Task Force to Study Point–of–Care Testing for Lead Poisoning

Dr. Clifford S. Mitchell
Chairperson

January 16, 2014

The Honorable Martin O'Malley
Governor
State of Maryland
Annapolis, MD 21401-1991

The Honorable Thomas M. Middleton
Senate Finance Committee
3 East
Miller Senate Building
Annapolis, MD 21401

The Honorable Peter A. Hammen
House Health and Government Operations Committee
Room 241
House Office Building
Annapolis, MD 21401

RE: Final Report of the Task Force to Study Point–of–Care Testing for Lead Poisoning

Dear Governor O'Malley, Chair Middleton, and Chair Hammen:

Pursuant to House Bill 303, Chapter 365 of the Acts of 2013, the Task Force to Study Point–of–Care Testing for Lead Poisoning submits this report on the findings and recommendations of the Task Force related to point-of-care testing for lead poisoning.

I hope this information is useful. If you have questions about this report, please contact me at 410-767-7438 or cliff.mitchell@maryland.gov.

Sincerely,

Dr. Clifford S. Mitchell
Chairperson

cc: Christi Megna, JD
Laura Herrera, MD, MPH
Donna Gugel, MHS
Sarah Albert, MSAR #9606

REPORT TO THE GENERAL ASSEMBLY
BY THE
TASK FORCE ON POINT OF CARE TESTING
FOR LEAD POISONING
CHAPTER 365

Maryland Department of Health and Mental Hygiene

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EXECUTIVE SUMMARY

Chapter 365 (House Bill 303), enacted by the Maryland General Assembly in 2013, established a Task Force to Study Point of Care Testing for Lead Poisoning (the Task Force). The goal of the Task Force was to study and make recommendations regarding the use of and reimbursement for point-of-care (POC) testing to screen and identify children with elevated blood-lead levels. The following information was to be included in the study:

(1) The benefits of point-of-care testing waived under the federal Clinical Laboratory Improvement Amendments (CLIA);
(2) The use of point-of-care testing in other states;
(3) Barriers to point-of-care testing, including regulatory barriers related to licensing of medical laboratories;
(4) Determining appropriate reimbursement for point-of-care testing and reporting; and
(5) Any other items the task force considers important relating to point-of-care testing.

The recommendations adopted by the Task Force are:

(1) Maryland should encourage the use of POC testing for lead;
(2) The Task Force encourages the Laboratories Administration to consider ways of promoting the wider use of POC tests for lead, particularly by making it easier for providers to implement POC testing using either a LeadCare II CLIA-waived test, a filter paper Tamarac™ test, or any other future approved POC test;
(3) The Task Force urges the Department of Health and Mental Hygiene (DHMH) and the Department of the Environment (MDE) to consider additional practices to increase testing rates;
(4) Any decision to promote more widespread use of POC testing should be accompanied by an active outreach to providers, parents, members of the public, payors and others, to actively promote the use of the POC testing to increase testing rates, and to explain why increased testing is important in eradicating lead exposure and lead poisoning.

BACKGROUND AND INTRODUCTION

Chapter 365 (House Bill 303), enacted by the Maryland General Assembly in 2013, established a Task Force to Study Point of Care Testing for Lead Poisoning. Exposure to lead remains the most significant and widespread environmental hazard for children in Maryland (MD). While the prevalence of elevated blood lead levels in children has declined significantly over the years, there are still children who continue to be exposed to lead through a variety of exposure sources. With the recognition that there are no "safe levels" of lead in the body, and in light of the US Centers for Disease Control and Prevention's (CDC) new recommendations making 5 micrograms per deciliter a level of concern, the challenge is how best to target testing of MD children. The goal of the Task Force was to study and make recommendations regarding the use of and reimbursement for point-of-care (POC) testing to screen and identify children with elevated blood-lead levels. The following information was to be included in the study:

- The benefits of point-of-care testing waived under the federal Clinical Laboratory Improvement Amendments (CLIA);
- The use of point-of-care testing in other states;
- Barriers to point-of-care testing, including regulatory barriers related to licensing of medical laboratories;
- Determining appropriate reimbursement for point-of-care testing and reporting; and
- Any other items the task force considers important relating to point-of-care testing.

The membership and meeting schedule of the Task Force are shown in Appendices 1 and 2.

LEAD POISONING AND LEAD TESTING IN MARYLAND

Lead poisoning and lead exposure remain significant public health problems in Maryland. In 2011, 110,539 Maryland children aged 0 – 72 months were tested for blood lead levels, of whom 364 (0.3%) were identified with a blood lead level ≥10micrograms per deciliter (µg/dL).[1] Overall, this represents a testing rate of 21.7% of the children born during this period who would be in the eligible age-range, state-wide. The highest testing rates for children 0-72 months were found in jurisdictions that require testing of all children at age 1 and 2 years, including Somerset County (34.3%), Baltimore City (33%), Allegany County (27.2%), and Worcester County (26.4%). A detailed breakdown of testing rates by jurisdiction is provided in Appendix 3.

