube label, biohazard bag with absorbent pad, FedEx return shipping box/envelope pre-labeled with the receiving laboratory delivery address.

The above described product is authorized to be accompanied with authorized labeling (available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>). “Authorized labeling” includes the following documents: EUA Summary, EmpowerDX At-Home COVID-19 PCR Test Kit patient instructions “Home Collection Kit Instructions,” the COVID-19 Questionnaire “COVID-19 Viral Test Assessment,” and the “Self-Collection Specimen Receipt and Accessioning SOP.”

The above described product, when accompanied by the authorized labeling is authorized to be distributed to and used by individuals (accompanied with only “Home Collection Kit Instructions”), and authorized laboratories (accompanied by all authorized labeling) as set forth in this letter and pursuant to the conditions in 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 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 by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS-CoV-2 RNA from the self-collected human specimen 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, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

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

Clinical Enterprise, Inc. (You) and Authorized Distributor(s)⁶

- 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 and authorized distributor(s) will make available the “Home Collection Kit Instructions,” both in the shipped kit and on your website(s).
- C. You and authorized distributor(s) will inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product, or the authorized labeling.
- D. Through a process of inventory control, you and authorized distributor(s) will maintain records of the numbers and locations to which your product is distributed.
- E. You and authorized distributor(s) will 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.
- 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.

Clinical Enterprise, Inc. (You)

⁶ “Authorized Distributor(s)” are identified by you, Clinical Enterprise, Inc., in your EUA submission as an entity allowed to distribute your product.

- G. You will notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).
- H. You will notify FDA of any authorized laboratories designated by Clinical Enterprise, Inc. to use your product, including the name, address, and phone number of any authorized laboratories.
- I. You will provide authorized distributor(s) and authorized laboratories with a copy of this EUA and communicate any subsequent revisions that might be made to this EUA and its authorized accompanying materials.
- J. 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.
- K. You will comply with the following requirements under FDA regulations: Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).
- L. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the tests released for distribution have the clinical and analytical performance claimed in the authorized labeling.
- M. If requested by FDA, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.
- N. You will have a process in place to track adverse events associated with your product, including occurrences of false results and report to FDA pursuant to 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUAREporting@fda.hhs.gov).
- O. You will notify FDA of any changes to the COVID-19 questionnaire, the “COVID-19 Viral Test Assessment,” used by a healthcare provider to determine eligibility of an individual to receive the EmpowerDX At-Home COVID-19 PCR Test Kit.
- P. You will submit to FDA a summary report within 30 calendar days of this letter

summarizing the results of any testing performed using nasal specimens collected with the EmpowerDX At-Home COVID-19 PCR Test Kit during that timeframe, including how many kits were requested and sent for home collection to individuals, how many kits were shipped and returned according to the instructions, how many specimens had to be rejected during accession and the main reasons for rejection, and the positivity rate of the first EmpowerDX At-Home COVID-19 PCR Test Kit lot.

Authorized Laboratories

- Q. Authorized laboratories testing nasal swab specimens self-collected using your product must have in place a suitable specimen receipt and accessioning SOP or follow your “Self-Collection Specimen Receipt and Accessioning SOP” standard operating procedure when accepting specimens for testing.
- R. Authorized laboratories using your product will use it only in conjunction with COVID-19 in vitro diagnostic (IVD) molecular tests that are authorized for use with your product.
- S. Authorized laboratories will 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 (MFasolino@clinicalenterprise.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

Clinical Enterprise, Inc. (You), Authorized Distributors and Authorized Laboratories

- T. You, authorized distributors, and authorized laboratories using your product 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

- U. 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.
- V. 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.
- W. All descriptive printed matter, including advertising and promotional materials, relating to the use of your product shall clearly and conspicuously state that:
 - This home-collection kit has not been FDA cleared or approved;

- This home-collection kit has been authorized by FDA under an EUA;
- This home-collection kit has been authorized only for the self-collection and maintenance of nasal swab specimens as an aid in detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- This home-collection kit is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in medical devices during the COVID-19 outbreak 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 medical devices during the COVID-19 outbreak is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure