NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION PROGRAM

COMMENTS and RESPONSES to PROPOSED BLOOD LEAD STANDARDS

The Proposed Standards in the areas of Toxicology – Blood Lead were circulated for comment on April 1, 2016. The announcement was sent to NYS-permitted facilities that held or were in application for a permit (facilities). This distribution was by e-mail to the facility and laboratory contact person's e-mail address. The documents were posted to the CLEP website.

The comment period ended May 27, 2016. Three comments were received.

The standards are considered to be accepted and will be adopted and effective as of August 5, 2016.

Proposed Standard	Proposed Guidance
Blood Lead Sustaining Standard of Practice 12 (BL S12): Reporting In addition to the report requirements defined in Reporting Sustaining Standard of Practice 1 (Reporting S1): Report Content, the laboratory report must contain: a) the methodology used in analysis; and b) for test results on exposed adults, a reference interval of <5 ug/dL.	
Blood Lead ASV Sensors Sustaining Standard of Practice 13 (BLS S13): Reporting In addition to the report requirements defined in Reporting Sustaining Standard of Practice 1 (Reporting S1): Report Content, the laboratory report must contain: a) the methodology used in analysis; and b) for test results on exposed adults, a reference interval of <5 ug/dL.	

Comment 1:
Do the proposed changes apply to workplace exposure to lead where the samples are submitted using the blood lead standard profile?

Comment 2:
In regards to the new section BL S12 under Reporting (see below) it is requiring we place a specific reference interval on the final report for exposed adults, I would propose that a reference to OSHA's website for workplace information be substituted for a specific reference interval. For laboratories such as ours who service multiple states it would reduce conflict between varying state requirements.

RESPONSE 1:
The department's Center for Environmental Health (CEH) considers a blood lead level (BLL) of greater than or equal to 5 ug/dL to be elevated for all adults who have been exposed to lead including those with occupational exposures (see attached letter).

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Standard	Guidance
Blood Lead ASV Sensors Sustaining Standard of Practice 10 (BLS S10): Confirmatory Testing with LeadCare and/or LeadCare II When blood lead concentrations greater than or equal to 5 micrograms/dL are obtained from a venous sample the laboratory must either: a) if sufficient sample remains, refer the specimen to a NYS-permitted laboratory holding the permit category of Toxicology – Blood Lead - Comprehensive for confirmatory testing by a high complexity reference method (ICP-MS or GFAAS); or b) indicate on the report the method used and that the result needs to be confirmed by a high complexity reference method (ICP-MS or GFAAS).	a) An unopened venous specimen is preferable for confirmatory testing. When this is not possible or feasible (e.g. with young children), and the confirmed result is also elevated, the confirming laboratory can acknowledge the issue on the test report. Test result comment example: “The test specimen may have been compromised during previous testing. Result should be confirmed with another venous blood specimen.” b) Preliminary results may be released with a comment that results of confirmatory testing by a high complexity reference method are pending. b) Examples of reference methods include high complexity tests such as inductively coupled mass spectrometry (ICP-MS) and graphite furnace atomic absorption spectrometry (GFAAS). b) The following comment can be used on laboratory test reports to clinical health care providers: “For children 5 years old and younger, blood lead levels ≥5 µg/dl indicate that they may have been exposed to lead at levels higher than most children. The blood lead level should be confirmed using a venous blood sample and a NYS-permitted high complexity analytic method according the recommendations of the CDC Advisory Committee on Childhood Lead Poisoning Prevention. Since no safe BLL in children has been identified, no detectable level should be considered ‘normal’.”
Blood Lead ASV Sensors Sustaining Standard of Practice 11 (BLS S11): Confirmatory Testing with LeadCare Plus or LeadCare Ultra When blood lead concentrations greater than or equal to 40 micrograms/dL are obtained from a venous sample the laboratory must either: a) if sufficient venous blood remains, refer the specimen to a NYS-permitted laboratory holding the permit category of Toxicology – Blood Lead - Comprehensive for confirmatory testing by a high complexity reference method (ICP-MS or GFAAS); or b) indicate on the report the method used and that the result needs to be confirmed by a high complexity reference method (ICP-MS or GFAAS).	a) An unopened venous specimen is preferable for confirmatory testing. When this is not possible or feasible (e.g. with young children), and the confirmed result is also elevated, the confirming laboratory can acknowledge the issue on the test report. Test result comment example: “The test specimen may have been compromised during previous testing. Result should be confirmed with another venous blood specimen.” a) Preliminary results may be released with a comment that results of confirmatory testing are pending. b) Examples of reference methods include high complexity tests such as inductively coupled mass spectrometry (ICP-MS) and graphite furnace atomic absorption spectrometry (GFAAS). b) The following comment can be used on laboratory test reports to clinical health care providers: “For children 5 years old and younger, blood lead levels ≥5 µg/dl indicate that they may have been exposed to lead at levels higher than most children. The blood lead level should be confirmed using a venous blood sample and a NYS-permitted high complexity analytic method according the recommendations of the CDC Advisory Committee on Childhood Lead Poisoning Prevention. Since no safe BLL in children has been identified, no detectable level should be considered ‘normal’.”

