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.

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Collection of Capillary Blood Specimens

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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.

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Contents

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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

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

2.9.1.1 Limitations for Capillary Puncture Site Selection

Limitations when the capillary puncture site is selected include but are not restricted to those listed in Table 3.

Table 3. Site Selection Limitations When a Capillary Blood Specimen Is Collected

Sites That Must Not Be Used	
Site	**Rationale**
Infected sites	• Potential for altered examination results • Exacerbation of infection • Patient discomfort
Fifth (smallest) finger	• Tissue depth is insufficient to prevent bone injury
Sites That Require Physician's Permission	
Site	**Rationale**
Limbs on the side of a mastectomy[16]	• Risk of lymphedema • Potential for altered examination results
Sites That Should Be Avoided	
Site	**Rationale**
Extensive scarring, healed burns	• Device insertion complications
Inflamed sites	• Patient discomfort and possible complications
Edematous sites	• Potential for altered examination results
Previous puncture sites	• Patient discomfort • Potential contamination from accumulated tissue fluid
Earlobes[17]	• Increased risk of accidental puncture through the thin flesh, especially in infants • Patient apprehension, because site is outside patient's field of vision
Thumb	• Possible arterial puncture or contamination • Lack of references to recommend this site

2.9.1.2 Capillary Blood Collection From Fingers

Fingers are acceptable capillary puncture sites for adults and older children.[18] Fingers of newborns and infants less than 6 months of age must not be used for capillary blood collection. The distance from the capillary surface to the bone in the thickest portion of the last segment of each finger of newborns varies from 1.2 to 2.2 mm. This short distance increases the risk of bone injury using currently available lancets. In newborns, local infection and gangrene are also potential complications of finger puncture.

For children between 6 and 12 months of age, the decision to use the finger instead of the heel must be based on the child's weight. For infants weighing more than 10 kg, the finger can be used as long as the lancet depth does not exceed 1.5 mm.[19-23] Using this depth accounts for the use of spring-loaded retractable devices and assumes

3 Special Considerations

3.1 Analyte Variations Between Capillary Puncture and Venipuncture Specimens

Capillary and venous blood serum can only be used interchangeably for certain tests. A comparison of capillary and venous specimens in fasting healthy adults showed inorganic phosphorus and urea concentrations to be identical, whereas total protein, bilirubin, calcium, sodium, and chloride concentrations were shown to be significantly lower (≥ 5%) in capillary than in venous serum. In nonhemolytic capillary sera, the potassium concentration was nearly the same as in venous specimens.[51] Glucose concentrations were higher in capillary than in venous serum.[52] These results were validated only in the studied patient population. Manufacturers' specifications and literature should be consulted when a specimen type is chosen. For newborns, capillary hemoglobin levels and hematocrit values are up to 12% higher than venous values on postnatal day one.[53]

3.2 Patients for Whom Capillary Puncture May Be Inappropriate

Patient conditions or physiological states that can negatively affect the quality or quantity of capillary blood specimens are presented below. Capillary blood collection may be inappropriate for:

- Patients who are severely dehydrated
- Patients with poor circulation
  - **NOTE:** Low blood pressure combined with poor peripheral circulation can complicate capillary blood specimen collection.
- Patients for whom plasma-based coagulation studies are required
- Patients for whom examinations require large volumes of blood (ie, erythrocyte sedimentation rate, blood cultures)
- Patients who present with a callus, skin ulceration, or blister at the intended puncture site
- Patients with thrombocytopenia and/or platelet abnormalities
- Patients with peripheral edema
  - **NOTE:** Tissue fluid can contaminate and/or dilute the blood specimen.
- Patients from whom blood gas measurements for pO_2 are needed to evaluate the gas exchange function of the lungs

CLSI document C46[39] provides detailed instructions and discussion of blood gases, pH analysis, and related measurements. The principal limitation of CBGs is poor capillary and arterial pO_2 correlation, a key parameter in the evaluation of critically ill patients.[54,55] CBGs underestimate patient oxygenation status in newborns, children, and sick adults.[33,54,56,57]

Patients with other physical conditions or specific diseases may necessitate the use of alternative methods of obtaining blood specimens.

