



March 18, 2022

Eveline Arnold
Director, Regulatory Affairs
Tempus Labs, Inc.
600 W Chicago Ave, Ste 510
Chicago, IL 60654

Device: iC SARS-CoV-2 Test

EUA Number: EUA201695

Laboratory: Tempus Labs, Inc.

Indication: Qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal (NP), anterior nares (AN or anterior nasal), mid-turbinate nasal, and oropharyngeal (OP) swab specimens collected from individuals suspected of COVID-19 by their healthcare provider.

This test is also for use with AN swab specimens that are self-collected unsupervised at home by individuals 18 years of age or older using the Tempus Nasal Sample Collection Kit, when determined to be appropriate by their healthcare provider.

Emergency use of this test is limited to the authorized laboratory.

Authorized Laboratories: Testing is limited to laboratories designated by Tempus Labs, Inc. which 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 Eveline Arnold:

On October 1, 2020, based on your¹ request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the iC SARS-CoV2 Test, 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 Subsequently, on March 22, 2021 FDA reissued the letter in its entirety

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

² The October 1, 2020, letter authorized the iC SARS-CoV2 Test for the qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory tract specimens (including nasopharyngeal (NP), anterior nares (AN or nasal), mid-turbinate nasal, and oropharyngeal (OP) swab specimens) collected from individuals suspected of COVID-19 by their healthcare provider. Testing was limited to Tempus Labs, Inc.’s laboratories located at 600 W Chicago Ave, Ste 510, Chicago, IL 60654 and 3155 Northwoods Place, Peachtree Corners, GA 30071, which are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests.

with revisions incorporated.³ In addition, FDA established additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2 on September 23, 2021.⁴

On December 21, 2021, and December 30, 2021, you requested to amend your Emergency Use Authorization (EUA). Based on those requests and having concluded that revising the March 22, 2021, 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 March 22, 2021, letter in its entirety with the revisions incorporated.⁵ 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 product⁶ is now intended for 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.⁷

³ On March 22, 2021, the revisions to the October 1, 2020, letter and authorized labeling included: (1) addition of the claim for use with AN swab specimens that are self-collected unsupervised at home by individuals 18 years of age or older using the Tempus Nasal Sample Collection Kit, when determined to be appropriate by their healthcare provider, (2) addition of RNase P Assay for testing self-collected anterior nares specimens, (3) removal of the Tempus Labs, Inc. location at 3155 Northwoods Place, Peachtree Corners, GA 30071 as an authorized laboratory, (4) addition of winter specimen shipping/stability study data, (5) removal of Condition L. (from the October 1, 2020, letter) which was fulfilled, (6) update of the healthcare provider fact sheet, (7) addition of conditions of authorization specific to the home collection kit, and (8) addition of limitations, including a statement regarding performance with circulating variants. A technical correction was issued March 24, 2021, to correct errors in the letter and EUA Summary.

⁴ The Viral Mutation Revision Letter – September 23, 2021, can be accessed at:

<https://www.fda.gov/media/152406/download>.

⁵ The revisions to the March 22, 2021, letter and authorized labeling include: (1) updating the intended use to authorize testing at “laboratories designated by Tempus Labs, Inc. which are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests”, (2) updating the Fact Sheet for Patients and Fact Sheet for Healthcare Providers to reflect the updates to the intended use and/or reflect language used in more recent authorizations, (3) updates to the letter of authorization that reflect the updated intended use, including the addition of authorized laboratories section under the Conditions of Authorization, and to reflect language used in more recent authorizations, (4) incorporation of language to address Condition of Authorization (1) from the Viral Mutation Revision Letter – September 23, 2021 into the authorized labeling, (5) incorporation of Conditions of Authorization (2) and (3) from the Viral Mutation Revision Letter – September 23, 2021 (Conditions O. and P. below), and (6) updates to Condition of Authorization N. (below) to reflect the agreed upon study with FDA.

⁶ For ease of reference, this letter will use the term “your product” to refer to the iC SARS-CoV-2 Test used for the indication identified above.

⁷ 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).

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.⁸

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 NP, AN, mid-turbinate nasal, and OP swab specimens collected from individuals suspected of COVID-19 by their healthcare provider. Your product is also for use with AN swab specimens that are self-collected unsupervised at home by individuals 18 years of age or older using the Tempus Nasal Sample Collection Kit, when determined to be appropriate by their healthcare provider.

Testing is limited to laboratories designated by Tempus Labs, Inc. which are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests.

SARS-CoV-2 RNA is generally detectable in upper respiratory 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

⁸ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The Tempus Nasal Sample Collection Kit consists of materials (or other authorized materials as maybe requested under Condition L. below) required to collect, store and maintain the AN swab specimen, as described in the “The Tempus Nasal Sample Collection Kit” collection instructions. When using the Tempus Nasal Sample Collection Kit, patients should follow all specimen collection and mailing instructions provided in the kit.

To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from the specimens. The purified nucleic acid is then reverse transcribed into cDNA 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.

Your product requires the use of control materials, or other authorized control materials (as may be requested under Condition L. below), that are processed in the same way as the patient samples that must generate expected results in order for a test to be considered valid, as outlined in the authorized labeling (described below). 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 (described below).

The above described product is authorized to be accompanied by 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>), as well as the “Tempus Labs, Inc iC SARS-CoV-2 Test Laboratory Standard Operating Procedures (SOP)” and the following fact sheets pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Tempus Labs, Inc. – iC SARS-CoV-2 Test
- Fact Sheet for Patients: Tempus Labs, Inc. – iC SARS-CoV-2 Test

The above described product, when accompanied by the EUA Summary, “Tempus Labs, Inc iC SARS-CoV-2 Test Laboratory Standard Operating Procedures (SOP),” and the two Fact Sheets is authorized to be distributed and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

The Tempus Nasal Sample Collection Kit, with the “The Tempus Nasal Sample Collection Kit” collection 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 Tempus Nasal Sample Collection Kit” collection instructions, EUA Summary, “Tempus Labs, Inc iC SARS-CoV-2 Test Laboratory Standard Operating Procedures (SOP),” 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 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, distribution and storage of your product.

IV. Conditions of Authorization

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

Tempus Labs, 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).

⁹ “Authorized Distributor(s)” are identified by you, Tempus Labs, Inc., in your EUA submission as an entity allowed to distribute the Tempus Nasal Sample Collection Kit.

- 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 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 and authorized distributor(s) must make available all instructions related to the self-collection of anterior nares swab specimens using the Tempus Nasal Sample Collection Kit, both in the shipped kit and on your website.
- E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers and locations to which the Tempus Nasal Sample 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.

Tempus Labs, Inc. (You)

- H. You must notify FDA of any authorized distributor(s) of the Tempus Nasal Sample Collection Kit, including the name, address, and phone number of any authorized distributor(s).
- I. You must maintain records of the laboratories you designate as authorized laboratories and you must also maintain records of test usage by all such authorized laboratories.
- J. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any authorized revisions that might be made to this EUA and its authorized accompanying materials.
- K. You must ensure that the authorized laboratories using your product have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- L. 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.

- M. 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.¹⁰ After submission to and concurrence by FDA, DMD/OHT7-OIR/OPEQ/CDRH will update the EUA summary to reflect the additional testing.
- N. You must submit to FDA a summary report summarizing the results of any testing performed using the agreed upon number of specimens collected with the Tempus Nasal Sample Collection Kit for use with your product, 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.
- O. 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).
- P. 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 mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- Q. You must have a process in place to track adverse events, including any occurrence of false results with your product, including with the Tempus Nasal Sample Collection Kit, and report any such events 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-EUA-Reporting@fda.hhs.gov).

Authorized Laboratories

- R. Authorized laboratories using your product 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.

¹⁰ 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.

- S. Authorized laboratories using your product 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/or authorized materials required to use your product are not permitted.
- T. When testing authorized specimens self-collected using the Tempus Nasal Sample Collection Kit with your product, authorized laboratories must follow any specimens accessioning protocols provided with the collection kit when accepting specimens for testing.
- U. Authorized laboratories using your product must notify the relevant public health authorities of your intent to run your product.
- V. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- W. 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 (eveline.arnold@tempus.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.
- X. 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.

Tempus Labs, Inc. (You), Authorized Distributor(s) and Authorized Laboratories

- Y. You, authorized distributor(s), and authorized laboratories 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.

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 set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, 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 for use by the 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,

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

Enclosure