



Department of Health and Human Services
Maine Center for Disease Control and Prevention
286 Water Street
11 State House Station
Augusta, Maine 04333-0011
Tel: (207) 287-8016; Fax (207) 287-9058
TTY Users: Dial 711 (Maine Relay)

Maine Health Alert Network (HAN) System

PUBLIC HEALTH ADVISORY

To: All Health Care
From: Dr. Siiri Bennett, State Epidemiologist
Subject: Increased COVID-19 Testing Capacity at Maine CDC Laboratory
Date / Time: Monday, May 18, 2020 at 11:50AM
Pages: 6
Priority: Normal
Message ID: 2020PHADV022

INCREASED COVID-19 TESTING CAPACITY AT MAINE CDC LABORATORY

I. BACKGROUND

On March 25, 2020, Maine met U.S. CDC's criteria for a Moderate level of community transmission for coronavirus disease 2019 (COVID-19). Since then Maine's testing capacity has been inhibited by the limited national supply of laboratory materials and testing equipment. To preserve specimen collection and testing supplies for patients who may develop severe COVID-19 illness, Maine CDC's Health and Environmental Testing Laboratory (HETL) has, until now, had to prioritize testing for individuals in high-risk categories.

Maine CDC has expanded its capacity for COVID-19 testing. This expansion results largely from a partnership with IDEXX (Westbrook, Maine) to use the OPTI SARS-CoV-2 RNA PCR Test Kit, which recently received US FDA Emergency Use Authorization. The test kit is based on real-time reverse transcription polymerase chain reaction (RT-PCR), which provides detection of the viral RNA in the sample.

II. PREVIOUS COVID-19 TESTING CRITERIA RESCINDED AND NEW GUIDELINES ESTABLISHED

The acquisition of the IDEXX PCR Test Kit enables HETL to process up to 1,000 tests each day. Training on the new equipment and quality assurance have been completed. Therefore, HETL can now conduct an increased number of tests:

- Effective Monday May 18, 2020, **the testing priorities and tiers** outlined in the March 19, 2020, HAN "Updated Guidance for COVID-19: Prioritization of Testing and Discontinuation of Home Isolation" **are rescinded and the following new guidelines are established:**
- **HETL will now test specimens from any person who has one or more symptoms** that are consistent with COVID-19. Testing must be ordered by a clinician.

- Consistent with the guidance set forth in this Public Health Advisory, Maine health care providers should use their clinical judgment to determine if a patient has signs and symptoms compatible with COVID-19 and whether the patient should be tested.
- **Symptoms.** People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2-14 days after exposure to the virus and may include:
 - Cough
 - Shortness of breath or difficulty breathing
 - Fever
 - Chills
 - Muscle pain
 - Sore throat
 - New loss of taste or smell
 - Other, less common, symptoms have been reported, including gastrointestinal symptoms like nausea, vomiting, or diarrhea.
- HETL will **now also test persons without symptoms who may be at risk for transmitting COVID-19 to others.** As examples, these may include but are not limited to:
 - Asymptomatic close contacts of confirmed COVID-19 cases in an outbreak setting. For reference, Maine CDC generally defines an “outbreak” as three or more epidemiologically linked cases of a specific disease, and generally defines “close contacts” as individuals who have spent 30 minutes or more within 6 ft of an individual with confirmed COVID-19;
 - Asymptomatic health care workers, including first responders, who have had contact with or exposure to a confirmed COVID-19 case; or
 - Asymptomatic persons tested as part of a sentinel COVID-19 disease surveillance program established by Maine CDC.
- In order to maintain laboratory capacity for the activities noted above, HETL will not test specimens collected by congregate facilities that choose to conduct universal testing of their staff and residents when that recommendation has not been approved by Maine CDC.

III. ACCESSING TESTING AT HETL

If facility has not previously submitted specimens to HETL, please set up an account with HETL PRIOR to submitting any samples to HETL for COVID testing. To set up an account, please fax the following information to HETL at 207-287-1727:

- Facility name
- Contact name
- Facility address
- Phone number, and
- Confidential fax number.
- HETL will contact your facility with confirmation of receipt of the information.
- Once an account is established, specimens can be forwarded to HETL.

