

April 13, 2021

Ernst J. Schaefer, MD
Clinical Enterprise, Inc.
175 Crossing Blvd.
Framingham, MA 01702

Device: Clinical Enterprise SARS-CoV-2 RT-PCR Assay DTC
EUA Number: EUA210023
Company: Clinical Enterprise, Inc.
Indication: The Clinical Enterprise SARS-CoV-2 RT-PCR Assay DTC is a direct-to-consumer product for testing of individual anterior nasal (nasal) swab specimens collected at home using the EmpowerDX COVID-19 Home Collection Kit DTC when used consistent with its authorization, by any individuals including individuals without symptoms or other reasons to suspect COVID-19.

Clinical Enterprise SARS-CoV-2 RT-PCR Assay DTC is limited to authorized laboratories.

Authorized Laboratories: Testing is limited to laboratories designated by Clinical Enterprise, 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 Dr. Schaefer:

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. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of

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 Clinical Enterprise SARS-CoV-2 RT-PCR Assay DTC (CE SARS-CoV-2 RT-PCR Assay DTC) used for the indication identified above.

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

The Clinical Enterprise SARS-CoV-2 RT-PCR Assay DTC is a direct to consumer product for testing of individual anterior nasal swab specimens collected at home using the EmpowerDX COVID-19 Home Collection Kit DTC when used consistent with its authorization, by any individuals including individuals without symptoms or other reasons to suspect COVID-19.

Testing of collected anterior nasal swab specimens is limited to laboratories designated by Clinical Enterprise, Inc., which are certified under CLIA and meet the requirements to perform high-complexity tests.

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.

Results are for the qualitative detection of SARS-CoV-2 RNA. 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 medical history and other diagnostic information is necessary to determine 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. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities. Negative results do not preclude SARS-CoV-2 infection.

Use of your product is not a substitute for visits to a healthcare provider. The information provided by this product should not be used to start, stop, or change any course of treatment unless advised by your healthcare provider.

To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from the anterior nasal swab specimens collected at home using the EmpowerDX COVID-19 Home Collection Kit DTC consistent with its authorization. The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection using an authorized real-time (RT) PCR instrument.

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

- RNase P Specimen Control - RNase P (RP) control in home-collected specimens: The RP primer and probe set is included to test for human RP, to ensure an adequate biological specimen is collected from home-collected specimens.
- MS2 Phage Control: – MS2 added to every clinical specimen and control prior to extraction. Monitors internal lysis, extraction and amplification.
- Negative Extraction Control (NEC) - known negative phosphate buffered saline or TE buffer goes through the entire extraction and RT-PCR process monitors for any carryover or cross-contamination that occurs during the RT-PCR process.
- No Template Control/Negative Amplification Control (NTC) – Rnase/DNase-free water is used to monitor the possibility of sample contamination in the assay run and is used once on every PCR assay plate.
- RT-PCR SARS-CoV-2 amplification control (PC) – two synthetic *in vitro* transcribed RNA SARS-CoV-2 positive amplification controls (low and high) is used to verify that the assay run is performing as intended.
- Positive Extraction Control (PEC) – two pooled positive clinical samples (high and low) included in each extraction and are used to monitor the entire process and test reagents.

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.

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 “Clinical Enterprise SARS-CoV-2 RT-PCR Assay DTC SOP” 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: Clinical Enterprise, Inc. - Clinical Enterprise SARS-CoV-2 RT-PCR Assay DTC
- Fact Sheet for Individuals: Clinical Enterprise, Inc. - Clinical Enterprise SARS-CoV-2 RT-PCR Assay 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 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.

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:

Clinical Enterprise, Inc. (You)

- 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 must make your product available with the authorized labeling to authorized laboratories.
- C. 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.
- D. 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. You must also ensure that authorized laboratories using your product have a process in place for providing test results via the agreed upon process as authorized by the EmpowerDX COVID-19 Home Collection Kit DTC.
- E. You must maintain records of the authorized laboratories to which you distribute your product, and test usage.
- 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 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.
- H. You must make available on your website(s), if applicable, the Fact Sheet for Healthcare Providers and Fact Sheet for Individuals.
- I. You must evaluate the analytical limit of detection and assess traceability of your product with any FDA-recommended reference material(s), if requested by FDA.⁵

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

After submission to and review of and concurrence with the data, FDA will update the EUA Summary to reflect the additional testing.

- J. You must have a process in place to track adverse events, including any occurrence of false results with your product, including with the EmpowerDX COVID-19 Home Collection Kit DTC, 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-EUAREporting@fda.hhs.gov).
- K. 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.
- L. You must submit to FDA a summary report within 30 calendar days of authorization summarizing the results of any testing performed using anterior nasal specimens collected with the EmpowerDX COVID-19 Home Collection Kit DTC used 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.

Authorized Laboratories

- M. Authorized laboratories using your product 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.
- N. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized laboratory procedures, including the authorized instruments, authorized extraction 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. Authorized laboratories when testing anterior nasal swab specimens self-collected using the EmpowerDX COVID-19 Home Collection Kit DTC authorized for use with your product must follow any specimen accessioning protocol provided with the self-collection kit when accepting specimens for testing.
- P. Authorized laboratories must notify the relevant public health authorities of their intent to run your product.
- Q. 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

FDA may request, for example, that you perform this study in the event that we receive reports of adverse events concerning your product.

your product must also have a process in place for reporting test results via the agreed upon process as authorized by the EmpowerDX COVID-19 Home Collection Kit DTC.

- R. 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 (via email: 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 you become aware.
- S. All laboratory personnel using your product must be appropriately trained in molecular techniques and use appropriate laboratory and personal protective equipment when handling this product, and use your product in accordance with the authorized laboratory procedure.

Clinical Enterprise, Inc. (You) and Authorized Laboratories

- T. You 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

- U. 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.
- V. No descriptive printed matter, advertising, and 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, 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 by FDA under an EUA for use by authorized laboratories;
 - 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,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure