



December 22, 2021

W. Justin Lawson, MS
Director of Laboratory Operations
Tide Laboratories, LLC
913 Airport Road W.
Fort Payne, AL 35968

Device: DTPM COVID-19 RT-PCR Test

EUA Number: EUA200086

Company: Tide Laboratories, LLC

Indication: Qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swabs, oropharyngeal swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasal aspirates, and nasal washes collected from individuals suspected of COVID-19 by their healthcare provider.

Emergency use of this test is limited to authorized laboratories.

Authorized Laboratories: Laboratories designated by Tide Laboratories, LLC, including Tide Laboratories, LLC, located at 913 Airport Rd., Fort Payne, AL 35968, that are also certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a and meet the requirements to perform high-complexity tests.

Dear Mr. Lawson:

On June 10, 2020, based on your¹ request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the DTPM COVID-19 RT-PCR Test for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swabs, oropharyngeal swabs, nasal swabs, and mid-turbinate swab specimens collected from individuals suspected of COVID-19 by their healthcare provider, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). Testing was limited to Tide Laboratories, LLC or other laboratories designated by Tide Laboratories that are also certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests. FDA established additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2 on September 23, 2021.²

¹ For ease of reference, this letter will use the term “you” and related terms to refer to Tide Laboratories, LLC.

² The Viral Mutation Revision Letter – September 23, 2021, can be accessed at:
<https://www.fda.gov/media/152406/download>.

On August 14, 2020, March 3, 2021, and in response to FDA’s request on November 29, 2021, you requested to amend your Emergency Use Authorization (EUA). Based on that request, and having concluded that revising the June 10, 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 June 10, 2020, letter in its entirety with the revisions incorporated.³ Accordingly, your product⁴ is hereby authorized pursuant to section 564 of the Act when used pursuant to the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter.

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

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:

³ The revisions to the June 10, 2020 letter and authorized labeling include: (1) update the intended use to include nasal aspirates and nasal washes as authorized specimen types, and specify “nasal” as anterior nasal, (2) modification of the assay to include multiplex detection of SARS-CoV-2 and the internal control in a single well, (3) addition of an additional extraction method, (4) addition of a reverse primer to detect the Omicron variant, (5) consolidation of Conditions of Authorization J to P of the June 10, 2020, letter into Condition F (below), addition of new Conditions of Authorization related to post-authorization testing for the Omicron variant (Conditions I and J below) and addition of Conditions of Authorization (2) and (3) from the Viral Mutation Revision Letter – September 23, 2021 (Conditions K and L below), and (6) update the intended use, the “DTPM COVID-19 RT-PCR Test Determination of SARS-CoV-2 RNA (COVID-19) using Real Time Polymerase Chain Reaction (RT-PCR)” Policies and Procedures, the Fact Sheets for Healthcare Providers and Patients and the Letter of Authorization to reflect language used in more recent authorizations.

⁴ For ease of reference, this letter will use the term “your product” to refer to the DTPM COVID-19 RT-PCR Test 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).

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 nasopharyngeal swabs, oropharyngeal swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasal aspirates, and nasal washes collected from individuals suspected of COVID-19 by their healthcare provider.

Testing is limited to laboratories designated by the Tide Laboratories, LLC, including Tide Laboratories, LLC, 913 Airport Rd., Fort Payne, AL 35968, that are also certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a and meet the requirements to perform high-complexity tests.

The SARS-CoV-2 nucleic acid is generally detectable in 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 sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

To perform the DTPM COVID-19 RT-PCR Test, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from authorized specimens. The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection with the DTPM COVID-19 RT-PCR Test 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 F below), that are processed in the same way as the patient samples and are required to be included with each batch of specimens tested with your product. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the authorized labeling:

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

- Positive Control – contains nucleic acid sequences that correspond to genomic regions targeted by the kit. The positive control is used to monitor for failures of rRT-PCR reagents and reaction conditions.
- Endogenous Extraction Control – the primer and probe set is included in each run to test for the presence of a human ribosomal gene, which controls for specimen quality, demonstrates that nucleic acid was generated by the extraction process and monitors for failures in the reaction conditions.
- No Template Control (NTC) - Nuclease-free, molecular-grade water used to monitor non-specific amplification, cross-contamination during experimental setup, and nucleic acid contamination of 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 above described product, is authorized to be accompanied with laboratory procedures (described below) and 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 “DTPM COVID-19 RT-PCR Test Determination of SARS-CoV-2 RNA (COVID-19) using Real Time Polymerase Chain Reaction (RT-PCR)” Policies and Procedures 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: Tide Laboratories, LLC - DTPM COVID-19 RT-PCR Test
- Fact Sheet for Patients: Tide Laboratories, LLC - DTPM COVID-19 RT-PCR Test

The above described product, when accompanied by the EUA Summary, the “DTPM COVID-19 RT-PCR Test Determination of SARS-CoV-2 RNA (COVID-19) using Real Time Polymerase Chain Reaction (RT-PCR)” Policies and Procedures and the two Fact Sheets (collectively referenced as “authorized labeling”), 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 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:

Tide Laboratories, LLC (You)

- 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 must make available on your website(s), if applicable, the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients.
- C. 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.
- D. You must collect information on the performance of your product. You will report to 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) 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.
- E. 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.

- F. 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 DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.
- G. You must evaluate the analytical limit of detection and assess traceability⁷ 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.
- H. You must have a process in place to track adverse events, including any occurrence of false results with your product and report to FDA pursuant to 21 CFR Part 803.
- I. You must provide results of analytical test performance comparing material representing Delta and Omicron specific sequences within 10 days of authorization using materials and methods requiring concurrence of DMD/OHT7-OIR/OPEQ/CDRH. After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- J. You must further evaluate test performance using inactivated virus and/or clinical samples sequence confirmed to be SARS-CoV-2 Omicron variant within one month of authorization using methods requiring concurrence of DMD/OHT7-OIR/OPEQ/CDRH. After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- K. 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).
- L. 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.

⁷ Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

Authorized Laboratories

- M. 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.
- N. 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 authorized materials required to use your product are not permitted.
- O. Authorized laboratories using your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- P. 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.
- Q. 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 (help@tidelaboratories.com; (256) 445-5000) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
- R. 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.

Tide Laboratories, LLC (You), and Authorized Laboratories

- S. You 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

- T. All descriptive printed matter, including 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.
- U. No descriptive printed matter, including 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.

V. All descriptive printed matter, including 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 authorized laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high complexity tests;
- 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