Comment 1:
Under Proposed Standard, do you mean Confirmatory Testing "for" LeadCare and/or Leadcare II? Does this include the LeadCare Ultra analyzer?

Does Leadcare Ultra ("this analyzer is not intended for Point of Care use") follow the same proposed standards as the LeadCare and/or Leadcare II, it isn't specified.

The methodology being shown on the reports, is that internal or external report? Please clarify.

RESPONSE 1:
Blood Lead ASV Sensors Sustaining Standard of Practice 10 (BLS S10): Confirmatory Testing with LeadCare and/or LeadCare II defines the requirements for confirmatory testing of results obtained from a Lead Care or Lead Care II device.

Blood Lead ASV Sensors Sustaining Standard of Practice 11 (BLS S11): Confirmatory Testing with LeadCare Plus or LeadCare Ultra defines the requirements for confirmatory testing of results obtained from a Lead Care Plus or Lead Care Ultra device.

The Lead Care Plus and the Lead Care Ultra are both ASV screen-printed sensor devices and therefore would be subject to the body of standards proposed under Blood Lead – ASV Screen-Printed Sensors. Please note the name of the permit category for the 2016-2017 permit year changed from Blood Lead – Screening Tests Only to Blood Lead – ASV Screen-Printed Sensors, thereby removing any implication that the category relates to only point-of-care devices.

The reference to reporting in BLS S10 and BLS S11 refer to the report issued to the health care provider and patient.

NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

July 26, 2016

Reference range(s) for reporting blood lead test results on adults

Dear Laboratory Director:

There has been much debate in recent years regarding the most appropriate reference range for reporting blood lead (BPb) test results on adults, and even for older children (>6 years old). The debate has been driven by the recent change in the definition of elevated BPb levels for young children (≥5 µg/dL), that was recommended by the CDC's Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP). Indeed, in 2013 the CDC concurred with the ACCLPP recommendation that 5 µg/dL represents the definition of an elevated BPb level, based on the NHANES 97.5th percentile for the years 2007-2010, for children aged 6 months to 5 years.

The issue of adult BPb reference values and interpretive guidance has been the subject of discussion too, and some recommendations have been developed by other agencies. Some experts[i] have noted that there is, "considerable variability among laboratories regarding the content of such guidance", and they recommend no action be taken when BPb levels are <5 µg/dL. Interpretive guidance on report forms is recommended based on a BPb level range. The Council on State and Territorial Epidemiologists (CSTE) Occupational subcommittee has also adopted management guidelines for BPb levels in adults, based on the publication cited above.[ii] The CSTE guidance also recommended no action when BPb levels are <5 µg/dL. The National Institute of Occupational Safety and Health (NIOSH) and Occupational Safety and Health Administration (OSHA) support these guidelines.

Given that the 2011-2012 NHANES 95th percentile for adult BPb levels is 3.16 µg/dL, and that <5 µg/dL represents a consensus reference value for adult BPb levels, the NYS DOH is recommending that all clinical laboratories holding a NYS permit in Toxicology – Blood Lead use < 5 µg/dL as the BPb reference value, or the upper limit of the reference interval, on their test report forms for all specimens regardless of age. Interpretive guidance based on the BPb level can be added to test reports. The NYS DOH has developed "Management Guidelines for Blood Lead Levels in Adults in New York State" (appended) for use with BPb laboratory test reports. These guidelines are consistent with those recommended by the CSTE.

It is recognized that some clinical laboratories may cater to occupational health facilities, and so elevated BPb levels may be more common than for those laboratories specializing in pediatric BPb screening. The final decision on use of these management guidelines rests with the clinical laboratory director. Should you have any further questions regarding recommendations for clinical laboratory test reports for BPb, please contact Dr. Patrick Parsons, Chief, Laboratory of Inorganic and Nuclear Chemistry at the NYS DOH's Wadsworth Center (518-474-7161 or patrick.parsons@health.ny.gov). Questions regarding laboratory permits should be directed to the Clinical Laboratory Evaluation Program (CLEP) at Wadsworth (518- 485-5378), and

questions related to NYS' management guidelines for BPb levels in adults should be directed to Dr. Kitty Gelberg, Director, Bureau of Occupational Health and Injury Prevention, Center for Environmental Health, (518-402-7900 or kitty.gelberg@health.ny.gov) at the NYS DOH.

Sincerely,

Patrick J. Parsons, PhD.
Chief, Laboratory of Inorganic and Nuclear Chemistry,
Wadsworth Center

Kitty H. Gelberg, PhD
Director, Bureau of Occupational Health and Injury Prevention,
Center for Environmental Health

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[i] Kosnett MJ, Wedeen RP, Rothenberg SJ, et al. Recommendations for Medical Management of Adult Lead Exposure. *Environmental Health Perspectives* 2007;115(3):463-471. doi:10.1289/ehp.9784.

[ii] Management Guidelines for Blood Lead Levels in Adults (June 2013). Council of State and Territorial Epidemiologists (CSTE) Occupational Health Subcommittee. Atlanta, GA. Retrieved from HYPERLINK "http://c.ymcdn.com/sites/www.cste.org/resource/resmgr/OccupationalHealth/ManagementGuidelinesforAdult.pdf"