CLINICAL AND LABORATORY STANDARDS INSTITUTE®

7th Edition

GP41

Collection of Diagnostic Venous Blood Specimens

This standard provides procedures for the collection of diagnostic venous blood specimens, including line draws, blood culture collection, and venipuncture in children.

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

Clinical and Laboratory Standards Institute

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

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Collection of Diagnostic Venous Blood Specimens

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Abstract

Clinical and Laboratory Standards Institute standard GP41—*Collection of Diagnostic Venous Blood Specimens* provides a descriptive, stepwise process and procedures reflecting the quality system essentials format for diagnostic venous blood specimen collection. Special considerations for collections from vascular access devices, blood culture collection, and collections in isolation environments are included, as well as how to handle emergency situations. An expanded appendix section provides helpful tips for collecting specimens from pediatric and other challenging patients.

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Foreword

Numerous errors can occur during the collection and handling of blood specimens, which pose significant and avoidable risks to the patient and the phlebotomist. When global standards are not fully implemented, it is more likely that patients will be injured during the procedure, biologically representative specimens will not be obtained from patients, and test results will not be comparable from one facility to another.

The process and procedures detailed in this standard are intended to prevent specimen collection errors that threaten specimen quality, protect health care professionals from accidental exposure, and prevent patients from the injuries, complications, and medical mistakes that can result from improperly collected specimens.

Since 1977, CLSI has recognized the importance of the preexamination phase of laboratory testing, including correct blood specimen collection and handling. Highly sophisticated testing technology cannot produce a good result from a poorly collected specimen.

Overview of Changes

This standard replaces the sixth edition of the standard (GP41-A6, formerly H03-A6), which was published in 2007. Many changes were made in this edition. One of the most prominent changes involved reorganizing the content into a process with multiple procedures, which is consistent with CLSI instilling QMS principles into its documents. This standard now articulates a sequence of chronological procedures that compose the process of successfully and safely performing a venipuncture. The QSEs are foundational building blocks that function effectively to support the laboratory's path of workflow. Although not all aspects of the QSEs may be mandatory to perform the venipuncture procedure, adherence to the QSEs ensures that the venipuncture is performed at a higher level of overall quality.

Other changes include:

- Greater detail on patient ID, specimen labeling, patient positioning, collecting from mastectomy patients, tourniquet use, adverse reactions, needle relocation, prioritizing veins in the antecubital area, and preventing iatrogenic anemia
- Changes to what constitutes acceptable venipuncture sites
- Significant revision of the information on collecting specimens from vascular access devices and during infusions
- Information on trace elements tubes in regards to the order of draw
- Comprehensive sections on remedies for difficult collections
- Updated references

KEY WORDS

Antecubital anatomy
Blood specimen
Complications from phlebotomy
Patient identification
Phlebotomist
Phlebotomy
Veins
Venipuncture

Chapter 1

Introduction

This chapter includes:

- Standard's scope and applicable exclusions
- Standard precautions information
- "Note on Terminology" that highlights particular use and/or variation in use of terms and/or definitions
- Terms and definitions used in the standard
- Abbreviations and acronyms used in the standard

Collection of Diagnostic Venous Blood Specimens

NOTE:

These procedures are intended as an appropriate model for adoption by all health care providers responsible for blood specimen collection in outpatient and inpatient settings.

1 Introduction

1.1 Scope

This standard establishes criteria for suitable venous blood specimen collection for medical laboratory testing. These procedures are intended as an appropriate model for adoption by all health care providers responsible for blood specimen collection in outpatient and inpatient settings.

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

1.3.1 A Note on 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.

The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system (QMS) approach in the development of standards and guidelines, which facilitates project management; defines a document structure using a template; and provides a process to identify needed documents. The QMS approach applies a core set of "quality system essentials" (QSEs), basic to any organization, to all operations in any health care service's path of workflow (ie, operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager's guide. The QSEs are as follows:

Organization	Personnel	Process Management	Nonconforming Event Management
Customer Focus	Purchasing and Inventory	Documents and Records	Assessments
Facilities and Safety	Equipment	Information Management	Continual Improvement

GP41 covers the QSE indicated by an "X." For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section.

Organization	Customer Focus	Facilities and Safety	Personnel	Purchasing and Inventory	Equipment	Process Management	Documents and Records	Information Management	Nonconforming Event Management	Assessments	Continual Improvement
						X					
						AUTO12					
		GP17									
						GP39					
						GP42					
						GP44					
						GP48					
						H21					
		M29									
						M47					
						NBS01					
QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01
							QMS02				
			QMS03								
											QMS06
									QMS11		
										QMS12	

Related CLSI Reference Materials*

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.

GP17 **Clinical Laboratory Safety. 3rd ed., 2012.** This document contains general recommendations for implementing a high-quality laboratory safety program, which are provided in a framework that is adaptable within any laboratory.

GP39 **Tubes and Additives for Venous Blood Specimen Collection. 6th ed., 2010.** This document contains requirements for venous blood collection tubes and additives, including technical descriptions of ethylenediaminetetraacetic acid (EDTA), sodium citrate, and heparin compounds used in blood collection devices.

GP42 **Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens. 6th ed., 2008.** This document provides a technique for the collection of diagnostic capillary blood specimens, including recommendations for collection sites and specimen handling and identification. Specifications for disposable devices used to collect, process, and transfer diagnostic capillary blood specimens are also included.

GP44 **Procedures for the Handling and Processing of Blood Specimens. 4th ed., 2010.** This document includes criteria for preparing an optimal serum or plasma specimen 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.

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

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.

* 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)

M47 **Principles and Procedures for Blood Cultures. 1st ed., 2007.** This document provides recommendations for the collection, transport, and processing of blood cultures as well as guidance for the recovery of pathogens from blood specimens taken from patients who are suspected of having bacteremia or fungemia.

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 **Quality Management System: A Model for Laboratory Services. 4th ed., 2011.** This document provides a model for medical laboratories that will assist with 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 **Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality. 1st ed., 2010.** This document provides guidance on development of quality indicators and their use in the medical laboratory.

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