



CLINICAL AND
LABORATORY
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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Clinical and Laboratory Standards Institute

P: +1.610.688.0100

F: +1.610.688.0700

www.clsi.org

standard@clsi.org

Measurement Procedures for the Determination of Lead in Whole Blood

Patrick J. Parsons, PhD, CChem, FRSC
Carl E. Wolf, PhD, MS, F-ABFT
Mahesheema Ali, MSc, PhD, NRCC, FAACC
Sanjib Bhattacharyya, PhD
Mary Jean Brown, ScD, RN
Saswati Das, MD, MBBS
Trivikram Dasu, PhD, D(ABMLI)
Adrienne S. Ettinger, ScD, MPH, MS, FACE
Montserrat Gonzalez-Estecha, MD, PhD
Guray Guven, PhD
Jeffery M. Jarrett, MS

Deanna M.R. Jones, PhD
Robert L. Jones, PhD
Juliane Lessard, PhD
Nelly Mañay, PhD
Fred Leland McClure, MSc, PhD, F-ABFT
Michelle McLean, MS, MLS(ASCP), BS
Karen E. Murphy, BS
Emily J. Pacer, MS
Christopher D. Palmer, PhD
Noel V. Stanton, MS
Daniel Zhou, MHA, MLS(ASCP)^{CM}, SC^{CM}

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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Committee Membership

Consensus Council

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Document Development Committee on Lead Determination in Whole Blood

Patrick J. Parsons, PhD, CChem, FRSC
Chairholder
New York State Department of Health
USA

Guray Guven, PhD
 Meridian Bioscience Inc.
 USA

Michelle McLean, MS, MLS(ASCP), BS
 Roche Diagnostics
 USA

Carl E. Wolf, PhD, MS, F-ABFT
Vice-Chairholder
VCU Health
USA

Robert L. Jones, PhD
 Centers for Disease Control and
 Prevention
 USA

Karen E. Murphy, BS
 National Institute of Standards and
 Technology
 USA

Mary Jean Brown, ScN, RN
Committee Secretary
Harvard Chan School of Public Health
USA

Jennifer Lowry, MD
 The Children's Mercy Hospital
 USA

Noel V. Stanton, MS
 Wisconsin State Laboratory of
 Hygiene
 USA

Montserrat Gonzalez-Estechea, MD, PhD
 Hospital General Universitario
 Gregorio Marañón; Sociedad Española
 de Medicina de Laboratorio SEQC-ML
 Spain

Nelly Mañay, PhD
 University of the Republic of Uruguay,
 Faculty of Chemistry
 Uruguay

Expert Panel on Clinical Chemistry and Toxicology

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Staff

Clinical and Laboratory Standards
 Institute
 USA

Laura Martin
Editorial Manager

Kristy L. Leirer, MS
Editor

Emily J. Gomez, MS, MLS(ASCP)^{CM}MB^{CM}
Program Manager

Catherine E.M. Jenkins, ELS
Editor

Lisa M.W. Walker, MS, ELS
Editor

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Mahesheema Ali, MSc, PhD, NRCC,
FAACC
The MetroHealth System; Case
Western Reserve University School of
Medicine
USA

Sanjib Bhattacharyya, PhD
City of Milwaukee Health Department
USA

Saswati Das, MD, MBBS
Ram Manohar Lohia Hospital
India

Trivikram Dasu, PhD, D(ABMLI)
Amazon Diagnostics
USA

Adrienne S. Ettinger, ScD, MPH, MS,
FACE
Centers for Disease Control and
Prevention
USA

Jeffery M. Jarrett, MS
Centers for Disease Control and
Prevention
USA

Deanna M.R. Jones, PhD
Centers for Disease Control and
Prevention
USA

Juliane Lessard, PhD
FDA Center for Devices and
Radiological Health
USA

Fred Leland McClure, MSci, PhD,
F-ABFT
USA

Emily J. Pacer, MS
New York State Department of Health
USA

Christopher D. Palmer, PhD
New York State Department of Health
USA

Charles Thornton, PhD
Meridian Bioscience Inc.
USA

Daniel Zhou, MHA, MLS(ASCP)^{CM}, SC^{CM}
UCSF Health
USA

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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

Chapter ①

Introduction