



CLINICAL AND
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STANDARDS
INSTITUTE

3rd Edition

CLSI C40™

Measurement Procedures for the Determination of Lead in Whole Blood

CLSI C40 provides recommendations on the measurement of lead (Pb) in whole blood, including specimen collection procedures and determination of Pb by graphite furnace atomic absorption spectrometry, anodic stripping voltammetry (based on disposable screen-printed electrode technologies), and inductively coupled plasma mass spectrometry. It also includes quality assurance and quality control guidance and information on proficiency testing programs and laboratory certification.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

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Abstract

Clinical and Laboratory Standards Institute C40—*Measurement Procedures for the Determination of Lead in Whole Blood* is intended for use by members of the medical laboratory community involved in the determination of lead (Pb) in blood, as well as by personnel involved in specimen collection. This guideline discusses the clinical significance of blood lead (BPb) measurements; specimen collection; and Pb determination by graphite furnace atomic absorption spectrometry, anodic stripping voltammetry (based on disposable screen-printed electrode technologies), and inductively coupled plasma mass spectrometry. It also discusses reference materials, QC procedures, and laboratory policies for BPb testing.

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Foreword

Lead (Pb) is a naturally occurring heavy metal, long known for its toxic effects on human health, especially in children. The determination of Pb in whole blood (ie, the blood lead [BPb] test) is considered the reference standard for assessing human exposure. Current methods of analysis are capable of measuring BPb at historically low concentrations and in very small sample volumes. Over the last 40 years, the blood lead level (BLL) deemed harmful to children has been lowered many times. In 2012, a blood lead reference value (BLRV) of 5 µg/dL (0.24 µmol/L) was adopted to identify children with BLLs that are higher than most children's levels.¹ Globally, population BLLs continue to decline as Pb is removed from products and thus from the environment. In 2019, updated data from the United States showed that the geometric mean for BPb had fallen to 0.820 µg/dL for the period 2015 to 2016. For children ages 1 to 5 years, the geometric mean BPb was 0.758 µg/dL for the same period, and the 95th percentile was 2.76 µg/dL. In 2021, a US public health organization lowered the BLRV from 5 µg/dL (0.24 µmol/L) to 3.5 µg/dL (0.17 µmol/L). This trend toward decreasing population BLLs has also been noted in other countries. Given that no safe BLL has been established, the importance of reporting results below 5 µg/dL (0.24 µmol/L) has only increased, along with a renewed interest in the accuracy, precision, and reliability of laboratory measurements. Better-quality BPb measurements are expected to support public health decision-making and mitigation efforts.

Overview of Changes

This guideline replaces CLSI C40-A2, published in 2013. Several changes were made in this edition, including:

- Adding detailed analytical procedures for BPb measurements based on inductively coupled plasma mass spectrometry
- Updating:
 - Information on the clinical and public health significance of BLLs < 5 µg/dL (0.24 µmol/L)
 - Guidance on anodic stripping voltammetry (ASV) devices that use disposable screen-printed electrode technologies
 - Guidance for laboratories on quality assurance practices at BLLs of 3.5 µg/dL
 - Current information on laboratory certification and proficiency testing programs (or external quality assessment) in the United States, Canada, and Europe, provided in Appendix A
 - The protocol for checking materials and specimen collection supplies for Pb contamination, provided in Appendix B
- Deleting:
 - The classic ASV procedure for older benchtop instrumentation
 - A procedure for urine Pb measurement, which is now considered redundant for clinical purposes

NOTE: The content of this guideline is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

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KEY WORDS

analysis

anodic stripping voltammetry

blood

electrothermal atomic
absorption spectrometry

graphite furnace atomic
absorption spectrometry

inductively coupled plasma
mass spectrometry

lead poisoning

quality control

reference materials

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Chapter ①

Introduction