STATE OF MAINE DEPARTMENT OF HEALTH AND HUMAN SERVICES STANDING ORDER FOR COVID-19 TESTING

This standing order is issued pursuant to the Maine Proclamation of State of Civil Emergency to Further Protect Public Health, declaring a public health emergency in Maine ("the state") because of the pandemic of COVID-19 ¹. This standing order allows individuals to undergo testing for SARS-CoV-2, the virus that causes COVID-19, subject to the terms set forth below.

I. AUTHORIZATION

This standing order ("Order") authorizes any health care provider or other trained personnel at a health care facility or medically-supervised COVID-19 testing site in the state (collectively, "testing site") to collect and submit for laboratory analysis specimens to be tested using a SARS-CoV-2 molecular test² for any individual in accordance with the conditions of this Order. It also authorizes the testing site that submitted the specimen for SARS-CoV-2 molecular testing under this Order to receive the results of the test directly from the testing laboratory. This Order further authorizes the laboratory that performed the molecular test for SARS-CoV-2 to provide test results directly to the individual who was tested.

II. ELIGIBILITY

Individuals who obtain testing pursuant to this Order must be (1) at least 12 months of age or older, and (2) fall into one of the categories outlined in sections A, B, or C below. Individuals may obtain testing under this Order irrespective of their state of permanent residence so long as the specimen collection occurs within Maine.

- A. Individuals who are known to have been exposed, or may have been exposed, to SARS-COV-2 within the incubation period for COVID-19 (pursuant to current guidelines), with or without symptoms³, who meet any one of the following conditions:
 - Persons who had close contact (within 6 feet for at least 30 minutes) with someone with laboratory-confirmed COVID-19; OR
 - · Health care workers and first responders; OR
 - Residents or staff of congregate living settings, including but not limited to longterm care facilities, group homes, assisted living facilities, shelters for people experiencing homelessness, or correctional facilities.
- B. Persons who do not have symptoms or known exposure to COVID-19 infection but have elevated risk for exposure as determined by the Maine Department of Health and Human Services ("Department"). These individuals include, though are not limited to, seasonal and migrant agricultural workers, employees of lodging facilities, employees of businesses who have direct, daily contact with members of the public, visitors from states with a COVID-19 prevalence higher than that in Maine, people participating in large gatherings, or other

¹ Proclamation of State of Civil Emergency to Further Protect Public Health, State of Maine, March 15, 2020, available at https://www.maine.gov/governor/mills/sites/maine.gov.governor.mills/files/inline-files/Proclamation%20of%20State%20of%20Civil%20Emergency%20To%20Further%20Protect%20Public%20Health.pdf

² SARS-CoV-2 molecular tests are defined as Nucleic Acid Amplification Tests (NAAT) such as Reverse Transcription Quantitative Polymerase Chain Reaction (PCR) tests and isothermal nucleic acid amplification tests.

³ Symptoms of COVID-19 include fever, cough, shortness of breath, chills, muscle pain, head ache, sore throat, recent loss of taste or smell, vomiting or diarrhea.

- individuals who may be at increased risk of COVID-19 based on the duration and density of their recent, potential exposures.
- C. Populations identified by the Department for COVID-19 testing as part of a population-based sentinel testing program, to be determined by, and at the discretion of the Department.

III. INFORMATION TO BE PROVIDED TO INDIVIDUALS BEING TESTED

Prior to collecting the specimen from the individual being tested, the testing sites shall provide appropriate educational information to the individual, which shall include but is not limited to the following:

- A. Written information on how and when the individual will receive test results; AND
- B. Written information on next steps to take following testing, including information on how to obtain follow-up medical care, and/or to address questions about diagnosis if they test positive for COVID-19.
- C. Additionally, testing sites must provide individuals who are known to be close contacts of individuals with laboratory-confirmed COVID-19, as defined above, with written information outlining expectations for maintaining self-quarantine for 14 days.

IV. SPECIMEN COLLECTION, TESTING AND TEST RESULTS

- A. Testing sites may collect specimens for SARS-COV-2 molecular tests approved by the U.S. Food and Drug Administration ("FDA"), authorized by the FDA through an Emergency Use Authorization.⁴ Testing sites must also adhere to federal guidance outlining requirements for COVID-19 laboratory reporting.⁵
- B. Testing sites must follow appropriate preparations to collect a specimen:
 - 1. Ensure correct testing materials according to manufacturer instructions and/or the laboratory who will be performing the test.
 - 2. Ensure appropriate personal protective equipment for testing facility staff to administer the test, including gloves, gowns, N95 respirator (or surgical mask if respirator not available), and eye protection (goggles or face shield).
- C. Testing sites must adhere to the following instructions when collecting specimens:
 - 1. Specimens must be collected by licensed health care provider or other appropriately trained and supervised personnel.
 - 2. Testing sites must follow manufacturer-specific and/or laboratory-specific instructions for specimen collection.
 - 3. Testing sites must follow CDC guidelines for Collecting, Handling, and Testing Clinical Specimens for Persons for Coronavirus Disease 2019, as amended and supplemented.⁶

⁴ U.S. Food & Drug Administration, Emergency Use Authorizations, available at https://www.fda.gov/medical-devices/emergency-use-authorizations

⁵ U.S. Health & Human Services, COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115, available at https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf

⁶ CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus available at https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

- D. Testing sites must ensure that laboratories conducting SARS-COV-2 molecular tests on the specimens being collected under this standing order report test results to the testing site that collected the specimen as soon as practicable.
- E. Testing sites must offer the individual being tested the option, with consent, the opportunity to receive testing results directly from the laboratory conducting the test. If the individual being tested declines to receive directly reported results, the testing site must furnish such results to the individual, as noted in Section V(A) below.
- F. Testing sites must collect complete information on the individual consistent with Department guidance.
- G. Testing sites must provide the Maine CDC with the total number of COVID-19 tests performed each day.

V. FOLLOW UP

- A. Testing sites must report COVID-19 test results to the individual as soon as possible after results are received, and no later than 1 business day after the testing site's receipt of the test results.
- B. Testing sites must inform individuals with a positive COVID-19 test result of the result and the requirement for self-isolation as outlined by the U.S. Centers for Disease Control and Prevention.⁷
- C. Testing sites must report positive COVID-19 test results to the Maine Center for Disease Control and Prevention in a manner prescribed by the Department within 1 business day of receiving test results.⁸

VI. TERM

This standing order shall take effect immediately. This standing order shall remain in force and effect for the duration of the public health emergency unless otherwise modified, supplemented and/or rescinded.

Maine Department of Health & Human Services Issuing Official

Siiri Bennett, MD

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Maine Medical License Number: MD20720

NPI: 1144269952

Date: June 8, 2020

Expiration Date: For the duration of the public health emergency declared under the Proclamation of State of Civil Emergency to Further Protect Public Health.¹

⁷ U.S. CDC Background Quarantine & Isolation: https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine-isolation.html

⁸ Maine CDC Health Alert: Temporary Updates to the Notifiable Diseases and Conditions List - SARS CoV-2 and COVID-19 Deaths https://www.maine.gov/dhhs/mecdc/health-advisory.shtml?id=2423264