A statute enacted by the Maryland General Assembly in 2000 requires testing of children at 12 and 24 months of age residing in "at risk" areas of the State.[2] Additionally, all children living in Baltimore City or children receiving Medicaid services, regardless of their residence in the State, are designated as "at risk" and are required to be tested. A lead exposure risk assessment questionnaire, assessing children for exposures to known sources of lead is also required of all children at their 12 and 24-month visits. Under MD law, a child under six years of age must

[1] Source: Maryland Department of the Environment. *Childhood Blood Lead Surveillance in Maryland, Annual Report 2012* ("MDE Annual Surveillance Report"). Accessed November 28, 2013 at: http://mde.maryland.gov/programs/Land/Documents/LeadReports/LeadReportsAnnualChildhoodLeadRegistry/LeadReportCLR2012.pdf.

[2] Md. Code Ann., Health-General § 18-106

have evidence of appropriate screening within 30 days of entering a child care center, family child care home, or nonpublic nursery school. In addition, the parent of a child who resides in or previously lived in an "at risk" area must provide documentation of lead testing at first enrollment into pre-kindergarten, kindergarten, or first grade.[3]

Concern about the overall state testing rate, and about testing rates in specific areas and populations, have been the focus of discussions in the Maryland Lead Poisoning Prevention Commission, and have also prompted DHMH to reassess the targeting strategy used to identify "at risk" areas.

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS AND THE WAIVER PROCESS

The U.S. Centers for Medicare & Medicaid Services is responsible for the regulation of all non-research laboratory testing on humans through the Clinical Laboratory Improvement Amendments process (commonly known as CLIA). CLIA requires that all entities that perform even one test, including a waived test on, "materials derived from the human body for the purpose of providing information for diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings" meet certain federal requirements. If any entity performs tests for these purposes, it is considered under CLIA to be a laboratory and must register with the CLIA program.

In accordance with COMAR 10.10.03.01, a person is required to possess a license before offering to perform or performing a medical laboratory test or examination in this State. Individuals performing such tests must apply for both the CLIA and Maryland lab license through the Office of Health Care Quality. The fees are $150 and $200 every two years for the CLIA and Maryland license respectively. Both are renewed every two years.

Currently in Maryland, blood lead testing in a clinical laboratory is a permitted, not excepted test, and requires enrollment in a proficiency testing program per COMAR 10.10.05.01. To have a test added to the excepted list requires recommending excepted test status to the Secretary's Laboratory Advisory Committee. The Laboratory Advisory Committee's responsibilities include making a recommendation to the Secretary in favor of or against granting a test excepted status. The pertinent regulation explaining this process can be found at COMAR 10.10.02.01 (E).

TECHNOLOGY OF POINT OF CARE LEAD TESTING

Lead exposure and lead poisoning are classically measured through the blood lead level (BLL). This test measures the amount of lead in blood. The test involves the following components:

- Sample collection – blood is obtained through a venipuncture sample (*venous*), which generally takes place in a provider office or commercial laboratory site; a collection with a *capillary* tube (again typically in a provider's office, it has the advantage of requiring a much smaller blood sample); or the collection of a blood spot on filter paper, which can

[3]Maryland Family Law Article 5-556.1

take place in virtually any setting. A key factor in test accuracy at this stage is the use of appropriate cleaning techniques, to prevent lead dust on the surface of either the skin or the sample collection equipment from contaminating and falsely elevating the reported lead result.

- Sample analysis – lead in the blood is measured by various techniques, commonly in commercial diagnostic laboratories by graphite furnace atomic absorption spectrometry. Important aspects of the test are the laboratory's internal quality analysis and quality control (QA/QC), as well as *proficiency testing*, which refers to a program in which an external agency sends an unknown sample periodically to the diagnostic laboratory for testing, thus providing a source of external quality checks on the diagnostic laboratory.

- Reporting – Once analyzed, the results must be reported to the health care provider. This can be done in some cases electronically directly from the instrument to a provider through electronic messaging; typically, it is through a fax or mailed (paper) report. Alternatively, the results may be displayed by the instrument and require transcription. In addition to reporting to the provider, in Maryland all blood lead tests for children must be reported to the Childhood Lead Registry, based at the Maryland Department of the Environment (MDE).

Point of care (POC) testing commonly refers to testing in which the test takes place in the location where the patient is being seen, although a distinction must be made between the collection of a sample and the processing of the test to determine the results of the test. Generally, POC testing refers to a system whereby the sample is collected, analyzed, and the results delivered all in the same location and same time that the patient is being evaluated. An example would be a urine dipstick test done in the provider's office while the patient is in the office.

In the case of blood lead tests, there are two systems commonly used for POC testing, although one only involves collection of the sample at the site, and so is not a true POC test as described above. This test, available from Tamarac Medical, Inc., involves collection of a small amount of blood on a filter paper, which is then sent to a laboratory for analysis and reporting. In this respect, although sample collection is simplified compared with either venous or capillary samples, there are still test attributes that resemble other non-POC tests – the sample must be sent to an offsite laboratory for analysis, then reported back to the provider.

The only US Food and Drug Administration (FDA) -approved POC test for blood lead in use today in the United States is manufactured by Magellan Diagnostics of Billerica, MA, currently being marketed as the LeadCare II. This device is a CLIA-waived POC test that involves collection of a blood sample (either capillary or venous), testing of a drop of blood by anodic stripping voltammetry (a technique to measure the amount of lead in blood by measuring the electric current needed to oxidize lead in the blood), and direct reporting to the operator by a visual display panel. Blood is collected either in a capillary tube or by venipuncture, then mixed with reagents and placed in the machine. The results are displayed directly by the machine.

It is important to recognize that the LeadCare II test is intended as a *screening* test only; if an elevated BLL is detected on screening, the provider must confirm the results through a venous blood level using a different approved laboratory method.

POTENTIAL BENEFITS OF POINT OF CARE TESTING IN MARYLAND

The Task Force heard from a number of health care providers and others about some of the advantages of POC testing. These included:

- ✓ Providers uniformly reported that the likelihood of getting a blood lead test is much higher with POC testing, due to the ease of testing in the office, the ability to provide immediate feedback to the patient and family, and the ability to perform a capillary blood draw, rather than a venous sample. In the absence of POC testing, patients receive a provider order for a lab test, go to the lab, have blood drawn, and wait for the sample to be sent to the lab, processed, and the results reported to the provider, and then wait for the provider to contact them or see them back again.

- ✓ With POC testing, the entire process takes place during one office visit, so if the BLL is not at or above the level of concern, and the patient and family learn the results immediately. If the BLL is below the reference value (5µgldL), the family is advised about the importance of prevention; if the BLL is of concern, the family is informed immediately and the patient is referred immediately for a confirmatory test. This also improves follow-up and reduces the time required to act on a confirmed elevated BLL.

- ✓ Because the number of separate provider and lab visits is fewer, the cost to the patient and family should be less. Less administrative staff time is needed to contact patients/families and arrange for follow-up visits. It is not clear whether insurers would realize savings from POC testing, however, because this depends on the rate of confirmatory testing needed, how many repeat office visits could be avoided in the alternative scenarios, the cost of commercial laboratory tests versus POC testing, and other variables.

- ✓ Improved compliance for blood lead testing.

- ✓ The effect of POC testing on patient flow through clinics and emergency departments may depend on whether the tests are incorporated as part of overall testing and vaccination. One provider reported to the Task Force that POC testing did not significantly affect the overall clinic flow, but this may depend on the frequency of testing and other factors.

BARRIERS TO POINT OF CARE TESTING IN MARYLAND

Technological Barriers

The Task Force identified a number of potential technical barriers, although it appears there are solutions for all of them. With respect to the accuracy of the lead POC test, it appears that the test has sufficient accuracy under normal operating conditions to serve as a valid screening device, when used as recommended by the manufacturer. The issues identified by the Task Force include:

Quality Assurance and Quality Control (QA/AC) – The reagent test kits come with sufficient reagent to do two QA/QC tests per 48-test kit. Questions were raised by Task Force members about whether the two QA/QC tests would be sufficient if the test kits were used slowly over a long period of time. Nothing was offered by other states or presenters that indicated this was a problem, but it might be an issue to be addressed in standard operating procedures or laboratory guidance.

Proficiency Testing –Proficiency testing is a way of ensuring the ongoing reliability of testing procedures. FDA's CLIA waiver means that proficiency testing is not required for the lead POC device. However, a number of states do require proficiency testing, and Maryland has previously approved other CLIA-waived tests for the Excepted list but required proficiency testing. A proficiency test requirement might slightly alter the economic and practice decisions of some providers, but probably not a large number.

Reporting –The Task Force noted that there is no direct electronic reporting capacity which would allow the test results to be reported directly to the Maryland Childhood Lead Registry (CLR). The software package developed by the manufacturer has a number of limitations which may make it problematic for practices to use, and this raises an issue for the expansion of POC tests. MDE currently allows providers to fax lead POC reports to the CLR. However, if use of lead POC devices increases, this would entail a significant data entry increase for the CLR, requiring additional personnel and increasing the opportunity for data entry errors.

Another possibility for reporting would be for the State to provide a direct data entry platform for provider offices, similar to Immunet, the immunization registry where providers enter and access vaccination information for their patients directly. This would also be an advantage for patients who may switch providers. The Task Force heard that the use of an Immunet-like system, or the direct coupling of blood lead test results with Immunization data was being done in a number of states, including Rhode Island, Wisconsin, Michigan, and New Jersey. The Task Force also heard from the CLR that there could be some issues of reporting accuracy with a direct coupling of the systems, but the concept was worthy of discussion. Another possibility, integration of lead reporting within provider electronic health records (EHRs) which could then be accessed

directly by the CLR, would require a series of technological and statutory innovations that are not yet available.

