CLINICAL AND LABORATORY STANDARDS INSTITUTE®

7th Edition

GP42

Collection of Capillary Blood Specimens

This standard provides procedures for collection of capillary blood specimens. Specifications for collection sites, puncture depth, and disposable devices used to collect, process, and transfer capillary blood specimens are also included.

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

Clinical and Laboratory Standards Institute

Setting the standard for quality in medical laboratory testing around the world.

The Clinical and Laboratory Standards Institute (CLSI) is a not-for-profit membership organization that brings together the varied perspectives and expertise of the worldwide laboratory community for the advancement of a common cause: to foster excellence in laboratory medicine by developing and implementing medical laboratory standards and guidelines that help laboratories fulfill their responsibilities with efficiency, effectiveness, and global applicability.

Consensus Process

Consensus—the substantial agreement by materially affected, competent, and interested parties—is core to the development of all CLSI documents. It does not always connote unanimous agreement but does mean that the participants in the development of a consensus document have considered and resolved all relevant objections and accept the resulting agreement.

Commenting on Documents

CLSI documents undergo periodic evaluation and modification to keep pace with advances in technologies, procedures, methods, and protocols affecting the laboratory or health care.

CLSI's consensus process depends on experts who volunteer to serve as contributing authors and/or as participants in the reviewing and commenting process. At the end of each comment period, the committee that developed the document is obligated to review all comments, respond in writing to all substantive comments, and revise the draft document as appropriate.

Comments on published CLSI documents are equally essential and may be submitted by anyone, at any time, on any document. All comments are managed according to the consensus process by a committee of experts.

Appeal Process

When it is believed that an objection has not been adequately considered and responded to, the process for appeal, documented in the CLSI *Standards Development Policies and Processes*, is followed.

All comments and responses submitted on draft and published documents are retained on file at CLSI and are available upon request.

Get Involved—Volunteer!

Do you use CLSI documents in your workplace? Do you see room for improvement? Would you like to get involved in the revision process? Or maybe you see a need to develop a new document for an emerging technology? CLSI wants to hear from you. We are always looking for volunteers. By donating your time and talents to improve the standards that affect your own work, you will play an active role in improving public health across the globe.

For additional information on committee participation or to submit comments, contact CLSI.

Clinical and Laboratory Standards Institute
P: +1.610.688.0100
F: +1.610.688.0700
www.clsi.org
standard@clsi.org

GP42-Ed7
September 2020
Replaces GP42-A6

Collection of Capillary Blood Specimens

Nancy Glasgow-Erickson, PBT(ASCP)
Anne-Marie Martel, MT
J. Eric Stanford, MHA, MLS(ASCP)CM
Julia H. Appleton, MT(ASCP), MBA
Dennis J. Ernst, MT(ASCP), NCPT(NCCT)
Kimberly Jo Flexter, MT(AMT), MLT(ASCP), PBT(ASCP)
Sharon M. Geaghan, MD, FCAP
Mark D. Kellogg, PhD, MT(ASCP), DABCC, FAACC
Ruth E. McCall, BS, MT(ASCP)
Teresa A. Miller, BS
Kimberly Noble Piper, RN, BS, CPH, CPHG
Shrita A. Smith, MS, MT(ASCP)
Susan S. Smith, BA, CPT(ASPT)

Abstract

Clinical and Laboratory Standards Institute standard GP42—*Collection of Capillary Blood Specimens* provides procedures for collection of capillary blood specimens that contribute to the accuracy of the results and the safety of the patient and the health care professional. Specifications for collection sites, puncture depth, and disposable devices used to collect, process, and transfer capillary blood specimens are also included.

Clinical and Laboratory Standards Institute (CLSI). *Collection of Capillary Blood Specimens.* 7th ed. CLSI standard GP42 (ISBN 978-1-68440-090-4 [Print]; ISBN 978-1-68440-091-1 [Electronic]). Clinical and Laboratory Standards Institute, USA, 2020.

Suggested Citation

CLSI. *Collection of Capillary Blood Specimens.* 7th ed. CLSI standard GP42. Clinical and Laboratory Standards Institute; 2020.

