



June 10, 2020

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

Company: Tide Laboratories, LLC

Indication: 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.

Emergency use of this test is limited to authorized laboratories.

Authorized Laboratories: Testing is 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.

Dear Mr. Lawson:

This letter is in response to Tide Laboratories, LLC's ("Tide Laboratories") request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the DTPM COVID-19 RT-PCR Test 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 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.<sup>1</sup>

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<sup>1</sup> 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*

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 the DTPM COVID-19 RT-PCR Test, (as described in the Scope of Authorization of this letter (Section II)), in individuals suspected of COVID-19 by their healthcare provider for the detection of SARS-CoV-2 by authorized laboratories, subject to the terms of this authorization.

## **I. Criteria for Issuance of Authorization**

I have concluded that the emergency use of the DTPM COVID-19 RT-PCR Test for testing individuals suspected of COVID-19 by their healthcare provider 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 the DTPM COVID-19 RT-PCR Test may be effective in diagnosing COVID-19, and that the known and potential benefits of the DTPM COVID-19 RT-PCR Test, when used for diagnosing COVID-19, outweigh the known and potential risks of such product; and
3. There is no adequate, approved, and available alternative to the emergency use of the DTPM COVID-19 RT-PCR Test for diagnosing COVID-19.<sup>2</sup>

## **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 use of the authorized DTPM COVID-19 RT-PCR Test by authorized laboratories for the qualitative detection of 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.

### **The Authorized DTPM COVID-19 RT-PCR Test**

The Tide Laboratories DTPM COVID-19 RT-PCR Test is a qualitative test for the detection of nucleic acid from the 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.

Testing is limited to Tide Laboratories or other laboratories designated by Tide Laboratories that are also certified under CLIA 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

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*Cosmetic Act, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 7, 2020).*

<sup>2</sup> No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses.

To perform the Tide Laboratories DTPM COVID-19 RT-PCR Test, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from nasopharyngeal swabs, oropharyngeal swabs, nasal swabs and mid-turbinate swab 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 the ThermoFisher QuantStudio 5 authorized real-time (RT) PCR instrument or other authorized instruments and software. The DTPM COVID-19 RT-PCR Test includes the following materials or other authorized materials: extraction reagents, master mix, PCR plates, molecular biology water, DTPM COVID-19 Forward and Reverse Primers, DTPM COVID-19 Probe, Endogenous Control Forward and Reverse Primers, Endogenous Control Probe, DTPM COVID-19 Positive Control and Endogenous Positive Control.

This DTPM COVID-19 RT-PCR Test requires the following control materials, or other authorized control materials, that are processed in the same way as the specimens and are required to be included with each batch of specimens tested with DTPM COVID-19 RT-PCR Test. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the “Tide Labs Laboratory Protocol for Determination of SARS-CoV-2 (COVID-19) Using Real-Time Polymerase Chain Reaction (RT-PCR).”

- 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 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 (Negative) Control - Nuclease-free, molecular-grade water used to monitor non-specific amplification, cross-contamination during experimental setup, and nucleic acid contamination of reagents.

The DTPM COVID-19 RT-PCR Test also requires the use of additional authorized materials and authorized ancillary reagents that are not included with the DTPM COVID-19 RT-PCR Test and are described in the “Tide Labs Laboratory Protocol for Determination of SARS-CoV-2 (COVID-19) Using Real-Time Polymerase Chain Reaction (RT-PCR).”

The DTPM COVID-19 RT-PCR Test described above is authorized to be accompanied with the labeling entitled “Tide Labs Laboratory Protocol for Determination of SARS-CoV-2 (COVID-19) Using Real-Time Polymerase Chain Reaction (RT-PCR),” and as described in the “EUA Summary” (available at <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>) and the following product-specific information pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: DTPM COVID-19 RT-PCR Test
- Fact Sheet for Patients: DTPM COVID-19 RT-PCR Test

The above described product, when accompanied by the “Tide Labs Laboratory Protocol for Determination of SARS-CoV-2 (COVID-19) Using Real-Time Polymerase Chain Reaction (RT-PCR),” “EUA Summary,” and the two Fact Sheets (collectively referenced as “authorized labeling”) is authorized to be used by Tide Laboratories or other laboratories designated by Tide Laboratories, 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 the authorized DTPM COVID-19 RT-PCR Test, when used as described within and used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such a 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 the DTPM COVID-19 RT-PCR Test may be effective in diagnosing COVID-19, when used consistently 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 I above, and concludes that the DTPM COVID-19 RT-PCR Test, when used for qualitative detection of the SARS-CoV-2 in the specified population (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 the DTPM COVID-19 RT-PCR Test 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) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), the DTPM COVID-19 RT-PCR Test described above is authorized to detect SARS-CoV-2 in individuals suspected of COVID-19 by their healthcare provider.

### **III. Waiver of Certain Requirements**

I am waiving the following requirements for the DTPM COVID-19 RT-PCR Test 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 the DTPM COVID-19 RT-PCR Test.

