May 18, 2021

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

Device:	EmpowerDX COVID-19 Home Collection Kit DTC
EUA Number:	EUA202189
Company:	Clinical Enterprise, Inc.
Indication:	A direct to consumer (DTC) product for collecting anterior nasal (nasal) swab specimens at home from individuals age 18 years and older (self-collected), 13 years and older (self-collected under adult supervision), or 3 years and older (collected with adult assistance), that are sent for testing with an in vitro diagnostic (IVD) molecular test that is indicated for use with the EmpowerDX COVID-19 Home Collection Kit DTC for collection of anterior nasal swab specimens, and the IVD is indicated for testing any individuals, including individuals without symptoms or other reasons to suspect COVID-19.
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.

Dear Ms. Lunn,

On October 15, 2020, based on your[1] request the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of the EmpowerDX At-Home COVID-19 PCR Test Kit, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3), 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. Testing was 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

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

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. On December 11, 2020, the EUA Summary was updated to fix an error in the original document. Based on your request, FDA also reissued the letter in its entirety on February 26, 2021.[2]

On December 18, 2020, you requested to further revise your EUA. Based on this request, and having concluded that revising the October 15, 2020, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the October 15, 2020, letter in its entirety with the revisions incorporated.[3] Pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, your product[4] is now authorized for use consistent with the indication described above.

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.[5] 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.[6]

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).

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[2] On February 26, 2021, revisions to the October 15, 2020, letter and authorized labeling included: (1) update the name of the product from EmpowerDX At-Home COVID-19 PCR Test Kit to EmpowerDX COVID-19 Home Collection Kit DTC, (2) update the intended use to add non-prescription direct-to-consumer claims using anterior nasal swab collection by any individuals, including individuals without symptoms or other reasons to suspect COVID-19, (and remove prescription claims), (3) update shelf life stability data and labeling to support the revised intended use, (4) add a Fact Sheet for Individuals and update the instructions for anterior nasal swab collection, and (5) update the conditions of authorization to reflect the revised intended use and language used in more recent letters of authorization.

[3] The revisions to the February 26, 2021, letter and authorized labeling include: (1) updates to the intended use to expand collection of anterior nasal (nasal) swab specimens at home to individuals age 18 years and older (self-collected), 13 years and older (self-collected under adult supervision), or 3 years and older (collected with adult assistance), (2) updates to the EUA Summary to include results of a human usability study in minors, (3) updates to the Fact Sheet for Individuals and the instructions for anterior nasal swab collection to reflect the revised intended use and language used in more recent letters of authorization, and (4) update Condition R as a result of the new intended use.

[4] For ease of reference, this letter will use the term "your product" to refer to the EmpowerDX COVID-19 Home Collection Kit DTC used for the indication identified above.

[5] 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).

[6] 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)

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.[7]

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 direct to consumer (DTC) product for collecting anterior nasal (nasal) swab specimens at home from individuals age 18 years and older (self-collected), 13 years and older (self-collected under adult supervison), or 3 years and older (collected with adult assistance), that are sent for testing with an IVD molecular test that is indicated for use with the EmpowerDX COVID-19 Home Collection Kit DTC for collection of anterior nasal swab specimens, and the IVD is indicated for testing any individuals, including individuals without symptoms or other reasons to suspect COVID-19. Testing is limited to laboratories designated by Clinical Enterprise, Inc. that are certified under CLIA and meet the requirements to perform high complexity tests.

When using your product, individuals must follow all specimen collection and mailing instructions provided with the kit. The EmpowerDX COVID-19 Home Collection Kit DTC includes the following materials or other authorized materials (as may be requested under Condition M. below): Instructions, Fact Sheet for Individuals, Label, Anterior nasal swab, Collection tube, Biohazard bag, Box, Shipping envelope.

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

All test results are delivered to the user via an online portal. Individuals with positive or inconclusive results will be contacted by a healthcare provider.[8] Your product is intended to enable users to access information about their COVID-19 infection status that could aid with determining if self-isolation or quarantine is appropriate and to assist with healthcare decisions after discussion with a healthcare provider.

The EmpowerDX COVID-19 Home Collection Kit DTC is not a substitute for visits to a healthcare provider. The information provided by this kit when combined with an authorized test should not be used to start, stop, or change any course of treatment unless advised by your healthcare provider.