Economic Barriers

The Task Force heard that Medicaid rates for lead tests, which are based on Medicare, are not necessarily what all insurers will pay to reimburse practices for POC tests. The reimbursement rates vary considerably, from no additional reimbursement for some insurers that bundle payments for testing, to separate reimbursement for sample collection, POC test, and counseling provided by other MCOs.

The Task Force also had a discussion regarding value-based purchasing (VBP) and the metrics applied to Medicaid Managed Care Organizations (MCOs) to assess their performance. Some Medicaid MCOs have expressed concern about differences between Healthcare Effectiveness Data and Information Set (HEDIS) quality measures they report, and the measures for lead testing rates in place in Maryland Medicaid for VBP. According to Medicaid, the measures for VBP are more specific to Maryland, which has more lead poisoning and lead exposure than many other parts of the country. While this might not constitute an economic barrier for POC testing, it was raised by MCOs in the context of the Task Force's discussion, and is included here for consideration in that context.

Another potential barrier is that reimbursement for counseling based on the blood lead test may be different for health care providers providing the counseling in an obviously clinical location, than reimbursement for counseling that occurs in other locations such as a WIC clinic. The Task Force heard that in some cases where the counseling occurs in such a location, there may be difficulty in obtaining reimbursement for counseling services. The Task Force also heard that in some locations providers can charge a well-child care office visit, but are not permitted to use other evaluation and management (E/M) codes at the same time.

Regulatory Barriers

As noted in the section on CLIA and the waiver process (page 5), this POC test can be placed on the Excepted List for Maryland based on an assessment and recommendation from the Laboratory Advisory Committee to the Laboratories Administration. To date, the Laboratory Advisory Committee has not considered this issue. Task Force members and others raised a number of issues that might be considered by the Laboratory Advisory Committee, including:

- ✓ Quality control and proficiency testing – the Task Force heard from both members and others that FDA (or some other entity) should hold manufacturers accountable for incorporating QC and PT into waived test device design.

- ✓ Proper device use – Task Force members had questions about how to assure that providers complied with the manufacturers' instructions for device operation, particularly for quality assurance and quality control.

- ✓ Reporting to the Maryland Childhood Lead Registry – Task Force members want to ensure appropriate mechanisms to provide test results to surveillance programs, as required by Maryland law.

- ✓ Challenges in how to code tests for billing and mandatory reporting purposes.

Barriers and Opportunities at the Level of Providers

The Task Force heard that other states use a number of strategies to encourage the use of POC testing by providers. One such strategy involves integration of POC testing with the Women, Infants, and Children (WIC) program, which already does blood collection to assess hemoglobin levels. Wisconsin and several other states have been able to increase screening by integrating POC testing with WIC blood collection.

Another strategy was described by Wisconsin, in which MCOs created "opportunity reports" for providers, quality reports that summarized the experience of the provider compared to external and/or internal MCO benchmarks, or other appropriate internal/external comparisons. Each provider was periodically supplied with an "opportunity report" that tracked how the provider was doing in lead testing.

Finally, there was also discussion of whether lead testing would be considered a "standard of care" measure.

USE OF POINT OF CARE TESTING IN OTHER STATES

The Task Force dedicated an entire meeting to hearing from other states, and also looked at publically available data from other states. The experience of these states is instructive.

Wisconsin-- In 2005, less than one-third of Wisconsin Medicaid children received their mandatory tests for lead at one and two years of age. In 2008, heath care providers in Wisconsin started to use POC testing for lead and Medicaid MCOs worked together with WIC to pay for lead testing at WIC clinics. Some of the considerations that went into WIC's decision to adopt POC testing:

1. The WIC clinics were able to bill for the POC lab test, although this required discussions with Medicaid. They were also able to bill separately for blood draws for lead tests, doubling their reimbursement.
2. They were not always able to participate in proficiency training.
3. Transmitting all of the lead test results to the state lead registry was a hurdle that had to be overcome. The eventual solution involved incorporating the lead registry with the immunization registry.

Wisconsin has ongoing challenges, but overall results have been extremely positive and their Medicaid testing rates have increased by 40%. One of the biggest factors in improving testing rates has been to issue individual "report cards" with testing rates to every Medicaid provider. In

addition, Wisconsin found it very helpful to "marry" lead test data to their immunization registry, so that providers had access to both registries in a single application.