Testing forms and information on acceptable swabs and transport media can be found on HETL's website at <https://www.maine.gov/dhhs/mecdc/public-health-systems/health-and-environmental-testing/micro/documents/SARS-CoV-2-Virus-Detection-using-RT-PCR-LSIS.pdf>

IV. IDSA RECOMMENDATIONS FOR COVID-19 TESTING

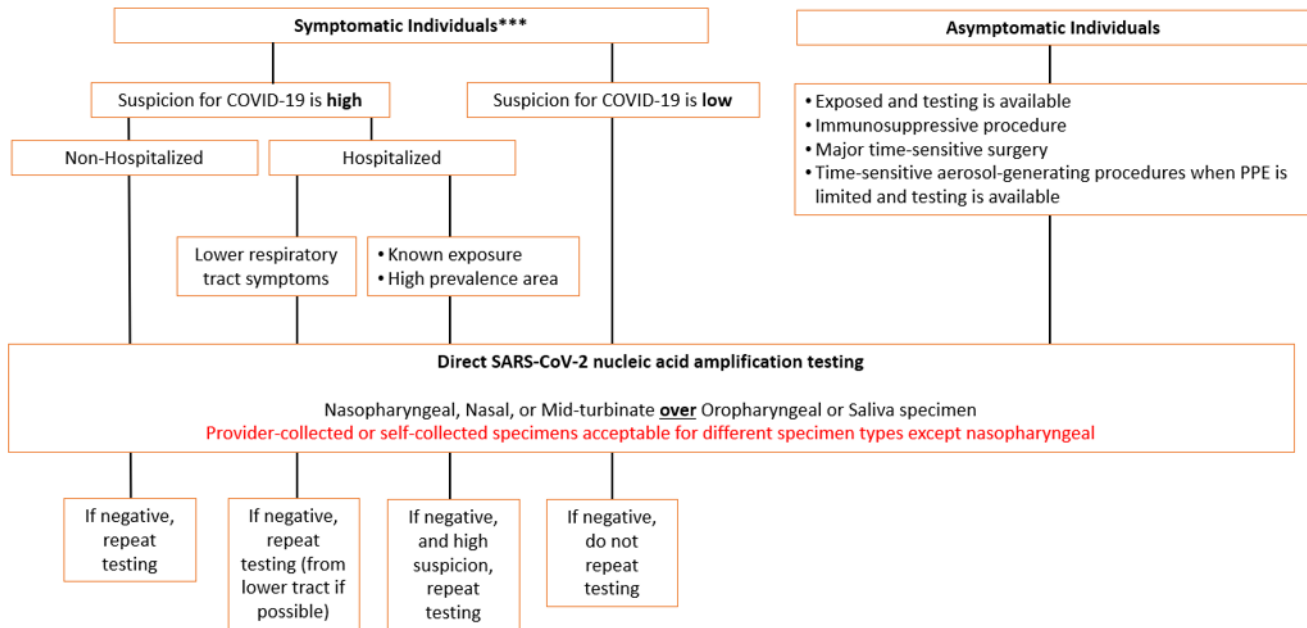
Accurate molecular diagnostic tests are necessary for confirming a diagnosis of COVID-19. Direct detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) nucleic acids in respiratory tract specimens informs patient, healthcare institution and public health level decision-making. Maine CDC recommends following the **Infectious Diseases Society of America (IDSA) Guidelines on the Diagnosis of COVID-19**. An executive summary, testing algorithm, and recommendations are below. A link to the IDSA Guidelines is [here](#) and in the References section below.

Summarized below are 15 recommendations for SARS-CoV-2 nucleic acid testing based on systematic reviews of the diagnostic literature conducted by IDSA. An algorithm based on these recommendations is provided to aid in decision-making (see Figure 1). Based on reviews of baseline risk, IDSA made assumptions about COVID-19 disease prevalence in the community and/or pretest probabilities in individual patients, both of which influence testing recommendations.

Summary of guidelines from the Infectious Disease Society of America (ISDA) on the Diagnosis of COVID-19:

- IDSA recommends nucleic acid polymerase chain reaction (PCR) testing for all symptomatic individuals suspected of having COVID-19.
- Testing is recommended for asymptomatic individuals with known or suspected contact with a COVID-19 case.
- Testing asymptomatic individuals without known exposure is suggested when the results will, for example:
 - (1) impact isolation/quarantine/personal protective equipment (PPE) usage decisions;
 - (2) dictate eligibility for surgery; or
 - (3) inform administration of immunosuppressive therapy.
- Ultimately, decisions on which patients to test will depend on institutional-specific resources and the needs of different patient populations.

Figure 1. IDSA Algorithm for SARS-CoV-2 Nucleic Acid Testing



*****Note:**

- Testing should be prioritized for symptomatic patients first.
- When resources are adequate, testing for selected asymptomatic individuals can also be considered.

*Per HETL guidelines, self-collected samples must be collected under direct medical supervision. In addition, HETL does not have self-collection kits available at this time.

