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PUBLIC HEALTH ADVISORY

To: Health Care Providers

From: Dr. Siiri Bennett, State Epidemiologist

Subject: Updated Guidance for COVID-19 Testing- March 2020

Date / Time: Monday, March 16, 2020 at 9:05pm

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Abstract:

On March 15, 2020, the U.S. Centers for Disease Control and Prevention (U.S. CDC) and the U.S. Food and Drug Administration (FDA) issued new guidance for collection, handling, and testing clinical specimens from persons for Coronavirus Disease 2019 (COVID-19). These new guidance can be found at https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.htm and https://www.fda.gov/medical-devices/faqs-diagnostic-testing-sars-cov-2.

Key Messages:

- U.S. CDC is now recommending collecting a single nasopharyngeal (NP) swab in viral transport media. Throat (OP) swabs are no longer required. If both swabs are used, they should be combined at collection in to a single vial.
- FDA has expanded options for specimen transport media.
- The Maine Health and Environmental Testing Laboratory (HETL) will no longer be running a respiratory viral panel with all submitted COVID-19 specimens.

Updated Guidance for COVID-19 Testing

Summary:

On March 15, 2020, the U.S. Centers for Disease Control and Prevention (U.S. CDC) and the U.S. Food and Drug Administration (FDA) issued new guidance for collection, handling, and testing clinical specimens from persons for Coronavirus Disease 2019 (COVID-19). This new guidance can be found at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2.

Summary of Changes for COVID-19 Testing and Specimen Collection:

- U.S. CDC is now recommending collecting a single nasopharyngeal (NP) swab in viral transport media. Throat
 (OP) swabs are no longer required. If both swabs are used, they should be combined at collection in to a single
 vial.
 - U.S. CDC does not recommend use of calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing.
- The FDA has expanded the list of allowable media in which specimens can be transported. New acceptable media include:
 - o Liquid Amies-based transport media.
 - Supplies:
 - E-Swab by Copan (Catalogue # 481C and 482C) with regular or flex minitip applicator
 - Opti-Swab by Puritan (Catalogue # LA-117), swab included in kit (Catalog#3317-H).
 - Storage: Up to 72 hours at 4°C, or frozen for longer storage.
 - o Dry swab in saline
 - Supplies:
 - Puritan: 25-3317-H, 25-3316-U, 25-3316-H, 25-3317-U, 25-3318-U, 25-3318-H, 25-3319-H, 25-3320-U, 25-3320-U EMB 100MM, 25-3320-U EMB 80MM, 25-3320-H and 25-3320-H EMB 80MM
 - Copan: 501CS01, 503CS01, 516CS01, 518CS01 and 534CS01
 - Storage: Up to 72 hours at 4°C, or frozen for longer storage.
- The Maine Health and Environmental Testing Laboratory (HETL) will no longer be running a respiratory viral panel with all submitted COVID-19 specimens.
 - HETL will perform testing for respiratory viruses, including as a panel, when indicated on the HETL specimen submission form, which can be found at mainepublichealth.gov/lab.

For more information:

- Maine CDC's COVID-19 website <u>www.maine.gov/dhhs/coronavirus</u> or by calling Maine CDC at **1-800-821-5821**.
- U.S. CDC's COVID-19 website https://www.cdc.gov/coronavirus/2019-nCoV/index.html