Maryland
DEPARTMENT OF HEALTH

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

(Updated December 22, 2020)

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

Point of Care Test Use

All facilities utilizing point of care tests shall follow the CDC "Interim Guidance for Antigen Testing for SARS-CoV-2" released on December 5, 2020 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 be submitted via established electronic laboratory reporting processes (contact mdh.didsurveillancee@maryland.gov for more details); or*
>
> *2) via data entry into CRISP.*

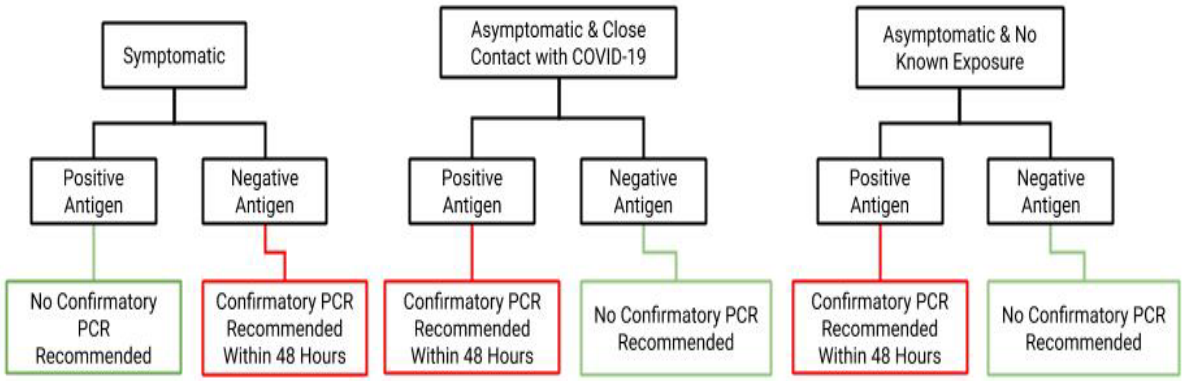
Point of Care Test Use

Pursuant to a December 12, 2020 statement, CMS will not cite facilities with a CLIA Certificate of Waiver for using antigen POC tests on asymptomatic individuals outside of the test's authorization when the information in the FDA's FAQ is considered, including:

- Use when highly sensitive tests are not feasible, or turnaround times are prolonged
    - In congregate care setting, repeated use of antigen 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 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* FDA COVID-19 Test Uses: FAQs on 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

Pursuant to the CDC "Interim Guidance for Antigen Testing for SARS-CoV-2", "Evaluating the results of an antigen test for SARS-CoV-2 should take into account the performance characteristics (e.g., sensitivity, specificity) and the instructions for use of the FDA-authorized assay, the prevalence of SARS-CoV-2 infection in that particular community (positivity rate over the previous 7–10 days or the rate of cases in the community), and the clinical and epidemiological context of the person who has been tested."



Please note, this chart is a condensed version of the algorithm depicted in the CDC guidance. For more details and useful technical notes, please see the CDC "Interim Guidance for Antigen Testing for SARS-CoV-2".

The following resources may also be helpful when assessing a patient's individual situation:
Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes,
Testing Guidelines for Nursing Homes,
Interim Considerations for K-12 School Administrators for SARS-CoV-2 Testing,
Considerations for Non-Healthcare Workplaces,
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.

Dennis R. Schrader
Secretary (Acting)