Point-of-Care COVID-19 Testing in Maryland

Official Guidance, Considerations, and Forms

(Updated February 3, 2021)

The Maryland Department of Health and other public health agencies have published official guidance, considerations, and forms related to rapid point-of-care COVID-19 testing ("rapid POC testing"). These documents are provided here for the reference of health care professionals and other groups responsible for implementing testing programs.

Health care providers are required by federal Clinical Laboratory Improvement Amendments law to follow test manufacturers' recommendations for the proper use of tests, testing devices, and other related products.

Guidance Document	Subject	Publisher	Date
Considerations for Non-Health Care Workplaces	Strategies for employers to consider when incorporating testing into a workplace COVID-19 preparedness, response, and control plan	U.S. Centers for Disease Control and Prevention	October 21, 2020
COVID-19 Rapid Point-of-Care Test Distribution	Overview of federal rapid POC test distribution program	U.S. Department of Health and Human Services	December 7, 2020
Guidance for Use and Interpretation of SARS-CoV-2 (COVID-19) Point-of-Care Tests (Amended)	Use of rapid antigen tests and other POC tests for diagnostic or screening purposes and the interpretation of results	Maryland Department of Health	November 17, 2020

Guidance Document	Subject	Publisher	Date
Interim Considerations for Testing for K-12 School Administrators and Public Health Officials	Considerations for testing in school settings intended for K-12 school administrators working in collaboration with state and local public health officials	U.S. Centers for Disease Control and Prevention	December 4, 2020
Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency related to Long-Term Care (LTC) Facility Testing Requirements and Revised COVID19 Focused Survey Tool	Provides guidance about the requirement for long-term care facilities to test residents and staff, including individuals providing services under arrangement and volunteers, for COVID-19 based on parameters set forth by the HHS Secretary	U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services	August 26, 2020
Interim Guidance for Antigen Testing for SARS-CoV-2	Provides guidance for effective clinical use of antigen tests for different testing situations. Applies to all clinical uses of antigen tests and is not specific to any particular age group or setting. Supplements and is consistent with CDC's Overview of Testing for SARS-CoV-2 guidance.	U.S. Centers for Disease Control and Prevention	December 5, 2020

Guidance Document	Subject	Publisher	Date
Interim Guidance on Management of Coronavirus Disease 2019 (COVID-19) in Correctional and Detention Facilities	Principles for health care and non-health care administrators of correctional and detention facilities to assist in preparing for introduction, spread, and mitigation of SARS-CoV-2 in their facilities	U.S. Centers for Disease Control and Prevention	December 3, 2020
Notice: October 2020 COVID-19 Updates to Nursing Homes and Assisted Living Programs	Omnibus update to various COVID-19 guidance affecting nursing homes and assisted-living programs in Maryland	Maryland Department of Health	October 1, 2020
Nursing Home Visitation	Guidance for nursing home visitation during the COVID-19 public health emergency	U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services	September 17, 2020

Forms Library

Form	Purpose	Publisher
Clinical Laboratory Improvement Amendments (CLIA) Application for Certification	Apply for a federal CLIA certification	U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services

Form	Purpose	Publisher
State Compliance Application	Apply for a Maryland laboratory license	Maryland Department of Health
Laboratory Licensing Change Form	Apply to update a Maryland laboratory license to include rapid POC testing	Maryland Department of Health
Chesapeake Regional Information System for our Patients (CRISP) Registration Form	Register to use CRISP to report COVID-19 test results	CRISP
Rapid POC Testing Supplies Interest Form	Indicate interest in future purchase of rapid POC testing supplies (this is NOT an order form)	Maryland Department of Health

Commonly Asked Questions

- **What is a rapid point-of-care COVID-19 test (POC test)?**

  Generally, the term “rapid point-of-care test” refers to COVID-19 tests that provide results quickly (some tests provide results within 15-20 minutes). The majority of rapid POC tests are antigen tests, which show active COVID-19 infection by detecting active proteins from the SARS-CoV-2 (COVID-19) virus.

- **Is CLIA certification required to use rapid POC tests?**

  Yes. Facilities are required to expand their state laboratory license and CLIA certificate to add rapid POC testing systems.

  To obtain or change the required lab license and certification:

  - If you already have a Maryland laboratory license and CLIA certification, fully complete a change form to add the COVID antigen test.
  - To apply for a Maryland laboratory license, fully complete a State Compliance Application.

- To apply for CLIA certification, fully complete a CLIA Certification Application.
- Submit both applications with original signatures to the address on the State Compliance Application form.

- **Where must we report rapid POC test results? Do negative results need to be reported?**

  Organizations that are performing rapid POC COVID-19 testing are required to report results to MDH through CRISP if they do not have access to an existing mechanism for reporting. Instructions for registering with CRISP can be found on CRISP's website. Both positive and negative results must be immediately reported to the State.

- **Where can we obtain more rapid POC testing supplies (tests or devices)?**

  To reorder BD or Quidel rapid POC testing supplies, please contact Medline, McKesson, or your normal medical supply vendor first. Nursing homes that have received shipments of Abbott testing supplies from the U.S. Department of Health and Human Services (HHS) can expect to receive additional shipments on a weekly basis. At this time, there is no way to reorder supplies from Abbott directly. Eligible entities interested in procuring supplies through the State may complete this interest form so that an estimate of demand and determination of the need for additional orders can be made. Completion of this form does not constitute order fulfillment. For any additional questions, please email MDH.RapidPOCtest@Maryland.gov

- **Are we required to use rapid POC tests?**

  No; *however, there are special considerations for nursing homes.* Nursing home facilities can meet the testing requirements through the use of rapid POC diagnostic testing devices or through an arrangement with an off-site laboratory. POC testing is diagnostic testing that is performed at or near the site of resident care. For a facility to conduct these tests with their own staff and equipment (including POC devices provided by the U.S. Department of Health and Human Services), the facility must have a CLIA Certificate of Waiver.

  Facilities without the ability to conduct COVID-19 POC testing should have arrangements with a laboratory to conduct tests to meet these requirements. Laboratories that can quickly process large numbers of tests with rapid reporting of results (e.g., within 48 hours) should be selected to rapidly inform infection prevention initiatives to prevent and limit transmission.

  Please refer to the Centers for Medicare & Medicaid Services' *Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the*

COVID-19 Public Health Emergency related to Long-Term Care (LTC) Facility Testing Requirements and Revised COVID19 Focused Survey Tool.