Related CLSI Reference Materials[a]

AUTO12 **Specimen Labels: Content and Location, Fonts, and Label Orientation. 1st ed., 2011.** The purpose of this standard is to reduce human errors currently associated with the lack of standardization of labels on clinical laboratory specimens. The standard identifies the required human-readable elements to appear on specimen labels and specifies the exact locations, fonts, and font sizes of these elements.

C46 **Blood Gas and pH Analysis and Related Measurements. 2nd ed., 2009.** This document provides clear definitions of the quantities in current use, and provides a single source of information on appropriate specimen collection, preanalytical variables, calibration, and quality control for blood pH and gas analysis and related measurements.

GP33 **Accuracy in Patient and Specimen Identification. 2nd ed., 2019.** This standard specifies the processes required to ensure accurate patient and specimen identification in manual and electronic systems across the health care organization. Processes include system design considerations, differences in requirements for patients with or without identification bands, and provisions for patients with communication barriers.

GP41 **Collection of Diagnostic Venous Blood Specimens. 7th ed., 2017.** This standard provides procedures for the collection of diagnostic venous blood specimens, including line draws, blood culture collection, and venipuncture in children.

GP44 **Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests. 4th ed., 2010.** This document includes criteria for preparing an optimal serum or plasma sample and for the devices used to process blood specimens.

GP48 **Essential Elements of a Phlebotomy Training Program. 1st ed., 2017.** This guideline is a resource for health care professionals and educators for development and implementation of curricula for phlebotomy training programs and courses.

H07 **Procedure for Determining Packed Cell Volume by the Microhematocrit Method. 3rd ed., 2000.** This document describes a standard microhematrocrit method for determining packed cell volume; specifications for recommended materials and information on potential sources of error are also included.

H21 **Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays. 5th ed., 2008.** This document provides procedures for collecting, transporting, and storing blood; processing blood specimens; storing plasma for coagulation testing; and general recommendations for performing the tests.

[a] CLSI documents are continually reviewed and revised through the CLSI consensus process; therefore, readers should refer to the most current editions.

Related CLSI Reference Materials (Continued)

M29 **Protection of Laboratory Workers From Occupationally Acquired Infections. 4th ed., 2014.** Based on US regulations, this document provides guidance on the risk of transmission of infectious agents by aerosols, droplets, blood, and body substances in a laboratory setting; specific precautions for preventing the laboratory transmission of microbial infection from laboratory instruments and materials; and recommendations for the management of exposure to infectious agents.

NBS01 **Blood Collection on Filter Paper for Newborn Screening Programs. 6th ed., 2013.** This document highlights specimen collection methods, discusses acceptable techniques for applying blood drops or aliquots to the filter paper segment of the specimen collection device, and provides instructions on proper specimen handling and transport to ensure quality specimens are consistently obtained for newborn screening analysis.

QMS01 **A Quality Management System Model for Laboratory Services. 5th ed., 2019.** This guideline provides a model for medical laboratories to organize the implementation and maintenance of an effective quality management system.

QMS02 **Quality Management System: Development and Management of Laboratory Documents. 6th ed., 2013.** This document provides guidance on the processes needed for document management, including creating, controlling, changing, and retiring a laboratory's policy, process, procedure, and form documents in both paper and electronic environments.

QMS03 **Training and Competence Assessment. 4th ed., 2016.** This guideline provides a structured approach for developing effective laboratory personnel training and competence assessment programs.

QMS06 **Quality Management System: Continual Improvement. 3rd ed., 2011.** This guideline considers continual improvement as an ongoing, systematic effort that is an essential component of a quality management system. A continual improvement program may consist of fundamental processes and common supporting elements described in this guideline.

QMS11 **Nonconforming Event Management. 2nd ed., 2015.** Grounded in the principles of quality management, risk management, and patient safety, this guideline provides an outline and content for developing a program to manage a laboratory's nonconforming events.

QMS12 **Developing and Using Quality Indicators for Laboratory Improvement. 2nd ed., 2019.** This guideline describes how laboratories can develop and use quality indicators to measure and monitor performance of laboratory processes and identify opportunities for improvement.

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