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Procedures for the Handling and Processing of Blood Specimens; Approved Guideline—Third 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 NCCLS consensus process.

NCCLS...

Global Consensus Standardization for Health Technologies

NCCLS is an international, interdisciplinary, nonprofit, standards-developing, and educational organization that promotes the development and use of voluntary consensus standards and guidelines within the healthcare community. It is recognized worldwide for the application of its unique consensus process in the development of standards and guidelines for patient testing and related healthcare issues. NCCLS is based on the principle that consensus is an effective and cost-effective way to improve patient testing and healthcare services.

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- the development and open review of documents
- the revision of documents in response to comments by users
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Healthcare professionals in all specialties are urged to volunteer for participation in NCCLS projects. Please contact the NCCLS Executive Offices for additional information on committee participation.

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Abstract

NCCLS document H18-A3—*Procedures for the Handling and Processing of Blood Specimens; Approved Guideline—Third 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.

Criteria for optimal serum, plasma, or whole blood samples are established, as well as criteria for the performance of *in vitro* devices used to process blood specimens. Implementation of recommended procedures should assist laboratories in the pursuit of excellent performance, with useful, accurate patient test results as the ultimate goal.

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Contents

Foreword

This guideline specifies criteria that should assist the laboratory and other healthcare providers in recognizing and reducing or eliminating preanalytic error resulting from improper handling of blood specimens. The document is the result of considerable discussion and comment; appropriate references are indicated.

Recognition of the need for procedures that address the different areas of specimen collection is evidenced by the following NCCLS documents:

- H1—*Tubes and Additives for Venous Blood Specimen Collection*;
- H3—*Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture*;
- H4—*Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens*;
- H11—*Procedures for the Collection of Arterial Blood Specimens*;
- H18—*Procedures for the Handling and Processing of Blood Specimens*; and
- H21—*Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays*.

In this document, certain abbreviations have been used: AST (aspartate aminotransferase, SGOT); ALT (alanine aminotransferase, SGPT); LD (lactic dehydrogenase, LDH); CK (creatine kinase, CPK); APTT (activated partial thromboplastin time); T3 (tri-iodothyronine); T4 (thyroxine); and PCV (packed cell volume).

This document replaces the second-edition approved guideline, H18-A2, which was published in 1999. A number of changes have been made in this edition; chief among them is the expansion of the recentrifugation section to include gel and non-gel tubes (see Section 6.2.3). The recommendation that gel tubes should not be used for the collection of ionized calcium specimens has been deleted from Section 7.5 for consistency with NCCLS document C31—*Ionized Calcium Determinations: Precollection Variables, Specimen Choice, Collection, and Handling.*

Key Words

Chilled specimens; criteria for specimen rejection; handling and processing specimens; precentrifugation, centrifugation, and postcentrifugation phases; serum or plasma contact with clot or cells; serum/plasma separator devices; tube closure

Procedures for the Handling and Processing of Blood Specimens; Approved Guideline—Third Edition

1 Scope

This guideline addresses handling and processing of blood specimens for analytical determinations 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. Where 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 DNA analysis.

2 Introduction

This guideline addresses the multiple factors associated with handling and processing blood specimens. These factors can introduce test result inaccuracy or systematic bias after the specimen has been collected but before the test is performed. Performance criteria for *in vitro* diagnostic blood collection devices used to separate serum or plasma from cellular components are also addressed.

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; analyte concentration changes due to evaporation; incorrect storage temperature; the use of anticoagulants and serum/plasma separator devices; incorrect transport; and turnaround time (TAT) for patient results. Recognition and control of these variables should reduce error and contribute to the medical usefulness of patient test results.

3 Standard Precautions

Because it is often impossible to know what 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 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 U.S. Centers for Disease Control and Prevention (*Guideline for Isolation Precautions in Hospitals.* Infection Control and Hospital Epidemiology. CDC. 1996;17(1):53-80 and *MMWR* 1988;37:377-388). For specific precautions for preventing the laboratory transmission of all infectious agents from laboratory instruments and materials and for recommendations for the management of exposure to all infectious disease, refer to the most current edition of NCCLS document M29—*Protection of Laboratory Workers from Occupationally Acquired Infections*.

4 Definitions

Accuracy (of measurement) – Closeness of the agreement between the result of a measurement and a true value of the measurand (VIM93).[13]

Analyte – Component represented in the name of a measurable quantity (ISO 17511)[14]; **NOTES:** a) In the type of quantity "mass of protein in 24-hour urine," "protein" is the analyte. In "amount of substance of glucose in plasma," "glucose" is the analyte. In both cases, the long phrase represents the **Measurand**