Texas – Texas also conducts blood lead POC testing through the WIC program; the regulations to do so were only changed within the past year. Medicaid has also put in an amendment related to POC test reimbursement rates. Although all providers are supposed to report their test results to the lead registry, billing data shows that providers are billing for more tests than they are reporting to the registry. Medicaid is planning corrective actions related to reporting, but the Task Force does not have the details of these proposals. The Texas Health Department sends a letter to providers using LeadCare II about the requirement to report all blood lead results. Providers send in paper reports, and many agencies (such as Head Starts) send a big batch of results for July – October during school enrollment. The Texas Health Department lead program is working with Texas Medicaid to increase reporting, but this remains problematic. They have seen an increase in higher blood lead levels, but don't know whether levels of 15 μg/dL and above levels are real or a result of user error in performing the test. One issue they have noted is that some POC tests are being confirmed with the same venous sample used for the original POC test (rather than a separate venipuncture). Texas does not require proficiency testing, but they do encourage staff training.

Massachusetts – Massachusetts has approximately 60 lead POC users. Very few are using POC testing for screening in the office; in most cases samples are batch tested at a central location. Massachusetts is confident about reporting, but requires proficiency testing. The test is currently considered to be a moderately complex test by the State Laboratory, similar to Maryland. Their experience with reporting of blood lead test results to the lead registry is similar to that of other POC systems. One problem they have identified is that it is difficult to distinguish a clinical lab with a LeadCare II device from a commercial laboratory provider. Massachusetts has also identified the need for a universal laboratory reporting system for electronic reporting. The free software currently available for the LeadCare II system has limitations. For example, the field for lead test results allowed only three characters, which in some cases required rounding of decimal results: for example, 24.7 became 24. Ordinarily, Massachusetts would consider that a result of 24.7 to be 25μg/dL, but it was rounded down in data base. Magellan, the LeadCare II manufacturer, was not interested in expanding or updating the software. Adding data by providers is a burden, so software upgrades would be very helpful. Generally, Massachusetts's experience is that 75% – 80% of children tested are between the age of 9 – 48 months (the state screening requirement). Massachusetts has very good compliance, in part because children cannot be enrolled in group or family day care without lead testing. Massachusetts uses a standard that is different from the American Academy of Pediatrics and the CDC recommendations because they determined that enough children were lead poisoned after age 2 to require testing up to age 4. Massachusetts is not necessarily supporting the use of POC testing with the LeadCare II, because of concerns about the lack of proficiency testing.

New Jersey– New Jersey requires testing at 12 months, 24 months, and any child between three and six years of age who has never previously been screened. With respect to POC lead tests, New Jersey is moving cautiously because of costs of testing and a desire to have administrative procedures in place. Currently, they are not treating the lead POC test as CLIA-waived, and require three rounds of proficiency tests. New Jersey is considering a waiver after two

successful rounds of required proficiency tests, and started a pilot project in May 2012, when they were able to trade Lead Care I for Lead Care II machines. New Jersey State Laboratories have also provided some standard operating procedures (SOPs), which they are reviewing with clinical laboratories. New Jersey is also doing memorandas of understanding (MOUs) with some local health department (LHD) pilot sites. According to these MOUs, a medical director must be onsite at the LHD and all elevated test results must have venous confirmation. New Jersey has been working with the manufacturer (Magellan) regarding reagent expiration. They also have some issues with reporting, involving de-duplication of test results by date of birth. In addition, they are working with the New Jersey Medicaid program on reimbursement rates and confirmation of Medicaid participants. Generally, they have found the provider community to be very receptive to lead POC testing, and are planning to expand their pilot to look at children under 6 and adults participating in recovery/reconstruction using post-hurricane Sandy funds. In summary, New Jersey is planning to expand the use of lead POC testing, but is working on specific issues/requirements:

- Proficiency testing – they currently require three rounds, but are moving towards requiring two rounds of testing;
- Results reporting to the State registry – they do know roughly where the machines are, but don't always know who is doing the testing or who is getting a test (name, DOB confirmation are issues).

REIMBURSEMENT FOR POINT OF CARE TESTING

The Task Force members solicited input from the provider community and other stakeholders to develop some rough cost figures for analysis of implementing and maintaining a POC testing program within a clinical practice. According to this information, an estimate of costs for running a lead POC testing program within a practice would include the following:

Table 1. Estimated operational costs for point of care testing for lead in Maryland.

Program Component	Cost	Comments
LeadCare II device	$1,850 - $2,059	
CLIA waiver registration	$150.00	Every 2 years
Maryland fee for lead testing	$200.00	Every 2 years
Maryland application fee for lead test	$100.00	Every 2 years
Test kits	$2,928	Based on 144 tests free with machine purchase, then 366 tests at $8/test
Staff time	$893	Based on 2 tests/day/provider, or 510 tests/year
Proficiency testing (if required)	$460.00	Based on data from Wisconsin
Total costs	$6,581 - $6,790	

Based on these assumptions, the Task Force estimates that with current Medicaid reimbursement rates of $12.52 per test, a practice would break even with 434 tests in the first year and 429 tests in the second year. With either a higher reimbursement rate or additional reimbursement for the sample collection, the breakeven point would occur even sooner. Additional details of the economic analysis are presented in Appendix 4.

