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PUBLIC HEALTH ADVISORY

To: All Health Care

From: Dr. Siiri Bennett, State Epidemiologist

Subject: COVID-19 Testing at HETL

Date / Time: Tuesday, June 30, 2020 at 2:00PM

Pages: 3

Priority: Normal

Message ID: 2020PHADV026

COVID-19 TESTING AT HETL

The Maine CDC Health and Environmental Testing Laboratory ("HETL") has received several specimens for COVID-19 testing that do not have the appropriate paperwork attached. Federal rules under CLIA require HETL to only run tests that are accompanied by complete paperwork. Items most commonly missing are:

- Name of ordering physician
- Patient date of birth
- Specimen Source (e.g., NP, OP, nasal mid-turbinate, anterior nares)
- → Please make sure that the submission forms sent in with specimens contain <u>all</u> required information. If forms are incomplete, specimens will not be tested.

HETL is also rejecting several specimens because of leakage. In many instances, HETL has found that the swab shaft has not been broken properly or cut to allow it to fit into the tube with the Viral Transport Media (VTM). HETL also asks that collection sites place absorbent material in and around the tube prior to packaging to prevent potential biosafety hazards. Specimens that leak allow for contamination so they will be rejected and not tested. Please make sure that swab shafts are broken or cut properly to allow them to fit inside the vials.

The most current HETL requisition form is located at https://www.maine.gov/dhhs/mecdc/public-health-systems/health-and-environmental-testing/micro/documents/SARS-CoV-2-COVID-19-Priority-Specimen-Submission-Form.docx

STANDING ORDER FOR COVID-19 TESTING

On June 8, 2020, Maine CDC issued a Standing Order ("Order") that authorizes any health care provider or other trained personnel at a health care facility or medically-supervised COVID-19 collection site (collectively, "collection site") in the state to collect and submit specimens SARS-CoV-2 molecular testing. This Order was revised on June 18, 2020 to clarify language regarding specimen collection protocols.

The Standing Order is a physician's order that authorizes lab testing for COVID-19 for individuals in Maine who have symptoms suggestive of COVID-19, who may be at elevated risk of exposure to COVID-19, or who are part of a Department of Health and Human Services ("Department") population-based sentinel testing program.

The DHHS Standing Order is not meant to replace existing patient-provider relationships or provider-laboratory relationships. It can assist people who believe that they have been exposed or have an elevated risk of exposure and who do not have a primary care provider, cannot discuss this exposure in a timely way with their health care provider, or are vising Maine from another state for example.

The Order also authorizes the collection 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. The 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, with the individual's consent. The June 18th revision clarified in Section IV.C.1 that, in addition to licensed health care providers and other appropriately trained and supervised personnel, specimens may be collected by individuals themselves under the supervision of a licensed health care provider at the specimen collection site.

- The full Standing Order is available on the Maine CDC website at https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/airborne/documents/ME-DHHS_StandingOrder_COVID19testing_06-18-2020v2.pdf
- Standing Order FAQs for the public are available on the Maine CDC website at https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/airborne/documents/Standing-Order-FAQs.pdf
- Information regarding self-collection for SARS-CoV-2 testing can be found at https://www.maine.gov/dhhs/mecdc/public-health-systems/health-and-environmental-testing/micro/documents/self-collection-for-SARS-CoV-2.docx

KEY POINTS FOR PROVIDERS

- The Order permits, but does not require, any health care provider or COVID-19 test collection site to provide a test. The DHHS Standing Order is not meant to replace existing patient-provider relationships or provider-laboratory relationships.
- Individuals may obtain testing under this Order irrespective of their state of permanent residence so long as the specimen collection occurs within Maine.
- The Maine DHHS Standing Order for COVID-19 testing covers only molecular testing for COVID-19; it does not include antibody testing.
- The Order has been updated to cover specimens collected using medically supervised self-swabbing.
- All collection sites operating under the Order are responsible for contacting individuals with the results of their lab test.
- The Maine CDC Health and Environmental Testing Laboratory (HETL) will only conduct COVID-19 testing on samples taken from test collection sites that have established a relationship with it. Collection

sites must use the HETL submission form (https://www.maine.gov/dhhs/mecdc/public-health-systems/health-and-environmental-testing/) and register with HETL prior to submitting specimens for testing.

• For the duration of the national public health emergency, the Federal government requires all types of health insurance coverage to pay for COVID-19 testing with no out-of-pocket charges to individuals. The Maine Bureau of Insurance also clarified coverage of COVID-19 testing in Bulletin 450 https://www.maine.gov/pfr/insurance/legal/bulletins/pdf/450.pdf. Individuals should confirm coverage with their health plan directly as well as ask about any payments that may be required at the test collection site.