



January 20, 2022

Stewart Holt, Ph.D.
Technical Director
Premier Medical, Inc.
dba Premier Medical Laboratory Services
6000A Pelham Road
Greenville, SC 29615

Device:	PMLS SARS-CoV-2 Assay
EUA Number:	EUA210247
Laboratory:	Premier Medical Laboratory Services
Indication:	<p>This test is authorized for the following indications for use:</p> <p>Qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal swab specimens that are collected at home using the DoINeedaCOVID19Test.com Self-Collection Kit by any individual, 18 years or older (self-collected), 14 years and older (self-collected under adult supervision) or 2 years and older (collected with adult assistance), including individuals without symptoms or other reasons to suspect COVID-19, when determined to be appropriate by a healthcare provider.</p> <p>Qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal swab specimens that are collected using the RapidRona Self-Collection Kit when used consistent with its authorization.</p>
Authorized Laboratory:	Testing is limited to Premier Medical Laboratory Services, 6000A-1 Pelham Rd, Greenville, SC 29615, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263, and meets the requirements to perform high-complexity tests.

Dear Dr. Holt:

On January 7, 2022, based on your¹ request the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of the PMLS SARS-CoV-2 Assay,

¹ For ease of reference, this letter will use the term “you” and related terms to refer to Premier Medical, Inc. dba Premier Medical Laboratory Services.

pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) for the indication stated in the letter.²

On January 12, 2022, you requested to amend your EUA. Based on that request, and having concluded that revising the January 7, 2022, 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 January 7, 2022, 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 product⁴ 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. 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.⁵

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

² The January 7, 2022, letter authorized the PMLS SARS-CoV-2 Assay for the qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal swab specimens that are collected at home using the INeedaCOVID19Test.com Self Collection Kit by any individual, 18 years or older (self-collected), 14 years and older (self-collected under adult supervision) or 2 years and older (collected with adult assistance), including individuals without symptoms or other reasons to suspect COVID-19, when determined to be appropriate by a healthcare provider. Testing was limited to Premier Medical Laboratory Services, 6000A-1 Pelham Rd, Greenville, SC 29615, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263, and meets the requirements to perform high-complexity tests.

³ The revisions to the January 7, 2022, letter and authorized labeling include: (1) update the name of the INeedaCOVID19Test.com Self Collection Kit to the DoINeedaCOVID19Test.com Self-Collection Kit, (2) update the intended use and authorized labeling to include use of the test with anterior nasal swab specimens that are collected using the RapidRona Self-Collection Kit when used consistent with its authorization, (3) updates to the Conditions of Authorization O. and V. to include reference to the RapidRona Self-Collection Kit, and (4) updates to the Fact Sheet for Healthcare Providers to reflect the updated intended use and update the date on both Fact Sheets to match the date of reissuance.

⁴ For ease of reference, this letter will use the term “your product” to refer to the PMLS SARS-CoV-2 Assay 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).

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.⁶

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 anterior nasal swabs specimens that are collected at home using the DoINeedA COVID19 Test.com Self-Collection Kit by any individual, 18 years or older (self-collected), 14 years and older (self-collected under adult supervision) or 2 years and older (collected with adult assistance), including individuals without symptoms or other reasons to suspect COVID-19, when determined to be appropriate by a healthcare provider.

This test is also for use with anterior nasal swab specimens that are collected using the RapidRona Self-Collection Kit when used consistent with its authorization.

Testing is limited to Premier Medical Laboratory Services, 6000A-1 Pelham Rd, Greenville, SC 29615, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263, and meets the requirements to perform high-complexity tests.

The SARS-CoV-2 nucleic acid 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 nucleic acid; 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. 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

⁶ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

followed by PCR amplification and detection using an authorized real-time (RT) PCR instrument described in the authorized labeling (described below).

The product uses all commercially sourced materials or other authorized materials and authorized ancillary reagents commonly used in clinical laboratories as described in the authorized labeling.

The DoIneedaCOVID19Test.com Self-Collection Kit consists of materials required to collect, store and maintain the anterior nasal swab specimen, as described in the “DoIneedaCOVID19Test.com Self-Collection Kit Instructions for Use.”

Your product requires control materials, or other authorized control materials (as specified under Condition M. below), specified in the EUA Summary.