Based on input from Task Force members, other states, and clinical practitioners, the testing could be incorporated in typical practices without significant difficulty or alteration of patient flow. One clinician noted that he was able to send all of his POC test results to the Maryland Childhood Lead Registry by fax, and the CLR was then able to enter the data manually. It should be noted that while it is likely that practices would be able to submit faxed reports to the CLR, it is not clear that the CLR has sufficient personnel to enter the additional test results, and there is also the issue of additional transcription/data entry errors with manual data entry.

FINDINGS AND RECOMMENDATIONS

The Task Force considered a number of options in making its recommendations. The options included:

Option 1: No changes to the current status of POC testing, which would leave it off the Excepted List, but still allowed.

Option 2: Encourage POC testing by urging the Laboratory Advisory Committee and the Laboratories Administration to place the LeadCare II test (or similar POC tests, if available in the future) on the Excepted List.

Option 3: Encourage POC testing by urging the Laboratory Advisory Committee and the Laboratories Administration to place the LeadCare II test (or similar POC tests, if available in the future) on the Excepted List, but with qualifications related to proficiency testing, quality assurance and quality control, and reporting to the Maryland Childhood Lead Registry, discussed above.

In addition, the Task Force noted some of the reimbursement issues that were raised in the course of the meetings and discussed potential recommendations related to those issues.

Based on evidence reviewed by the Task Force, the following findings and recommendations are offered.

Finding 1: Point of care testing has been used successfully in Maryland and other states. When used in conjunction with other incentives, POC testing appears to encourage testing of children for lead exposure.

The Task Force heard consistently that POC testing has been used successfully in other states and in Maryland as a test to screen patients for lead exposure. There appear to be no significant issues regarding its reliability or validity, and it has obtained approval from the FDA as a CLIA-waived test. The Task Force heard from other states about some striking examples of programs

that successfully used POC testing, in combination with other measures (outreach to providers, use of POC tests in WIC clinics, alterations in reimbursement formulas, report cards to providers on their individual testing rates), to increase the rate of lead testing for children. There is no reason to assume the same measures would not have similar effects in Maryland.

Recommendation 1: Maryland should encourage the use of POC testing for lead.

The Task Force heard consistent evidence from health care providers and other states that use of lead POC testing had led to increased testing rates, without any evidence that patient safety had been compromised. POC testing appears to make for a better experience for patients and their families through more immediate connection between test results, patient education and intervention, and improved satisfaction. To encourage lead POC testing, Maryland should consider reducing barriers discussed in Finding 2.

Finding 2: Administrative and technological barriers to the expanded use of POC testing for lead in Maryland include: (1) The current regulatory status of the LeadCare II device as a non-excepted CLIA-waived test, which is more restrictive than necessary to assure patient safety, and serves as a deterrent to increased use of the device; and (2) The lack of an easy mechanism with which to report POC test results to the Maryland Childhood Lead Registry.

According to the Laboratories Administration, the Laboratory Advisory Committee has not previously had a request to consider whether the LeadCare II device (or any other lead POC test) should be on the Excepted List.

Recommendation 2: The Task Force encourages the Laboratories Administration to consider ways of promoting the wider use of POC tests for lead, particularly by making it easier for providers to implement POC testing using either a LeadCare II CLIA-waived test, a filter paper Tamarac™ test, or any other future approved POC test. Any decision to encourage the wider use of POC testing for lead with the LeadCare II or another approved POC test should be made in conjunction with policies that address quality assurance/quality control, proficiency testing, the use of standard operating procedures and mandatory reporting to the Maryland Childhood Lead Registry.

The Task Force heard from experts, other states, practitioners, and the industry, that several issues should be considered in deciding whether to adopt widespread use of POC testing. The Task Force feels particularly strongly that in deciding whether to promote wider use of the LeadCare II device, the Laboratory Advisory Committee and Laboratories Administration should strongly consider the following:

(1) Users of the device should have standard operating procedures to supplement manufacturer's recommendations that guide issues such as quality control and quality assurance, transportation and location of the device, temperature control for reagents, etc.;

(2) Proficiency testing should be required as a condition of being on the Excepted list; and

(3) The manufacturer should be required or encouraged to address the issue of direct reporting of results to the Maryland Childhood Lead Registry, or there should be some other mechanism to ensure reporting to the Childhood Lead Registry.

Finding 3: It appears that with current reimbursement rates, health care providers should be able to recover the costs of lead POC tests with moderate testing frequency. However, there are potential economic barriers for certain providers, particularly those providers with small practices, and those whose managed care organization contracts do not specifically reimburse for either lead testing or sample collection. There may be additional disincentives if lead POC testing is carried out outside of provider offices.