The labeling entitled "EmpowerDX COVID-19 Home Collection Kit DTC – How to perform your nasal swab" patient instructions, "EmpowerDX COVID-19 Home Collection Kit DTC" outer box label, the EUA Summary (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas), the following standard operating procedures (SOPs): "Self-Collection Specimen Receipt and Accessioning SOP EmpowerDX COVID-19 Home Collection Kit DTC," and the following fact sheet 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 Individuals: Clinical Enterprise, Inc. - EmpowerDX COVID-19 Home Collection Kit DTC

The above described product, when accompanied by the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed and used 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 product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product for such use.

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 home-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.

[8] For this EUA, a healthcare provider includes any health professional with prescribing abilities, including, but is not limited to, physicians, nurses, pharmacists, technologists, laboratory directors, and epidemiologists.

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)[9]

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) must make available all instructions related to the self-collection of anterior nasal swab specimens using the EmpowerDX COVID-19 Home Collection Kit DTC and the Fact Sheet for Individuals both in the shipped kit with the authorized outer box label and on your website(s).

C. You and authorized distributor(s) 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, or the authorized labeling.

D. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers and locations to which your product is distributed.

[9] "Authorized Distributor(s)" are identified by you, Clinical Enterprise, Inc., in your EUA submission as an entity allowed to distribute the EmpowerDX COVID-19 Home Collection Kit DTC.

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.

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)

G. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

H. You must 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 must 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 must ensure that the authorized laboratories using your product have a process in place for reporting test results to you, individuals, healthcare providers and relevant public health authorities, as appropriate.

K. You must maintain records of the authorized laboratories and test usage.

L. You must collect information on the performance of your product. You must report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of your product of which you become aware.

M. 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 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.

N. You must comply with the following requirements under FDA regulations: 21 CFR 820 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).

O. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the products released for distribution have the performance claimed in the authorized labeling.

P. 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.

Q. You must have a process in place to track adverse events associated with the EmpowerDX COVID-19 Home Collection Kit DTC, 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).

R. 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 EmpowerDX COVID-19 Home Collection Kit DTC during that timeframe and stratified by age group, including how many kits were requested and sent for home collection to individuals, how many kits were distributed 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 for the EmpowerDX COVID-19 Home Collection Kit DTC. Thereafter, monthly reporting must continue until FDA informs you that the cumulative data submitted within the monthly reports has sufficiently assessed updates made to your collection kit.

S. You must have a process in place for reporting all test results to individuals who use the EmpowerDX COVID-19 Home Collection Kit DTC. This process must include a requirement that all positive and invalid/indeterminate results must be reported to individuals who self-collected specimens using the EmpowerDX COVID-19 Home Collection Kit DTC by a healthcare provider, defined in footnote 8. This process must ensure the Fact Sheet for Individuals relevant to the IVD molecular test used on the specimen is made available to individuals with test results, for example via included weblink.

T. You must have a healthcare provider available to provide information and counseling to individuals using the EmpowerDX COVID-19 Home Collection Kit DTC. You will ensure these healthcare providers have the Fact Sheet for Healthcare Providers that is relevant to the IVD molecular test used on the specimen, for reference.

Authorized Laboratories

U. Authorized laboratories testing specimens self-collected using the EmpowerDX COVID-19 Home Collection Kit DTC must follow your "Self-Collection Specimen Receipt and Accessioning SOP EmpowerDX COVID-19 Home Collection Kit DTC" when accepting specimens for testing.

V. Authorized laboratories using your product will use it only in conjunction with COVID-19 IVD molecular tests that are indicated for use with the EmpowerDX COVID-19 Home Collection Kit DTC.

W. Authorized laboratories 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 (MFasolino@clinicalenterprise.com) any suspected occurrence of false positive or false negative results linked to use of your product and significant deviations from the established performance characteristics of your product of which they become aware.

X. Authorized laboratories using your product must have a process in place for reporting test results to relevant public health authorities, as appropriate. Authorized laboratories using your product must also have a process in place for reporting test results to you via the agreed upon process, as described in the EUA Summary, for your product.

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

Y. You, authorized distributor(s), 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

Z. 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 as set forth in section 502(a), (q)(1), and (r) of the Act and FDA implementing regulations.

AA. 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.

BB. 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 home 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
- The emergency use of this product only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use

of medical devices 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 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,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure