The Updated CDC Blood Lead Reference Value (3.5 µg/dL):

Guidance For State and Local Public Health Laboratories

In September 2021, the US Centers for Disease Control and Prevention (CDC) formally adopted a lower blood lead reference value (BLRV) as a way of identifying the 2.5% of US children ages 1–5 at greatest risk of lead exposure. The revised CDC BLRV at 3.5 µg/dL is based on the 97.5th percentile of the blood lead level (BLL) distribution among children 1–5 years old in the US from the two most recent cycles of data from the National Health and Nutrition Examination Survey (NHANES).

The revised BLRV of 3.5 µg/dL is based on a **population statistic**, determined by tests conducted in a single laboratory using rigorous practices to minimize contamination and maintain testing quality. Some laboratories will find it challenging to meet this lower level using their current practices. Laboratory staff should review sampling and testing processes to identify opportunities for improvement and to determine realistic performance criteria for routine samples using state-of-the-art methods of analysis. Actions needed may include:

- Reviewing and implementing the recommendations of the Blood Lead Reference Value Workgroup
- Assessing current blood lead method uncertainty at 3.5 µg/dL
- Improving the current method precision, changing instrument software and LIMS databases to support the reporting and storing of test results to a tenth of a micro- gram per deciliter: ##.# µg/dL
- Developing strategies to reduce lead contamination in the testing laboratory, including use of certifed or pre-screened reagents and supplies
- Implementing more stringent internal quality assurance (QA)/quality control (QC) practices in anticipation of the tighter proposed CLIA performance criteria for blood lead PT results (±2 µg/dL or ±10%, whichever is greater)
- Revising internal lab QA/QC criteria for confirming elevated blood lead test results based on a repeat analysis and eliminating bench contamination errors
- Modifying clinical test reports to reflect the current reference value, 3.5 µg/dL

BLOOD LEAD REFERENCE VALUE TOOL

CDC's Blood Lead Reference Value screening tool is used to identify children who have higher levels of lead in their blood compared with most children. The reference value is not health-based and is not a regulatory standard. States independently determine action thresholds based on state laws, regulations and resource availability. CDC encourages healthcare providers and public health professionals to follow the recommended follow-up actions based on confirmed blood lead levels.

INFORMATIONAL 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
- 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" may be available late 2022.
- Proficiency testing and quality assurance programs
- Peer-reviewed journal articles and conference presentations

ADDITIONAL RESOURCE:

Recommendations for a Revised Blood Reference Value

Prepared by The Blood Lead Reference Value Workgroup for The Lead Exposure and Prevention Advisory Committee

[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.

Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

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