Recommendation 3: The Task Force urges DHMH and MDE to consider additional practices to increase testing rates, including:

- Promotion of lead testing in WIC clinics;
- Working with Medicaid and private insurers to make testing easier through examining reimbursement rates and costs including reimbursement for sample collection; and
- Creation of "opportunity reports" for each provider, showing how that provider is doing relative to appropriate internal and external benchmarks.

Recommendation 4: Any decision to promote more widespread use of lead POC testing should be accompanied by an active outreach to providers, parents, members of the public, payors and others, to actively promote increased testing, and to explain why increased testing is important in eradicating lead exposure and lead poisoning.

The use of lead POC testing would make it easier for federally qualified health centers and other ambulatory care centers to extend testing to other at-risk populations, including older children not previously tested and pregnant women. The Task Force noted that the Maryland State Legislature might want to consider revising Maryland's requirements for blood lead testing in children up to age 6 for children who have not previously been tested. If testing takes place by age 2, no further testing is required.

The Task Force gratefully acknowledges the assistance of the following individuals who provided information about their state programs:

State	**Individuals**
Massachusetts Department of Public Health	Paul Hunter, Director, Childhood Lead Poisoning Prevention Program, Environmental Health Bureau Francine Medaglia, Clinical Coordinator, Childhood Lead Poisoning Prevention Program, Environmental Health Bureau

New Jersey Department of Health	Crystal Owensby, Coordinator, Child Health Program
Rhode Island Department of Health	Dr. Peter Simon, MD, MPH, Assistant Medical Director Rhode Island Department of Health
Texas Department of State Health Services	Teresa Willis, Blood Lead Surveillance, Environmental and Injury Epidemiology and Toxicology Unit
Wisconsin Department of Health Services	Charles Warzecha, Director of Environmental Health Margie Coons, Director, Lead Screening Program

Appendix 1. Membership of the Task Force on Point of Care Testing for Lead Poisoning

Clifford S. Mitchell, MS, MD, MPH (Chairman) – Director, Environmental Health Bureau, Prevention and Health Promotion Administration, Maryland Department of Health and Mental Hygiene

Paul Celli – Coordinator for Laboratory Licensing and Surveying, Office of Health Care Quality, Maryland Department of Health and Mental Hygiene

Shaketta Denson, Esquire. – Family Advocate Attorney, Coalition to End Childhood Lead Poisoning

Michael J. Ichniowski, MD – Maryland Chapter, American Academy of Pediatrics

Pat McLaine, DrPH, MPH, RN – Assistant Professor, University of Maryland School of Nursing, and Chairperson, Maryland Lead Poisoning Prevention Commission

Mary Mussman, MD, MPH – Physician Advisor, Office of the Deputy Secretary for Health Care Financing, Maryland Department of Health and Mental Hygiene

Honorable Shirley Nathan-Pulliam – Maryland House of Delegates

Honorable Nathaniel Oaks – Maryland House of Delegates

Amy Richardson, MD, MBA – Medical Director, Johns Hopkins HealthCare

Tina Wiegand – Manager, Childhood and Newborn Screening Program, Laboratories Administration, Maryland Department of Health and Mental Hygiene

APPENDIX 2. MEETING SCHEDULE OF THE TASK FORCE

- Meeting Dates:
  - September 26, 2013
  - October 1 9:00 AM
  - *October 3 Joint Meeting with Maryland Lead Poisoning Prevention Commission
  - October 10 9:00 AM
  - October 24 9:00 AM
  - November 14 9:00 AM
  - December 2 2:00 PM

APPENDIX 3. TESTING RATES FOR CHILDREN AGES 0 – 72 MONTHS BY JURISDICTION, 2012.

Blood Lead Testing of Children 0-72 Months by Jurisdiction in 2012[1]

