



## NOTICE - AMENDED GUIDANCE FOR USE AND INTERPRETATION OF SARS-CoV-2 (COVID-19) RAPID POINT OF CARE TESTS

(Updated November 17, 2020)

**This Amended Guidance updates and replaces all previous guidance and correspondence on SARS-CoV-2 (COVID-19) rapid point of care tests.**

### **Point of Care Test Use**

All facilities utilizing point of care tests shall follow the CDC [“Interim Guidance for Rapid Antigen Testing for SARS-CoV-2”](#) and the [FDA guidance](#) released on August 24, 2020.

*All Point of Care results (positive, negative, and inconclusive) must be reported to MDH immediately by*

- 1) an HL7-formatted message or formatted CSV file may submit via established electronic laboratory reporting processes (contact [mdh.didsurveillance@maryland.gov](mailto:mdh.didsurveillance@maryland.gov) for more details); or*
- 2) via manual data entry into CRISP.*

### **Point of Care Test “Off-Label Use”**

Pursuant to [August 24, 2020 guidance issued by the FDA](#), health care providers who are ordering an authorized SARS-CoV-2 diagnostic test to be used off-label (outside the authorization) to screen asymptomatic individuals not suspected of having COVID-19 should consider the following:

- Use only when highly sensitive tests are not feasible, or turnaround times are prolonged
  - In congregate care setting, repeated use of rapid POC testing may be superior to more sensitive PCR testing with longer turnaround times
- Use of tests in a general, asymptomatic screening population is generally intended to be used as part of an infection control plan
- If there is a significant new outbreak in a congregate care facility, or high clinical suspicion of an infection in an individual resident, a negative point of care test should be confirmed with a highly sensitive molecular test (“PCR assay”) (see [CDC Interim Guidance on Rapid Antigen Testing for SARS-CoV-2](#) ).
- It is not necessary to perform confirmatory high sensitivity molecular tests on individuals with negative antigen test or other point-of-care test results if they are obtained during routine screening or surveillance.

**Point of Care Test Result Interpretation for Healthcare Providers**

It is important to consider an individual’s probability of infection prior to administering the POC test, in order to appropriately interpret the POC results. Pre-test probability impacts the likelihood of a false positive and/or false negative. When interpreting the results of a POC test, consider the following guidance as set forth by the CDC.

<b><u>Pre-test probability of infection</u></b>	<b><u>Considerations</u></b>	<b><u>Guidance</u></b>
Probability of infection is low	<ul style="list-style-type: none"> <li>• Asymptomatic individual</li> <li>• No known exposure</li> <li>• Not part of an outbreak</li> <li>• Low community COVID-19 activity</li> <li>• County positivity rate is less than five percent</li> </ul>	<ul style="list-style-type: none"> <li>• If an antigen test result is positive, perform confirmatory PCR test within 48 hours. If the PCR test result is negative, treat it as a negative result.</li> </ul>
Probability of infection is high	<ul style="list-style-type: none"> <li>• Symptomatic individual</li> <li>• Known exposure</li> <li>• Part of an outbreak</li> <li>• High community COVID-19 activity</li> <li>• County positivity rate is greater than five percent</li> </ul>	<ul style="list-style-type: none"> <li>• If an antigen test result is positive, a confirmatory PCR test is unnecessary.               <ul style="list-style-type: none"> <li>○ If a PCR test is also performed and the result is negative, facilities should base their infection prevention and control actions on the positive antigen test result.</li> </ul> </li> <li>• If the antigen test result is negative, perform a confirmatory PCR test within 48 hours.</li> </ul>

The following resources may also be helpful when assessing a patient’s individual situation: [Testing Guidelines for Nursing Homes](#), [Interim Considerations for K-12 School Administrators for SARS-CoV-2 Testing](#), [Considerations for Non-Healthcare Workplaces](#), and [Interim Guidance on Management of Coronavirus Disease 2019 \(COVID-19\) in Correctional and Detention Facilities](#).

This Notice is effective immediately and shall remain in effect until it is revised or until the state of emergency has been terminated and the proclamation of the catastrophic health emergency has been rescinded.

Robert R. Neall  
Secretary