



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

Larry Hogan, Governor - Boyd Rutherford, Lt. Governor - Van Mitchell, Secretary

FREQUENTLY ASKED QUESTIONS: POINT OF CARE TESTING FOR LEAD

What is point of care testing?

Point of Care testing (POC testing) means a clinical test such as blood sugar or hemoglobin that is performed on site, rather than being sent to a laboratory elsewhere.

What is new about point of care testing for blood lead in Maryland?

In early 2015, the Department of Health and Mental Hygiene (DHMH) changed its regulations for POC testing using test methods that are waived under the Federal Clinical Laboratory Improvement Amendment (CLIA). The new regulations can be found at Code of Maryland Regulations ([COMAR](#)) [10.10.03.02.36](#). These new regulations allow the clinical provider to perform the test after obtaining a letter of exception from the DHMH Laboratories Administration, rather than having to obtain a permit, so long as: (1) the licensee enrolls in a proficiency testing program; (2) all staff are trained on the device; and (3) the licensee reports test results to the Maryland Department of the Environment as required.

Why did Maryland make these changes in point of care testing?

A [2014 task force report](#) recommended that Maryland encourage the use of POC testing for lead, make it easier for providers to adopt POC testing with CLIA-waived tests, and conduct outreach to providers, payors, and others to promote the use of POC testing in order to improve overall testing rates for childhood lead exposure. The task force found that POC testing was cost-effective, could be implemented with relatively little administrative burden in moderate- and larger-sized pediatric practices, and offered significant advantages for both patients, their caregivers, and health care providers.

How do I know whether a point of care test qualifies for a letter of exception, and how do I apply for a letter of exception?

Contact the DHMH Office of Health Care Quality at 410-402-8025/Fax 410-402-8213, or toll-free at 1-877-402-8202. You may also send e-mail to: ohcq.labs@maryland.gov. The website for more information is: <http://dhmh.maryland.gov/ohcq/Labs/default.aspx>.

What are the advantages of point of care testing for blood lead?

The most important advantages of POC testing for blood lead are that it saves time for patients and providers, shortens the time needed to get a test result back to the patient and the patient's family, and eliminates the need for many subsequent visits. It also increases the likelihood that a test is

carried out, and for many practices it is easily incorporated into the child's well child visit with minimal effort. The task force heard from providers and from other states with POC testing that it significantly increased the probability that testing was done, and also heard that providers and children's caregivers appreciated the ability to do the test, get the result, and discuss the result all in one visit.

Do point of care tests eliminate the need for blood draws?

No. Venous blood draws will still be needed to confirm an elevated initial test result.

What are the limitations of point of care blood tests for lead?

The task force heard that many of the problems with POC tests were due to inadequate preparation of the area of the skin from which the sample was drawn. Surface contamination of the skin can cause falsely elevated test results, so thorough preparation is required. This was one of the factors leading the Laboratories Administration to require that staff involved in use of the POC tests undergo training and demonstrate proficiency as part of the condition for obtaining a letter of exception.

Are there issues with reimbursement for point of care blood tests for lead?

DHMH is encouraging pediatric practices to consider the use of POC testing. The task force heard that reimbursement policies for POC testing were not in all cases aligned to promote its use. The Department will be following the issue of reimbursement closely, and will look at whether reimbursement policies are aligned to promote the appropriate use of POC testing for blood lead.

What are the requirements for reporting the results of POC tests?

General provider responsibilities for reporting blood lead levels are based on Maryland law and regulation, specifically, Maryland Code Annotated, Environment Article, §6-303, and the Code of Maryland Regulations (COMAR) 26.02.01. According to both the law and regulation, "A medical laboratory, office, or other facility that draws blood from any child 18 years and under for analysis of blood lead levels shall obtain all information required by the Department [of the Environment]. Point of care tests that qualify for letters of exception under COMAR 10.10.03.02.36 must comply with reporting requirements of the Department of the Environment. For more information about reporting requirements, contact the MDE Lead Poisoning Prevention Program at: (410) 537-3825 or 1-800-633-6101, Ext. 3825. The website is

<http://mde.maryland.gov/programs/Land/LeadPoisoningPrevention/Pages/index.aspx>.