Previous Editions:
July 1977, February 1979, March 1982, July 1986, July 1991, September 1999, June 2004, September 2008

GP42-Ed7

ISBN 978-1-68440-090-4 (Print)

ISBN 978-1-68440-091-1 (Electronic)

ISSN 1558-6502 (Print)

ISSN 2162-2914 (Electronic)

Volume 40, Number 12

Committee Membership

Consensus Council

James R. Petisce, PhD
Chairholder
BD Diagnostic Systems
USA

Mary Lou Gantzer, PhD, FACB
Vice-Chairholder
USA

Anne T. Daley, MS, MT(ASCP)DLM, CMQ/OE(ASQ)CSBB
ARUP Laboratories
USA

Avis Danishefsky, PhD
FDA Center for Devices and Radiological Health
USA

Collette Fitzgerald, PhD
Centers for Disease Control and Prevention
USA

Loralie J. Langman, PhD, DABCC, FACB, F-ABFT
Mayo Clinic
USA

Michelle McLean, MS, MT(ASCP), BS
Greiner Bio-One, Inc.
USA

Tania Motschman, MS, MT(ASCP)SBB
Laboratory Corporation of America
USA

M. Laura Parnas, PhD, DABCC
Roche Diagnostics
USA

Robert Rej, PhD
New York State Department of Health – Wadsworth Cente
USA

Matthew A. Wikler, MD, IDSA, MBA
IDTD Consulting
USA

Document Development Committee on Capillary Blood Collection

Nancy Glasgow-Erickson, PBT(ASCP)
Chairholder
USA

Anne-Marie Martel, MT
Vice-Chairholder
Canada

J. Eric Stanford, MHA, MLS(ASCP)CM
Committee Secretary
Vanderbilt University Medical Center
USA

Julia H. Appleton, MT(ASCP), MBA
Centers for Medicare & Medicaid Services
USA

Dennis J. Ernst, MT(ASCP), NCPT(NCCT)
Center for Phlebotomy Education
USA

Kimberly Jo Flexter, MT(AMT), MLT(ASCP), PBT(ASCP)
Sarah Bush Lincoln Health Center
USA

Sharon M. Geaghan, MD, FCAP
Stanford University School of Medicine
USA

Mark D. Kellogg, PhD, MT(ASCP), DABCC, FAACC
Boston Children's Hospital
USA

Ruth E. McCall, BS, MT(ASCP)
Central New Mexico Community College
USA

Teresa A. Miller, BS
Michigan Department of Health and Human Services
USA

Kimberly Noble Piper, RN, BS, CPH, CPHG
Iowa Department of Public Health
USA

Shrita A. Smith, MS, MT(ASCP)
BD Preanalytical Systems
USA

Susan S. Smith, BA, CPT(ASPT)
Sarstedt, Inc.
USA

Expert Panel on Preexamination Processes

Anne-Marie Martel, MT
Chairholder
Canada

Michelle McLean, MS, MT(ASCP), BS
Vice-Chairholder
Greiner Bio-One, Inc.
USA

Aparna Jha Ahuja, MD
BD Life Sciences – Preanalytical Systems
USA

Denise R. Cervelli, BA, BS, MT(ASCP)
Siemens Healthineers
USA

Judith Dixon, MS, MT(ASCP), BS
COLA
USA

Daniel Hesselgesser, MT(ASCP)
Centers for Medicare & Medicaid Services/CLIA Program
USA

Sharon Johnson
Mayo Clinic
USA

Nehal Mehta, MS
Roche Diagnostics Asia Pacific
Singapore

Estelle Ninneman, MT(ASCP)
ACL Laboratories
USA

Sheryl Thiessen, MT(ASCP), CLQM, BSMT, MLS(CSMLS), CLM
BC's Agency for Pathology and Laboratory Medicine
Canada

Elizabeth A. Wagar, MD
University of Texas, MD Anderson Cancer Center
USA

Staff

Clinical and Laboratory Standards Institute
USA

Katharine I. Castagna, MS, MT(ASCP) CT, MB
Project Manager

Jennifer K. Adams, MT(ASCP), MSHA
Project Manager

Megan L. Tertel, MA, ELS
Editorial Manager

Catherine E.M. Jenkins
Editor

Kristy L. Leirer, MS
Editor

Laura Martin
Editor

Contents

Abstract i
Committee Membership iii
Foreword vii
Chapter 1: Introduction 1
1.1 Scope 1
1.2 Standard Precautions 2
1.3 Terminology 2
Chapter 2: Capillary Blood Specimen Collection Process 5
2.1 Examination Request Is Received 7
2.2 Patient Is Registered 7
2.3 Patient Is Approached and Greeted 8
2.4 Patient Identification and Examination Request Are Verified at the Time of Collection 9
2.5 Precollection Requirements Are Assessed 10
2.6 Hand Hygiene Is Performed 11
2.7 Patient Is Assessed 11
2.8 Patient Is Positioned 12
2.9 Specimen Is Collected 14
2.10 Specimen Is Labeled 24
2.11 Postcollection Care Is Provided 26
2.12 Specimen Is Prepared and Transported 26
2.13 Gloves Are Removed and Hand Hygiene Is Performed 27
Chapter 3: Special Considerations 29
3.1 Analyte Variations Between Capillary Puncture and Venipuncture Specimens 30
3.2 Patients for Whom Capillary Puncture May Be Inappropriate 30
Chapter 4: Quality System Essentials 31
4.1 Organization and Leadership 32
4.2 Customer Focus 32
4.3 Facilities and Safety Management 32
4.4 Personnel Management 35
4.5 Equipment Management and Supplier and Inventory Management 35
4.6 Documents and Records Management 38
4.7 Information Management 38
4.8 Nonconforming Event Management 39

