10/20/2020

# MEMORANDUM

TO: Illinois Health Care Providers, Laboratories, Clinics and other Facilities/Institutions Implementing or Providing Care or Testing for Persons Suspected of Having COVID-19

FROM: Catherine A. Counard, MD, MPH, Medical Officer, Office of Health Protection

RE: Recommendations for Testing Individuals with Signs or Symptoms Consistent with COVID-19 Infection and/or Close Contact with a Confirmed or Probable Case of COVID-19

**Background**

Health care providers are strongly encouraged to test for SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19), when patients present with any signs or symptoms consistent with COVID-19 or have had a known exposure to a person with COVID-19 infection. Due to the nonspecific clinical presentation of COVID-19 and the potential for co-infection with other pathogens, every symptomatic person should be evaluated on a case-by-case basis and testing decisions should be based on the patient's personal health history. Because many COVID-19 cases have been observed in persons who originally discounted their symptoms due to other existing health conditions, e.g., allergies, prompt and early diagnosis of COVID-19 infection is strongly recommended to prevent further transmission.

**Testing**

Two kinds of tests are available for COVID-19: **viral** tests and **antibody** tests. Viral tests, including the Real-Time Reverse Transcriptase Polymerase Chain Reaction (RT-PCR), the rapid point-of-care (POC) molecular test, and the POC antigen test, are approved or authorized by the Food and Drug Administration (FDA) and are recommended to **diagnose current COVID-19 infection**. The RT-PCR molecular test is the "gold standard" for clinical diagnostic detection of SARS-CoV-2. Rapid POC molecular and POC antigen tests usually provide more rapid results than the RT-PCR but have a higher probability of missing an active infection. Therefore, it may be necessary to confirm a rapid POC antigen or rapid POC molecular test result with a RT-PCR test, especially if the result of the rapid POC test is inconsistent with the clinical perspective, i.e., a negative antigen test on a symptomatic individual or on a person who is a close contact to a confirmed or probable case. Both situations create a high pre-test probability (probability of a person having a disease before a test is even performed). When confirming a rapid POC molecular or antigen test result with a RT-PCR test, it is important that the time interval

between collection of samples for the two tests is less than two days, and there have not been any opportunities for new exposures between them. If more than two days separate the two collections, or if there have been opportunities for new exposures, the RT-PCR test should be considered a separate test – not a confirmatory test.

The results of viral tests for SARS-CoV-2 should be interpreted in the context of the information provided in the table below.

| Test Modality | Symptomatic | | Asymptomatic with HIGH index of suspicion[1] | | Asymptomatic with LOW index of suspicion[2] | |
|---|---|---|---|---|---|---|
| | POS | NEG | POS | NEG | POS | NEG |
| **RT-PCR** | Positive | Negative | Positive | Negative | Positive | Negative |
| **POC-Ag/Molecular** | Presumptive positive[3] | Possible false negative[4] | Presumptive positive[3] | Possible false negative[4] | Possible false positive[5] | Presumptive negative[3] |

[1]Known exposure to a case of COVID-19 in last 14 days; resident/visitor/staff in a congregate living/work setting in outbreak status; lives in an area with moderate/high community transmission (contact your local health department for details on your community's transmission status); or has history of travel to area with high community transmission in the past 14 days.
[2]No known exposure; resident/visitor/staff in a congregate living/work setting with no COVID-19 cases in last 14 days; lives in an area with low community transmission (contact your local health department for details on your community's transmission status); or no history of travel to an area with high community transmission in the past 14 days.
[3]No confirmatory testing is recommended in response to this POC testing result.
[4]Perform confirmatory RT-PCR based on clinical judgment with a new specimen collected within 48 hours of the previous test, i.e., the symptomatic person is a known close contact to a confirmed or probable case within the past 14 days.
[5]Consider performing confirmatory RT-PCR on new specimen collected within 48 hours of the previous test if the individual is NOT a close contact to a confirmed case within 14 days, NOT part of an ongoing outbreak or under the clinical discretion of the ordering provider.

CDC recommendations for SARS-CoV-2 testing are based on what is currently known about the virus. Information on testing for SARS-CoV-2 is updated as more information becomes available. Rapid antigen tests perform best when the person is tested in the early stages of infection with SARS-CoV-2 when viral load is generally highest. They also may be informative in diagnostic testing situations in which the person has a known exposure to a confirmed or probable case of COVID-19. At this time, rapid antigen tests for screening is most appropriately used in high-risk congregate settings in which repeat testing can quickly identify persons with a SARS-CoV-2 infection to inform infection prevention and control measures, thus preventing transmission.

Antibody tests approved or authorized by the FDA are used to **detect a past infection** with SARS-CoV-2. The Centers for Disease Control and Prevention (CDC) does **not** currently recommend using antibody testing as the sole basis for diagnosing current infection, or disproving a positive by viral testing. Depending on when someone was infected and the timing

of the test, the test may not find antibodies in someone with a current COVID-19 infection. In addition, it is not currently proven whether a positive antibody test indicates protection against future SARS-CoV-2 infection; therefore, antibody tests should **not** be used at this time to determine if someone is immune.

**Isolation**
Any patient for whom COVID-19 infection is suspected or who has a known exposure to COVID-19 should be instructed to isolate at home until test results are known. (Close contacts should already be in 14-day quarantine.) If the test result is positive, patients should be instructed to remain in isolation for a minimum of 10 calendar days from symptom onset (for those with symptoms) or from specimen collection date (for asymptomatic patients). If symptomatic, they should also remain in isolation until afebrile for 24 hours without use of fever-reducing medications and other symptoms have improved. Persons with severe illness, as determined by the provider in consultation with infection control experts, may produce replication-competent virus beyond 10 days that may warrant extending the duration of isolation for up to 20 calendar days after symptom onset.

Patients who test positive for COVID-19 should be encouraged to reflect on possible exposures during the 48 hours prior to symptom onset or date of specimen collection (if asymptomatic) and to answer calls from their local health department to provide important details about how they may have been infected and others they may have exposed.

**Regulatory Requirements for Performing POC Testing in Schools: Clinical Laboratory Improvement Amendment (CLIA) Waiver**
Laboratory and testing professionals who conduct ***diagnostic or screening testing*** for SARS-CoV-2 with rapid antigen or rapid molecular tests must comply with Clinical Laboratory Improvement Amendments (CLIA) regulations. Any laboratory or testing site that intends to report patient-specific test results must first obtain a CLIA waiver and meet all requirements to perform that testing. For more information, see the Centers for Medicare & Medicaid Service's (CMS) summary of the CLIA regulations. Schools can find information on how to obtain a CLIA waiver at: https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCertificateofWaiver.pdf.

**Reporting of Point of Care Testing**
Facilities that perform POC testing must report each individual positive and negative test result, per federal and state requirements. Facilities not currently sending Electronic Laboratory Reporting files to IDPH must report to IDPH according to the instructions below.

- Register in IDPH's reporting system with the facility's CLIA certificate number at: https://redcap.link/dph.illinois.gov.poccovid19registration.
- You will need your CLIA number, ordering provider, facility name, address, phone number, the type of testing platform & the point of contact email and phone number.
- Once the facility's registration has been processed, the individual who submitted the registration will receive an email with a link to begin reporting. This link is unique to the

facility and can be shared with facility staff who will be reporting results.
- Each positive and negative test result must be reported to IDPH system within 24 hours.
- If you have questions, please email: dph.elrresp@illinois.gov

**References**

Public Health Guidance for Community-Related Exposure