INFORMATION FOR STATE AND LOCAL LABORATORIES FOR IMPLEMENTING 3.5 µg/dL AS THE UPDATED CDC BLOOD LEAD REFERENCE VALUE

BACKGROUND

In 2012, CDC adopted a blood lead reference value (BLRV) as a way of identifying the 2.5% of U.S. children ages 1–5 at greatest risk of lead exposure. The BLRV is based on the 97.5th percentile of the BLL distribution among children 1–5 years old in the U.S. from the two most recent cycles of data from the National Health and Nutrition Examination Survey (NHANES). Thus, based on NHANES data from 2015–2018, CDC accepted the Lead Exposure and Prevention Advisory Committee (LEPAC) recommendation to update the BLRV to 3.5 µg/dL.

The new blood lead reference value (BLRV) of 3.5 µg/dL may create challenges for laboratories that perform blood lead testing. Some laboratories may need to

- reduce lower reporting limit policies,
- adopt new repeat testing practices,
- improve limits of detection of lab developed tests,
- acquire new instrumentation, and/or
- validate new laboratory-developed tests.

Laboratories and surveillance systems may need to be updated to report blood lead levels to the tenth of a µg/dL (i.e., X.X µg/dL) if they currently only report BLLs in integer values.

Laboratory Path Forward:

One possible impact of lowering the BLRV is the increase in laboratory workload due to additional repeat and confirmatory testing. Laboratory technology such as graphite furnace atomic absorption spectroscopy or inductively coupled plasma mass spectrometry (ICP-MS) has the sensitivity to detect blood lead below 3.5 µg/dL. Even if they are using these technologies, labs may need to improve their laboratory-developed test or change their lab policies to report down to the new level.

The current requirement is the Clinical Laboratory Improvements Amendments (CLIA) Proficiency testing criteria of ±4 µg/dL or ±10%, whichever is greater. Tighter criteria are being considered. This may require changes to laboratory practices to remain CLIA-compliant. Labs should also take extra steps to prevent common lead contamination in laboratory consumables and the laboratory environment to prevent false positives in reporting at these lower levels.

More than 100 laboratories participate in CDC's Lead and Multi-element Program (LAMP). LAMP demonstrates that programs can maintain quality assurance and accurately measure blood lead levels in compliance with current CLIA PT criteria. However, the success rate drops slightly when the criteria is ±2 µg/dL or ±10% (whichever is greater), the proposed new PT criteria. The lower reporting limits of blood lead testing labs in general range from 0.02 to 5 µg/dL[2].

Information Resources for Laboratories:

- Documents on the CDC lead program website
    - Appendix C "The Lead Lab" of CDC's 1997 document "Screening Young Children for Lead Poisoning: Guidance for State and Local Public Health Officials".

- Laboratory methods
    - CDC's Blood multi-element analysis by ICP-MS. Contact CDC/NCEH/DLS/IRAT for the latest analytical method documentation.[1]
- National and State Biomonitoring Grantees meetings
- Laboratory Response Network – Chemical (LRN-C) program
- Manufacturer instructions (for FDA-approved point of care tests)
- Association of Public Health Laboratories (APHL)
    - National biomonitoring network website and online Biomonitoring Toolkit and guidance documents
- Clinical and Laboratory Standards Institute (CLSI) standards documents
    - CLSI C40-A2 "Measurement Procedures for the Determination of Lead Concentrations in Blood and Urine; Approved Guideline - Second Edition" October 2013.
    - CLSI C40-A3 "Measurement Procedures for the Determination of Lead in Whole Blood," should be available late 2021 or early 2022.
- Proficiency testing and quality assurance programs
- Peer-reviewed journal articles and conference presentations

Information Sources:

- Proficiency Testing Programs and Quality Assurance Programs
    - Wisconsin State Laboratory of Hygiene's Blood Lead Regulatory proficiency testing program.
    - CDC's Laboratory Response Network – Chemical (LRN-C) proficiency testing program, administered by the Wisconsin State Laboratory of Hygiene
    - CDC's Lead and Multi-element Program (LAMP) quality assurance program
- Association of Public Health Laboratories (APHL) surveys
- Document C40-A2 "Measurement Procedures for the Determination of Lead Concentrations in Blood and Urine; Approved Guideline - Second Edition" October 2013 from the Clinical and Laboratory Standards Institute (CLSI). Version 3 of this document should be available late 2021 or early 2022.
- Appendix C "The Lead Laboratory" of CDC's document Screening Young Children for Lead Poisoning: Guidance for State and Local Public Health Officials (1997)
- "Guidelines for Measuring Lead in Blood Using Point of Care Instruments", Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP) 2013.

[1] Jones, D., et al. (2017). "Analysis of whole human blood for Pb, Cd, Hg, Se, and Mn by ICP-DRC-MS for biomonitoring and acute exposures." Talanta (Oxford) 162: 114–122.

[2]Limits of detection were summarized from information submitted to the CDC's LAMP Program.