



August 23, 2021

Alberto Paniz-Mondolfi, MD, PhD
The Mount Sinai Hospital
Center for Clinical Laboratories
One Gustave L. Levy Place
New York, NY 10029

Device: Mount Sinai SARS-CoV-2 Assay
EUA Number: EUA210383
Company: The Mount Sinai Hospital, Center for Clinical Laboratories

Indication: Qualitative detection of nucleic acid from SARS-CoV-2 in saliva specimens that are collected at home using the Mount Sinai SARS-CoV-2 Collection Kit by any individuals age 18 years and older (self-collected), 14 years and older (self-collected under adult supervision), or 5 years and older (collected with adult assistance), including from 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 the authorized laboratory.

Authorized Laboratory: Testing is limited to the Mount Sinai COVID Laboratory, located at 281 First Avenue, 12th Floor Dazian Building, Room 1201, New York, NY 10003, which is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high complexity tests.

Dear Dr. Paniz-Mondolfi:

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).

¹ For ease of reference, this letter will use the term “you” and related terms to refer to The Mount Sinai Hospital, Center for Clinical Laboratories.

² For ease of reference, this letter will use the term “your product” to refer to the Mount Sinai SARS-CoV-2 Assay used for the indication identified 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. 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

Your product is a qualitative test for the detection of nucleic acid from SARS-CoV-2 in saliva specimens that are collected at home using the Mount Sinai SARS-CoV-2 Collection Kit by any

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.

individuals age 18 years and older (self-collected), 14 years and older (self-collected under adult supervision), or 5 years and older (collected with adult assistance), including from individuals without symptoms or other reasons to suspect COVID-19, when determined to be appropriate by a healthcare provider. Saliva specimens collected at home can be transported at ambient temperature to the laboratory for testing.

Testing is limited to Mount Sinai COVID Laboratory, located at 281 First Avenue, 12th Floor Dazian Building, Room 1201, New York, NY 10003, which is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets 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 saliva 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. 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 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. Negative results for SARS-CoV-2 RNA from saliva should be confirmed by testing of an alternative specimen type if clinically indicated.

The Mount Sinai SARS-CoV-2 Collection Kit includes the following items in the kit distributed on-site: empty sterile specimen container, biohazard specimen bag, funnel and instructions for use. The Mount Sinai SARS-CoV-2 Collection Kit will be distributed to users at an on-site location managed by Mount Sinai's logistics partner. Users will take the Mount Sinai SARS-CoV-2 Collection Kit home for registration and specimen collection. Collected specimens will be returned to an on-site dropbox within 36 hours of collection.

To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from saliva. 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 Mount Sinai SARS-CoV-2 Assay 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 O. below), that are to be run as outlined in the 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 laboratory procedures submitted as part of the EUA request:

- nCoV Internal Control - bacteriophage MS2 added clinical samples and controls for

- specimen quality and demonstrates that nucleic acid was generated by the extraction process.
- nCoV Positive Control - SARS-CoV-2 RNA fragments capsulated in bacteriophage. The positive control is used to monitor for failures of rRT-PCR reagents and reaction conditions.
 - nCoV Negative Control - buffer used to monitor non-specific amplification, crosscontamination during experimental setup, and nucleic acid contamination of reagents.

The above described product is authorized to be accompanied by the labeling listed below, and as described in 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>), and the following fact sheets pertaining to the emergency use, which are required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: The Mount Sinai Hospital, Center for Clinical Laboratories - Mount Sinai SARS-CoV-2 Assay
- Fact Sheet for Patients: The Mount Sinai Hospital, Center for Clinical Laboratories - Mount Sinai SARS-CoV-2 Assay

The above described product, when accompanied by the “Mount Sinai SARS-CoV-2 Assay” standard operating procedure, the EUA Summary, 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 Mount Sinai SARS-CoV-2 Collection Kit with the “Mount Sinai SARS-CoV-2 Collection Kit Instructions” is authorized to be distributed and used as part of the above described product as set forth in this EUA.

“Authorized labeling” refers to the EUA Summary, the “Mount Sinai SARS-CoV-2 Assay” standard operating procedure, the two Fact Sheets, and the “Mount Sinai SARS-CoV-2 Collection Kit Instructions.”

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:

The Mount Sinai Hospital Center for Clinical Laboratories (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 on your website(s), if applicable, the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients.
- C. You and authorized distributor(s) must make available all instructions related to the collection of saliva specimens using the Mount Sinai SARS-CoV-2 Collection Kit, both in the distributed kit and on your website.
- D. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers and locations to which the Mount Sinai SARS-CoV-2 Collection Kit is distributed.

⁵ “Authorized Distributor(s)” are identified by you, The Mount Sinai Hospital Center for Clinical Laboratories, in your EUA submission as an entity allowed to distribute the Mount Sinai SARS-CoV-2 Collection Kit.

- E. You and authorized distributor(s) must maintain customer complaint files concerning the Mount Sinai SARS-CoV-2 Collection Kit 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.
- 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.
- G. 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 will be made available to FDA for inspection upon request.

The Mount Sinai Hospital Center for Clinical Laboratories (You)

- H. You must notify FDA of any authorized distributor(s) of the Mount Sinai SARS-CoV-2 Collection Kit, including the name, address, and phone number of any authorized distributor(s).
- I. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials.
- J. You 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.
- 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 procedures, 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. When testing specimens using your product, you must have in place a suitable specimen receipt and accessioning SOP.
- O. 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.

- P. 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.⁶ After submission to and concurrence with the data by FDA, DMD/OHT7-OIR/OPEQ/CDRH will update the EUA Summary to reflect the additional testing.
- 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 Mount Sinai SARS-CoV-2 Collection Kit 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 collection kit.
- R. You must have a process in place to track adverse events, including any occurrence of false results with your product, including the Mount Sinai SARS-CoV-2 Collection Kit, and report to FDA in accordance with 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to DMD/OHT7- OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).
- S. You 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) 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.
- T. 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 your product in accordance with the authorized labeling.
- U. You must evaluate the impact of SARS-CoV-2 viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected

⁶ Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material. FDA may request, for example, that you perform this study in the event that we receive reports of adverse events concerning your product.

performance of your device, you must notify FDA immediately.

- V. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA, such as those related to the impact of viral mutations on test performance. Such 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, as applicable, 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 product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by the authorized laboratory;
 - 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