Contents (Continued)

4.9 Assessments 40
4.10 Continual Improvement 40
Chapter 5: Conclusion 41
Chapter 6: Supplemental Information 43
References 44
The Quality Management System Approach 50
Related CLSI Reference Materials 51

Foreword

Proper capillary blood collection and handling procedures are critical to accurately reflect patient physiology. This standard provides guidance for proper capillary blood collection procedures and processes to ensure the safety of the patient as well as the health care professional responsible for blood specimen collections. Maintaining a standardized collection procedure will help reduce preexamination errors.

Overview of Changes

This standard replaces the previous edition of the approved standard, GP42-A6, published in 2008. Several changes were made in this edition. One of the principal changes is content reorganization to reflect a process composed of multiple procedures, consistent with the incorporation of QMS principles into CLSI documents. This standard provides sequential procedures that make up the process of successful, safe capillary blood specimen collections. The quality system essentials (QSEs) are foundational building blocks that function effectively to support the laboratory's path of workflow. Adherence to the QSEs ensures that collection is performed at a higher level of overall quality. Other changes include:

- Providing greater detail on patient identification, registration, and specimen labeling processes
- Revising identification of proper puncture sites
- Expanding patient positioning instructions
- Updating figures
- Updating references

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

KEY WORDS

Arterialization
Blood
Capillary
Finger
Heel
Incision
Lancet
Microcollection
Puncture
Warming

This page is intentionally left blank.

Chapter 1

Introduction

This chapter includes:

- Standard's scope and applicable exclusions
- Standard precautions information
- Terminology information, including:
  - Terms and definitions used in the standard
  - Abbreviations and acronyms used in the standard

Collection of Capillary Blood Specimens

1 Introduction

1.1 Scope

This standard describes the process and related procedures for collecting diagnostic capillary blood specimens, including capillary blood gases. It is intended for health care professionals responsible for obtaining specimens from patients, as well as for manufacturers of capillary puncture and incision devices and microcollection containers. GP42 also establishes requirements for single-use disposable devices for collecting, processing, and transferring capillary blood specimens, including those for point-of-care testing. This standard does not cover capillary puncture procedures for self-testing, nor does it cover procedures for point-of-care testing.

1.2 Standard Precautions

Because it is often impossible to know what isolates or specimens might be infectious, all patient and laboratory specimens are treated as infectious and handled according to "standard precautions." Standard precautions are guidelines that combine the major features of "universal precautions and body substance isolation" practices. Standard precautions cover the transmission of all known infectious agents and thus are more comprehensive than universal precautions, which are intended to apply only to transmission of bloodborne pathogens. Published guidelines are available that discuss the daily operations of diagnostic medicine in humans and animals while encouraging a culture of safety in the laboratory.[1] For specific precautions for preventing the laboratory transmission of all known infectious agents from laboratory instruments and materials and for recommendations for the management of exposure to all known infectious diseases, refer to CLSI document M29.[2]

1.3 Terminology

CLSI, as a global leader in standardization, is firmly committed to achieving global harmonization whenever possible. Harmonization is a process of recognizing, understanding, and explaining differences while taking steps to achieve worldwide uniformity. CLSI recognizes that medical conventions in the global metrological community have evolved differently in different countries and regions and that legally required use of terms, regional usage, and different consensus timelines are all important considerations in the harmonization process. CLSI recognizes its important role in these efforts, and its consensus process focuses on harmonization of terms to facilitate the global application of standards and guidelines. Table 1 is provided to clarify the intended interpretations of the following terms.

Table 1. Common Terms or Phrases With Intended Interpretations

Term or Phrase	Intended Interpretation
"Needs to" or "must"	Explains an action directly related to fulfilling a regulatory and/or accreditation requirement or is indicative of a necessary step to ensure patient safety or proper fulfillment of a procedure
"Require"	Represents a statement that directly reflects a regulatory, accreditation, performance, product, or organizational requirement or a requirement or specification identified in an approved documentary standard
"Should"	Describes a recommendation provided in laboratory literature, a statement of good laboratory practice, or a suggestion for how to meet a requirement