### **IV. Conditions of Authorization**

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

**Tide Laboratories, LLC**

- A. The DTPM COVID-19 RT-PCR Test 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. Tide Laboratories will make available the authorized DTPM COVID-19 RT-PCR Test with the authorized labeling to authorized laboratories.
- C. Tide Laboratories may request changes to the authorized labeling. Such requests will be made by Tide Laboratories in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- D. Tide Laboratories will make available on their website(s) the authorized Fact Sheet for Healthcare Providers and the Fact Sheet for Patients.
- E. Tide Laboratories will inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to the DTPM COVID-19 RT-PCR Test, authorized labeling, including authorized Fact Sheets.
- F. Tide Laboratories will ensure that the authorized laboratories using the authorized DTPM COVID-19 RT-PCR Test have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- G. Tide Laboratories will maintain records of the authorized laboratories to which they distribute the test and number of tests they distribute.
- H. Tide Laboratories will collect information on the performance of the test. Tide Laboratories will report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the test of which Tide Laboratories become aware.
- I. Tide Laboratories is authorized to make available additional information relating to the emergency use of the DTPM COVID-19 RT-PCR Test that is consistent with, and does not exceed, the terms of this letter of authorization.
- J. Tide Laboratories may request changes to the Scope of Authorization (Section II in this letter) of the authorized DTPM COVID-19 RT-PCR Test. Such requests will be made by Tide Laboratories in consultation with DMD/OHT7-OIR/OPEQ/CDRH, and require concurrence of, Office of Counterterrorism and Emerging Threats (OCET)/Office of the

Chief Scientist (OCS)/Office of the Commissioner (OC) and DMD/OHT7-OIR/OPEQ/CDRH.

- K. Tide Laboratories may request the addition of other instruments and associated software for use with the authorized DTPM COVID-19 RT-PCR Test. Such requests will be made by Tide Laboratories in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- L. Tide Laboratories may request the addition of other extraction methods for use with the DTPM COVID-19 RT-PCR Test. Such requests will be made by Tide Laboratories in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- M. Tide Laboratories may request the addition of other specimen types for use with the DTPM COVID-19 RT-PCR Test. Such requests will be made by Tide Laboratories in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- N. Tide Laboratories may request the addition and/or substitution of primers or probes for use with the authorized DTPM COVID-19 RT-PCR Test. Such requests will be made by Tide Laboratories in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- O. Tide Laboratories may request the addition and/or substitution of control materials for use with the authorized DTPM COVID-19 RT-PCR Test. Such requests will be made by Tide Laboratories in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- P. Tide Laboratories may request the addition and/or substitution of other ancillary reagents and materials for use with the authorized DTPM COVID-19 RT-PCR Test. Such requests will be made by Tide Laboratories in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- Q. Tide Laboratories will evaluate the analytical limit of detection and assess traceability<sup>3</sup> of this DTPM COVID-19 RT-PCR Test with any FDA-recommended reference material(s). After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence with the data, Tide Laboratories will update its labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- R. Tide Laboratories will track adverse events, including any occurrence of false results and report to FDA under 21 CFR Part 803.

### **Authorized Laboratories**

- S. Authorized laboratories using the DTPM COVID-19 RT-PCR Test will include with test result reports of the DTPM COVID-19 RT-PCR Test, all authorized Fact Sheets. Under

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<sup>3</sup> Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

- T. Authorized laboratories using the DTPM COVID-19 RT-PCR Test will perform the DTPM COVID-19 RT-PCR Test 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 perform the DTPM COVID-19 RT-PCR Test are not permitted.
- U. Authorized laboratories using the DTPM COVID-19 RT-PCR Test must notify the relevant public health authorities of their intent to run the DTPM COVID-19 RT-PCR Test prior to initiating testing.
- V. Authorized laboratories using the DTPM COVID-19 RT-PCR Test will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- W. Authorized laboratories will collect information on the performance of the test and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: [CDRH-EUA-Reporting@fda.hhs.gov](mailto:CDRH-EUA-Reporting@fda.hhs.gov)) and Tide Laboratories ([justinl@dtpm.com](mailto:justinl@dtpm.com)) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which they become aware.
- X. All laboratory personnel using the test must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this test, and use the test in accordance with the authorized labeling.

#### **Tide Laboratories and Authorized Laboratories**

- Y. Tide Laboratories and authorized laboratories using the DTPM COVID-19 RT-PCR Test 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**

- Z. All descriptive printed matter, including advertising and promotional materials, relating to the use of Tide Laboratories' authorized DTPM COVID-19 RT-PCR Test shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.
- AA. No descriptive printed matter, including advertising or promotional materials, relating to the use of the DTPM COVID-19 RT-PCR Test may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.
- BB. All descriptive printed matter, including advertising and promotional materials,

relating to the use of the DTPM COVID-19 RT-PCR Test shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- This test 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

The emergency use of Tide Laboratories' authorized DTPM COVID-19 RT-PCR Test 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,

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RADM Denise M. Hinton  
Chief Scientist  
Food and Drug Administration

Enclosures