County	Population of Children[2]	Children Tested		Children with BLL 5-9 µg/dL						Children with BLL >=10 µg/dL					
				Old Cases[3]		New Cases[4]		Total		Old Cases[5]		New Cases[6]		Total	
		Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Allegany	4,853	1,320	27.2	14	1.1	40	3.0	54	4.1	4	0.3	8	0.6	12	0.9
Anne Arundel	48,260	8,338	17.3	10	0.1	64	0.8	74	0.9	0	0.0	5	0.1	5	0.1
Baltimore	67,225	16,329	24.3	28	0.2	174	1.1	202	1.2	8	0.0	26	0.2	34	0.2
Baltimore City	56,701	18,717	33.0	424	2.3	800	4.3	1,224	6.5	71	0.4	148	0.8	219	1.2
Calvert	7,159	715	10.0	0	0.0	7	1.0	7	1.0	0	0.0	1	0.1	1	0.1
Caroline	3,234	773	23.9	1	0.1	13	1.7	14	1.8	0	0.0	2	0.3	2	0.3
Carroll	13,047	1,247	9.6	9	0.7	18	1.4	27	2.2	3	0.2	1	0.1	4	0.3
Cecil	9,047	1,221	13.5	2	0.2	12	1.0	14	1.1	0	0.0	0	0.0	0	0.0
Charles	13,254	1,963	14.8	1	0.1	11	0.6	12	0.6	0	0.0	3	0.2	3	0.2
Dorchester	2,797	694	24.8	3	0.4	15	2.2	18	2.6	0	0.0	1	0.1	1	0.1
Frederick	20,976	3,039	14.5	3	0.1	23	0.8	26	0.9	4	0.1	3	0.1	7	0.2
Garrett	2,225	427	19.2	1	0.2	5	1.2	6	1.4	1	0.2	0	0.0	1	0.2
Harford	21,100	2,979	14.1	5	0.2	29	1.0	34	1.1	1	0.0	5	0.2	6	0.2
Howard	24,707	2,500	10.1	1	0.0	24	1.0	25	1.0	3	0.1	3	0.1	6	0.2
Kent	1,406	243	17.3	1	0.4	6	2.5	7	2.9	0	0.0	2	0.8	2	0.8
Montgomery	89,202	20,515	23.0	18	0.1	151	0.7	169	0.8	9	0.0	15	0.1	24	0.1
Prince George's	81,273	20,417	25.1	26	0.1	196	1.0	222	1.1	3	0.0	17	0.1	20	0.1
Queen Anne's	3,868	494	12.8	0	0.0	13	2.6	13	2.6	0	0.0	2	0.4	2	0.4
Saint Mary's	10,618	1,634	15.4	2	0.1	26	1.6	28	1.7	0	0.0	1	0.1	1	0.1
Somerset	1,774	608	34.3	5	0.8	13	2.1	18	3.0	0	0.0	2	0.3	2	0.3
Talbot	2,648	606	22.9	2	0.3	6	1.0	8	1.3	1	0.2	2	0.3	3	0.5
Washington	12,691	2,675	21.1	17	0.6	102	3.8	119	4.4	0	0.0	0	0.0	0	0.0
Wicomico	8,582	2,154	25.1	9	0.4	35	1.6	44	2.0	0	0.0	4	0.2	4	0.2
Worcester	3,240	856	26.4	1	0.1	6	0.7	7	0.8	0	0.0	2	0.2	2	0.2
County Unknown[7]		75		0		3		3		1		2		3	
Total	**509,885**	**110,539**	**21.7**	**583**	**0.5**	**1,792**	**1.6**	**2,375**	**2.1**	**109**	**0.1**	**255**	**0.2**	**364**	**0.3**

1. The table is based on the selection of the highest venous or the highest capillary in the absence of any venous test.
2. Adapted from Maryland census population 2010, provided by the Maryland Data Center, Maryland Department of Planning, www.planning.maryland.gov/msdc.
3. Children with a history of a blood lead level of 5-9 µg/dL. These children may have carried over from 2011 or had a blood lead level of 5-9 µg/dL in previous years. Any child with a history of blood lead test of ≥10 µg/dL is not counted in this column
4. Children with the very first blood lead level of 5-9 µg/dL in 2012. These children were either not tested in the past or their blood lead levels were below 5 µg/dL. If a child had a blood lead test of ≥10 µg/dL in 2012 or in the past is not counted in this column.
5. Children with a history of a blood lead level ≥10 µg/dL. These children may have carried over from 2011 or had a blood lead test of ≥10 µg/dL in previous years.
6. Children with the very first blood lead test of ≥10 µg/dL in 2011. These children were either not tested in the past or their blood lead levels were below 10 µg/dL. This definition may not necessarily match the criteria for the initiation of case management.
7. Includes cases with out-of-state residence address at the time of the highest blood lead test.

APPENDIX 4. ECONOMIC ANALYSIS OF POC LEAD TESTING

Start-up Expense

COSTS*		
Component	**Cost**	**Remarks**
Lead Care II device	2058.79	(Based on current price quote)
CLIA waiver registration	150.00	(every 2 years)
MD fee for lead testing	200.00	(every 2 years)
MD Application fee	100.00	(every 2 years)
Proficiency testing	460.00	(from Wisconsin's cost)
Test kits	336.68	(Test per kit, based on current price quote)
TOTAL	2968.79	
REIMBURSEMENT		
Alternative 1	1802.88	Assumes $12.52/test reimbursement and first 3 test kits free (144 free tests)
Alternative 2:	3242.88	Assumes $12.52 and $10 collection fee/test reimbursement and first 3 test kits free (144 free tests)

Testing reimbursement/expense

Less staff time cost @$1.75/test -252.00

$2990.88

At this reimbursement rate, the start-up expense is fully covered after performing the initial 144 tests.

Each 48-test kit would reimburse $1080.96, with an expense of $336.68 for the kit and staff time of an additional $84 for a total expense of $420.68. This would net a practice $660.28 for every test kit at this level of reimbursement.