

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

This standing order is issued to allow 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 collection site in the State of Maine (collectively, "collection site") to collect and submit for laboratory analysis specimens to be tested using only either a SARS- CoV-2 molecular¹ or antigen test for any individual in accordance with the conditions of this Order.¹ It also authorizes the collection site that submitted the specimen for SARS-CoV-2 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 test for SARS-CoV-2 to provide test results directly to the individual who was tested, with the individual’s consent.

II. ELIGIBILITY

Any individual in Maine who is at least 12 months of age or older may obtain testing for SARS-CoV-2 under this Order.

III. INFORMATION TO BE PROVIDED TO INDIVIDUALS BEING TESTED

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

- A. Written information on how and when the individual will receive test results.
- 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, collection sites must provide individuals who report as being close contacts of individuals with laboratory-confirmed COVID-19, as defined above, with written information outlining expectations for maintaining self-quarantine for 10 days.

IV. SPECIMEN COLLECTION, TESTING, AND TEST RESULTS

- A. Collection sites may collect specimens for SARS-CoV-2 tests approved by the U.S. Food and Drug Administration ("FDA"), or authorized by the FDA through an

¹ Antibody-based testing is not covered under this Order.

Emergency Use Authorization.² Collection sites must also adhere to federal guidance outlining requirements for COVID-19 laboratory reporting.³

- B. Collection sites must follow appropriate preparations to collect a specimen:
 - 1. Ensure correct testing materials according to manufacturer instructions and/or the laboratory that 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. Collection sites offering testing under this Order must adhere to the following instructions when collecting specimens:
 - 1. Specimens may be collected by a health care provider. Specimens may also be collected by individuals themselves under the supervision of a health care provider at the collection site.
 - 2. Collection sites must follow manufacturer-specific and/or laboratory-specific instructions for specimen collection.
 - 3. Collection sites must follow CDC guidelines for Collecting, Handling, and Testing Clinical Specimens for Persons for Coronavirus Disease 2019, as amended and supplemented.⁴
- D. Collection sites must ensure that laboratories conducting SARS-CoV-2 tests on the specimens being collected under this Order report test results to the testing site that collected the specimen as soon as practicable.
- E. Collection sites must offer the individual being tested the option, with consent, to receive testing results directly from the laboratory conducting the test. If the individual being tested declines to receive directly reported results, the collection site must furnish results to the individual, as noted in Section V(A) below.
- F. Collection sites must collect complete information on the individual consistent with Department guidance.
- G. Collection sites must provide the Maine CDC with the total number of COVID-19 tests performed under this Order upon request.

V. FOLLOW UP

- A. Collection 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 collection site's receipt of the test results.

² U.S. Food & Drug Administration, Emergency Use Authorizations, available at <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices>

³ 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>

⁴ 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>

- B. Collection 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.⁵
- C. Collection 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.⁶

VI. TERM

This standing order shall take effect immediately. This standing order shall remain in force and effect, unless otherwise modified, supplemented and/or rescinded.

Maine Department of Health & Human Services
Issuing Official

Jun-29-2021 Date:

DocuSigned by:

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⁵ U.S. CDC Background Quarantine & Isolation: <https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html>

⁶ Maine CDC Health Alert: Temporary Updates to the Notifiable Diseases and Conditions List - SARS CoV-2 and COVID-19