

PRE04

Handling, Transport, Processing, and Storage of Blood Specimens for Routine Laboratory Examinations

This guideline includes criteria for assessing blood specimen quality and acceptability.

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 guideline PRE04—*Handling, Transport, Processing, and Storage of Blood Specimens for Routine Laboratory Examinations* discusses multiple variables that are involved in handling and processing blood specimens. Its application should enable the user to recognize and control accuracy and precision factors that occur between the time of blood collection and the time of examination performance.

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Foreword

Many factors encountered in the handling, transport, processing, and storage of blood specimens can affect the integrity of the specimen and alter the trueness of the measurand result. This guideline provides recommendations for optimizing the stability of many routine laboratory measurands throughout the total testing process. It also provides the rationale for accepting or rejecting a specimen based on the individual effects to a particular measurand when optimal conditions cannot be maintained. Recognition and control of these processes should reduce errors and contribute to the medical usefulness of patient examination results. Understanding the many ways that specimens can be affected helps the laboratory protect the quality of each specimen for its intended use.

This guideline emphasizes specimen quality, and it is intended to serve as a concise, understandable, single reference guide to manage variables that are within the laboratory's control and thereby limit the deterioration or alteration of the trueness of the measurand before it happens. When variations occur, the laboratory can still evaluate the suitability of a specimen for the requested examination without automatically rejecting the specimen.

Overview of Changes

This guideline replaces the previous edition of the approved guideline, GP44-A4, published in 2010. Several changes were made in this edition, including:

- Combining common information on specimen handling, transport, processing, and storage to eliminate redundancy and/or potentially contradictory information across CLSI documents (while detailed information for specific measurands and/or specimen types is retained in applicable CLSI documents.)
- Describing *in vitro* variables that can affect the integrity of blood specimens throughout the path of workflow
- Adding specimen suitability criteria that consider each measurand to be examined
 - Conditions that are not suitable for one measurand may still be acceptable for others.
- Adding information related to the quality system essentials (QSEs) described in CLSI document QMS01¹
 - The QSE-related content discusses equipment, including internal and external transport systems, refrigeration and freezer units, temperature monitoring systems, and nonconforming event management, which includes monitoring the occurrence of unsuitable specimens.

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.

KEY WORDS

centrifugation

handling

postcentrifugation

precentrifugation

processing

specimen integrity

transport

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Chapter ①

Introduction

Handling, Transport, Processing, and Storage of Blood Specimens for Routine Laboratory Examinations

1 Introduction

1.1 Scope

This guideline provides recommendations for appropriate handling, transport, processing, and storage of specimens used as whole blood, serum, or plasma for routine laboratory examinations. It is intended to cover the general principles of preserving and maintaining the *in vivo* characteristics of specimens so the laboratory can develop a discriminatory thought process for evaluating specimen integrity.

This guideline focuses on many of the variables related to the preexamination phase of the path of workflow that affect specimen quality. However, it does not include an in-depth discussion of collection considerations, such as proper patient preparation (eg, fasting status, time of collection, particularly for therapeutic drugs or measurands with diurnal variation), collection methods (eg, collecting specimens through intravenous catheters, length of time tourniquet is applied), and skill of the health care professional. These factors can also have a direct effect on the outcome of the eventual examination result. In specimen collection, nothing can replace the value of a properly identified patient and accurately labeled specimen to provide clinically useful information on which the health care provider (HCP) can base medical, diagnostic, and treatment decisions. See CLSI documents GP33² for patient identification and specimen labeling, GP41³ for the venipuncture collection procedure, and GP42⁴ for the capillary blood collection procedure.

The number of measurands and types of specimens used for medical laboratory examinations is broad. This guideline covers many of the measurands and specimen types in use. Although it includes new technologies and methodologies, it is not a comprehensive discussion of all possible blood specimen requirements. PRE04 also includes a detailed discussion of centrifugation and centrifuged specimen quality, taking into consideration the specimen collection tube, additives, temperature, time of applied force, and other conditions. In addition, guidance on temperature monitoring during transport is provided. This guideline can be used globally to standardize processes and to help laboratories meet accreditation and regulatory requirements related to maintaining the quality of blood specimens throughout the laboratory's path of workflow.

This guideline can assist laboratorians and other health care professionals to recognize factors that affect specimen quality so that many sources of error can be minimized or eliminated before the specimen is affected. The recommendations focus solely on blood specimens, but the principles can be applied to specimens in other laboratory areas as well.

Regulatory and accreditation requirements for transporting hazardous or dangerous materials are only minimally discussed in this guideline. This guideline does not cover handling, transport, processing, or storage of:

- Nonblood specimens
- Blood gas specimens (refer to CLSI document C46⁵)
- Coagulation specimens (refer to CLSI document H21⁶)
- Specimens for point-of-care testing
- Blood culture specimens (refer to CLSI document M47⁷)