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Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition

This document includes criteria for preparing an optimal serum or plasma sample and for the devices used to process blood specimens.

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

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Advancing Quality in Health Care Testing

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A document is published as a standard, guideline, or committee report.

Standard A document developed through the consensus process that clearly identifies specific, essential requirements for materials, methods, or practices for use in an unmodified form. A standard may, in addition, contain discretionary elements, which are clearly identified.

Guideline A document developed through the consensus process describing criteria for a general operating practice, procedure, or material for voluntary use. A guideline may be used as written or modified by the user to fit specific needs.

Report A document that has not been subjected to consensus review and is released by the Board of Directors.

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The CLSI voluntary consensus process is a protocol establishing formal criteria for

- The authorization of a project
- The development and open review of documents
- The revision of documents in response to comments by users
- The acceptance of a document as a consensus standard or guideline

Most documents are subject to two levels of consensus—"proposed" and "approved." Depending on the need for field evaluation or data collection, documents may also be made available for review at an intermediate consensus level.

Proposed A consensus document undergoes the first stage of review by the health care community as a proposed standard or guideline. The document should receive a wide and thorough technical review, including an overall review of its scope, approach, and utility, and a line-by-line review of its technical and editorial content.

Approved An approved standard or guideline has achieved consensus within the health care community. It should be reviewed to assess the utility of the final document, to ensure attainment of consensus (that comments on earlier versions have been satisfactorily addressed), and to identify the need for additional consensus documents.

Our standards and guidelines represent a consensus opinion on good practices and reflect the substantial agreement by materially affected, competent, and interested parties obtained by following CLSI's established consensus procedures. Provisions in CLSI standards and guidelines may be more or less stringent than applicable regulations. Consequently, conformance to this voluntary consensus document does not relieve the user of responsibility for compliance with applicable regulations.

COMMENTS

The comments of users are essential to the consensus process. Anyone may submit a comment, and all comments are addressed, according to the consensus process, by the committee that wrote the document. All comments, including those that result in a change to the document when published at the next consensus level and those that do not result in a change, are addressed by the committee in an appendix to the document. Readers are strongly encouraged to comment in any form and at any time on any document. Address comments to Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

VOLUNTEER PARTICIPATION

Health care professionals in all specialties are urged to volunteer for participation in CLSI projects. Please contact us at customerservice@clsi.org or +610.688.0100 for additional information on committee participation.

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Abstract

Clinical and Laboratory Standards Institute document H18-A4—*Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition* considers 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 test performance.

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Contents

Foreword

Several issues in the handling and processing of blood specimens are documented in the scientific literature.[1-12] Specific concerns relate to prolonged contact of serum or plasma with cells or with tube stoppers; hemolysis; measurand concentration changes due to evaporation; incorrect storage temperature; the use of anticoagulants and serum/plasma separator devices; incorrect transport; and turnaround time for patient results. Recognition and control of these variables should reduce error and contribute to the medical usefulness of patient test results.

Several changes were made in this edition; chief among them are an expanded discussion of measurand stability and centrifugation times; the introduction of the appendix, which lists acceptability of specimen testing for representative measurands after centrifugation within 24 and 48 hours of the time of collection; the introduction of Table 1, which provides information on the effect of hemolysis on laboratory tests; incorporation of information on hormone stability; precentrifugation phase handling and processing information for ribonucleic acid (RNA)–based molecular testing; postcentrifugation phase considerations for biobanking; and a new illustration of the relative centrifugal force nomograph. References were incorporated and updated throughout as appropriate.

Key Words

Centrifugation, handling, plasma, postcentrifugation, precentrifugation, processing, serum, specimen

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1 Scope

This guideline addresses handling and processing of blood specimens for examination procedures using serum, plasma, or whole blood in the clinical laboratory. The variables associated with precentrifugation, centrifugation, and postcentrifugation phases of specimen handling and processing are emphasized. Factors that can introduce test result inaccuracy or systematic bias after the specimen is collected but before the test is performed are discussed and performance criteria for *in vitro* diagnostic blood collection devices used to separate serum or plasma from cellular components are also addressed.

This guideline specifies criteria to assist the laboratory and other health care providers in recognizing and reducing or eliminating preexamination errors resulting from improper handling of blood specimens. When applicable, the recommendations should be considered by the following laboratory areas: chemistry, coagulation, hematology, immunology, ligand assay, serology, toxicology/therapeutic drug monitoring, virology, blood bank, and molecular or deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) analysis. Information provided in this document on handling and processing of blood specimens for coagulation, hematology, and virology is limited. Users are referred to the current version of applicable CLSI documents for more detailed discussion as appropriate.

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 blood-borne pathogens. Standard and universal precaution guidelines are available from the US Centers for Disease Control and Prevention.[13] 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 disease, refer to CLSI document M29[14] or other country-specific safety regulations.

3 Terminology

3.1 A Note on Terminology

CLSI, as a global leader in standardization, is firmly committed to achieving global harmonization wherever 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 the United States, Europe, and elsewhere; that these differences are reflected in CLSI, ISO (International Organization for Standardization), and European Committee for Standardization (CEN) documents; and that legally required use of terms, regional usage, and different consensus timelines are all important considerations in the harmonization process. In light of this, CLSI's consensus process for development and revision of standards and guidelines focuses on harmonization of terms to facilitate the global application of standards and guidelines.

In H18, the term *analyte* was changed to *measurand* to be consistent with accepted international usage.