The above described product, is authorized to be accompanied with the laboratory procedures bundle,⁷ 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: Premier Medical Laboratory Services - PMLS SARS-CoV-2 Assay
- Fact Sheet for Patients: Premier Medical Laboratory Services - PMLS SARS-CoV-2 Assay

The above described product, when accompanied by the laboratory procedures bundle, EUA Summary, and the two Fact Sheets is authorized to be used by the Premier Medical Laboratory Services authorized laboratory under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

The DoIneedaCOVID19TEST.com Self-Collection Kit with the “DoIneedaCOVID19Test.com Self-Collection Kit Instructions for Use” 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 laboratory procedures bundle, EUA Summary, “DoIneedaCOVID19Test.com Self-Collection Kit Instructions for Use,” and the two fact sheets.

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

⁷ The laboratory procedures bundle includes the “Accessioning – Specimens Collected with DoIneedaCOVID19TEST.com Self-Collection Kit and RapidRona Self-Collection Kit” Standard Operating Procedure (SOP), the “COVID-19 Extraction for SARS-CoV-2 NA by Mag-Bind Viral DNA/RNA Kit on Hamilton Star/Starlet” SOP, and the “PMLS SARS-CoV-2 Assay on the Quant12K flex using IDT real time PCR reagents” SOP.

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 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:

Premier Medical Laboratory Services (You) and Authorized Distributor(s)⁸

- 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, Fact Sheet for Patients, and all instructions related to the collection of anterior nasal swab specimens for the

⁸ “Authorized Distributor(s)” are identified by you, Premier Medical Laboratory Services, in your EUA submission as an entity allowed to distribute the DoINeedaCOVID19TEST.com Self-Collection Kit.

DoINeedaCOVID19TEST.com Self-Collection Kit.

- C. You and authorized distributor(s) must make available all instructions related to the self-collection of anterior nasal swab specimens using the DoINeedaCOVID19TEST.com Self-Collection Kit in the shipped kit.
- D. You and authorized distributor(s) 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.
- E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers and locations to which the DoINeedaCOVID19TEST.com Self-Collection Kit is distributed.
- F. You and authorized distributor(s) must maintain customer complaint files 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.
- G. 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.
- H. You and authorized distributor(s) 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.

Premier Medical Laboratory Services (You)

- I. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).
- J. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that your product released for distribution has the clinical and analytical performance claimed in the authorized labeling.
- K. 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 them within 48 hours of the request.
- L. You must comply with the following requirements pursuant to 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).

- 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, 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.
- N. You must evaluate the analytical limit of detection and assess traceability⁹ 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.
- O. You must have a process in place to track adverse events, including any occurrence of false results with your product, including with the DoINeedaCOVID19TEST.com Self-Collection Kit and the RapidRona Self-Collection Kit and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) 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-EUA-Reporting@fda.hhs.gov).
- P. You must provide a summary report of the results obtained from the first 1000 anterior nasal swab specimens that are collected with the DoINeedaCOVID19Test.com Self-Collection Kit and tested using the PMLS SARS-CoV-2 Assay. The report will include analysis of positivity rate for each target analyte (including Ct values), as well as the failure rate for the RNase P endogenous control. You will also provide a summary of calls to eTrueNorth customer service and any complaints received regarding either the DoINeedaCOVID19Test.com Self-Collection Kit or test results obtained with the PMLS SARS-CoV-2 Assay.
- Q. 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 performance of your device, you must notify FDA immediately (via email: CDRH-EUA-Reporting@fda.hhs.gov).
- R. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA regarding the impact of viral

⁹ Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

- S. 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 product and use your product in accordance with the authorized laboratory procedure.
- T. 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.
- U. 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.
- V. When testing specimens collected using the DoINeedaCOVID19TEST.com Self-Collection Kit or the RapidRona Self-Collection Kit you must follow the “Accessioning – Specimens Collected with DoINeedaCOVID19TEST.com Self-Collection Kit and RapidRona Self-Collection Kit” standard operating procedure when accepting specimens for testing.
- W. You must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- X. You must collect information on the performance of your product. You will report to DMD/OHT7-OIR/OPEQ/CDRH 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.

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, as applicable, 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 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,

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Enclosure