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To: Healthcare Providers, Clinical Laboratories and Local Boards of Health
From: Catherine M. Brown, DVM, MSc, MPH, State Epidemiologist
Larry Madoff, MD, Medical Director, BIDLS
Sandra Smole, PhD, Director, State Public Health Laboratory
Date: August 7, 2020
RE: Testing of Persons with Suspect COVID-19

This document includes guidance about appropriate use of laboratory testing for COVID-19. In addition, it indicates which subset of specimens can be submitted to the MA State Public Health Laboratory (SPHL). This guidance is not intended to replace or supersede clinical judgment; clinicians concerned that their patient has COVID-19 or has been exposed to COVID-19 should utilize testing as they deem appropriate.

RECOMMENDATIONS FOR DIAGNOSTIC COVID-19 TESTING:

To evaluate individuals for current infection, a molecular diagnostic test to detect the presence of the virus by polymerase chain reaction (PCR) or other nucleic acid amplification methodology is the gold standard and is the preferred test type.

A second method to detect the presence of viral proteins is a diagnostic antigen test. Although these newer diagnostic antigen tests are faster to run, they are **less sensitive and less specific** and antigen test results must be confirmed by a molecular test.

Symptomatic Individuals: All symptomatic individuals in Massachusetts, even those with mild symptoms, should be tested. Symptoms of COVID-19 include:

- Fever or chills;
- Signs of a lower respiratory illness (e.g., cough, shortness of breath, lowered oxygen saturation);
- Fatigue, sore throat, runny nose or congestion, headache, body aches/myalgia, or new loss of sense of taste or smell;
- Other less common symptoms can include gastrointestinal symptoms (e.g. nausea, vomiting, diarrhea), rash, inflammatory conditions such as "COVID toes", and thromboembolic events;
- In elderly, chronically ill, or debilitated individuals such as residents of a long-term care facility, symptoms of COVID-19 may be subtle such as alterations in mental status or in blood glucose control; and
- Children with multisystem inflammatory syndrome.

It should be noted that although serology testing is rarely indicated for diagnostic purposes, it is often part of an appropriate diagnostic testing algorithm for suspect pediatric cases of multisystem inflammatory syndrome.

Close Contacts of confirmed or clinically diagnosed COVID Cases: All individuals in Massachusetts identified as a close contact should be tested with a diagnostic test. A Local Board of Health, the Massachusetts Department of Public Health, the Community Tracing Collaborative, or a healthcare provider can all recommend testing of a close contact.

Close contact is defined as:

- a) Being less than 6 feet from a confirmed or clinically diagnosed COVID-19 case for at least 10-15 minutes, while the case was symptomatic or within the 48 hours before symptom onset. Close contact can occur anywhere. Examples include caring for, living with, visiting, or sharing a healthcare waiting area or room with a confirmed or clinically diagnosed COVID-19 case.

OR

- b) Having direct contact with infectious secretions of a confirmed or clinically diagnosed COVID-19 case (e.g., being coughed on) while not wearing recommended personal protective equipment or PPE (e.g., gown, gloves, facemask, eye protection).

Recommended timing of testing for close contacts:

- Close contacts without symptoms should be tested as soon as possible after they are notified of their exposure to COVID-19. The contact is required to quarantine for the full 14 days, even following a negative test result.
- Close contacts that develop any symptom at any time during their quarantine period should be tested promptly. Testing should occur even if the person previously had a negative test result during their quarantine period

Admission to a healthcare facility:

All individuals should be tested upon inpatient admission to a healthcare facility, including but not limited to, a hospital operated or licensed by the Department of Public Health or Mental Health, long-term acute care hospital, or skilled nursing facility.

Asymptomatic Individuals:

Asymptomatic individuals not identified as close contacts can be recommended for diagnostic testing at the direction of their healthcare provider, the Department of Public Health or a state agency, or a local Board of Health. Testing generally requires a clinician's order and **asymptomatic individuals are strongly encouraged to contact their insurer to confirm coverage.**

Previously Positive Individual Cleared from Isolation:

Individuals previously diagnosed with COVID-19 infection confirmed by molecular diagnostic testing may continue to have PCR detection of viral RNA for several weeks. This does not correlate with the presence or transmissibility of live virus and those who have been cleared from isolation by either the symptom-based or test-based strategy, are not recommended for re-testing within 90 days of their original positive test. These individuals are also not subject to quarantine during this period.

Until further data are available, individuals who were previously diagnosed with COVID-19, are more than 6 weeks past their release from isolation, and who develop clinically compatible symptoms, should be retested. If viral RNA is detected by PCR testing, the patient should be isolated and considered to be re-infected. Additionally, individuals who were previously diagnosed with COVID-19 and are more than 90 days from their initial positive test who are identified as a close contact of a confirmed case, are subject to quarantine.

Serology Testing:

Commercially manufactured antibody tests check for SARS-CoV-2 antibodies and are available through healthcare providers and commercial laboratories. Antibody tests may demonstrate whether an individual was previously infected with SARS-CoV-2 and antibody testing is important to help understand how many people in a population have been exposed to the virus. Antibody tests are rarely indicated for diagnostic purposes in adults. However, the test is often part of an appropriate diagnostic testing algorithm for suspect pediatric cases of multisystem inflammatory syndrome. In order to be appropriately interpreted, more data are needed on the performance characteristics of these tests, the

immune response to COVID-19, the timing and duration of antibody response, and how antibodies correlate to protective immunity.

- **If an antibody test is performed, it is recommended that healthcare providers order a molecular diagnostic test at the same time.**
- **At this time, antibody testing should not be used to guide release from isolation or for return to work purposes and are rarely indicated for diagnostic purposes.**

This guidance is not intended to cover every possible situation. To discuss specific scenarios, please call the Massachusetts Department of Public Health Epidemiology line at 617-983-6800 available 24/7.