V. SPECIFIC RECOMMENDATIONS FROM ISDA

A detailed description of background, methods, evidence summary and rationale that support each recommendation, and research needs can be found online in the full text. Briefly, an expert panel consisting of clinicians, medical microbiologists and methodologists critically appraised the COVID-19 diagnostic literature using Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology to assess the certainty of evidence. Per GRADE, recommendations are categorized as “strong” or “conditional”. The word “recommend” indicates a strong recommendation and “suggest” implies conditional recommendation. The panel:

1. Recommends a SARS-CoV-2 nucleic acid amplification test (NAAT) in symptomatic individuals in the community suspected of having COVID-19, even when the clinical suspicion for COVID-19 is low (strong recommendation, very low certainty of evidence).
2. Suggests collecting nasopharyngeal, or mid-turbinate, or nasal swabs rather than oropharyngeal swabs or saliva alone for SARS-CoV-2 RNA testing in symptomatic individuals with upper respiratory tract infection (URTI) or influenza like illness (ILI) suspected of having COVID-19 (conditional recommendation, very low certainty of evidence).
3. Suggests that nasal and mid-turbinate (MT) swab specimens may be collected for SARS-CoV-2 RNA testing by either patients or healthcare providers, in symptomatic individuals with upper respiratory tract

infection (URTI) or influenza like illness (ILI) suspected of having COVID-19 (conditional recommendation, low certainty of evidence).

4. Suggests a strategy of initially obtaining an upper respiratory tract sample (*e.g.*, nasopharyngeal swab) rather than a lower respiratory sample for SARS-CoV-2 RNA testing in hospitalized patients with suspected COVID-19 lower respiratory tract infection. If the initial upper respiratory sample result is negative, and the suspicion for disease remains high, the IDSA panel suggests collecting a lower respiratory tract sample (*e.g.*, sputum, bronchoalveolar lavage fluid, tracheal aspirate) rather than collecting another upper respiratory sample (conditional recommendations, very low certainty of evidence).
5. Suggests performing a single viral RNA test and not repeating testing in symptomatic individuals with a low clinical suspicion of COVID-19 (conditional recommendation, low certainty of evidence).
6. Suggests repeating viral RNA testing when the initial test is negative (versus performing a single test) in symptomatic individuals with an intermediate or high clinical suspicion of COVID-19 (conditional recommendation, low certainty of evidence).
7. Makes no recommendations for or against using rapid (*i.e.*, test time \leq 1 hour) versus standard RNA testing in symptomatic individuals suspected of having COVID-19 (knowledge gap).
8. Suggests SARS-CoV-2 RNA testing in asymptomatic individuals who are either known or suspected to have been exposed to COVID-19 (conditional recommendation, very low certainty of evidence).
9. Suggests against SARS-CoV-2 RNA testing in asymptomatic individuals with no known contact with COVID-19 who are being hospitalized in areas with a low prevalence of COVID-19 in the community (conditional recommendation, very low certainty of evidence).
10. Recommends SARS-CoV-2 RNA testing in asymptomatic individuals with no known contact with COVID-19 who are being hospitalized in areas with a high prevalence of COVID-19 in the community (*i.e.*, hotspots) (conditional recommendation, very low certainty of evidence).
11. Recommends SARS-CoV-2 RNA testing in immunocompromised asymptomatic individuals who are being admitted to the hospital regardless of exposure to COVID-19 (strong recommendation, very low certainty of evidence).
12. Recommends SARS-CoV-2 RNA testing (versus no testing) in asymptomatic individuals before immunosuppressive procedures regardless of a known exposure to COVID-19 (strong recommendation, very low certainty of evidence).
13. Suggests SARS-CoV-2 RNA testing in asymptomatic individuals without known exposure to COVID-19 who are undergoing major time-sensitive surgeries (conditional recommendation, very low certainty of evidence).
14. Suggests against SARS-CoV-2 RNA testing in asymptomatic individuals without a known exposure to COVID-19 who are undergoing a time-sensitive aerosol generating procedure (*e.g.*, bronchoscopy) when PPE is available (conditional recommendation, very low certainty of evidence).
15. Suggests SARS-CoV-2 RNA testing in asymptomatic individuals without a known exposure to COVID-19 who are undergoing a time-sensitive aerosol generating procedure (*e.g.*, bronchoscopy) when PPE is limited, and testing is available (conditional recommendation, very low certainty of evidence).

VI. REFERENCES

OPTI SARS-CoV-2 RT-PCR test specifics <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

OPTI Medical <https://www.optimedical.com/>

U.S. Centers for Disease Control and Prevention priorities for testing <https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html>

Maine Center for Disease Control and Prevention (Maine CDC)
<https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/airborne/coronavirus.shtml>

Maine Health and Environmental Testing Laboratory (HETL) SARS-CoV-2 Testing Requirements
<https://www.maine.gov/dhhs/mecdc/public-health-systems/health-and-environmental-testing/micro/documents/SARS-CoV-2-Virus-Detection-using-RT-PCR-LSIS.pdf>

IDSA Guidelines <https://www.idsociety.org/COVID19guidelines/dx>