H21-A5
Vol. 28 No. 5
Replaces H21-A4
Vol. 23 No. 35

Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline—Fifth Edition

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

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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.

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- the authorization of a project
- the development and open review of documents
- the revision of documents in response to comments by users
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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.

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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.

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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.

H21-A5
ISBN 1-56238-657-3
Volume 28 Number 5 ISSN 0273-3099

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Abstract

Clinical and Laboratory Standards Institute H21-A5—*Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline—Fifth Edition* is an update of the previous edition published in 2003. The guideline provides procedures for the collection, transport, and processing of blood specimens for plasma-based and molecular coagulation testing. Tests of the coagulation system are very sensitive to storage (time and temperature), concentration of anticoagulant, and surface of containers; attention to these parameters is important. H21-A5 is primarily directed toward laboratory and/or clinical personnel responsible for obtaining patient specimens and preparing samples for plasma-based or molecular coagulation testing.

Clinical and Laboratory Standards Institute (CLSI). *Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline—Fifth Edition.* CLSI document H21-A5 (ISBN 1-56238-657-3). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2008.

Suggested Citation

(CLSI. *Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline—Fifth Edition.* CLSI document H21-A5. Wayne, PA: Clinical and Laboratory Standards Institute; 2008.)

Proposed Guideline
September 1980

Tentative Guideline
January 1982

Approved Guideline—First Edition
December 1986

Approved Guideline—Second Edition
December 1991

Approved Guideline—Third Edition
December 1998

Approved Guideline—Fourth Edition
December 2003

Approved Guideline—Fifth Edition
January 2008

ISBN 1-56238-657-3
ISSN 0273-3099

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Contents

Foreword

Because of the many variables that can affect coagulation test results, CLSI has made available this guideline, which describes procedures for collection, transport, preparation, and storage of samples for plasma-based coagulation assays and molecular hemostasis testing. This publication should enhance the uniformity of sample collection, preparation, and handling and, thereby, reduce many of the preanalytical variables that can affect the test results.

This document replaces the fourth edition of the approved guideline, H21-A4, which was published in 2003. Several changes were made in this edition; chief among them is the revision of transportation and storage guidelines for plasma-based hemostasis testing and the addition of information pertinent to the collection, transportation, and processing of specimens for molecular hemostasis assays.

Key Words

Activated partial thromboplastin time, citrate, coagulation, preanalytical variables, prothrombin time, sample storage, specimen collection, specimen transport

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1 Scope

This guideline covers the procedures for the collection, transport, and processing of specimens for plasma-based coagulation and molecular hemostasis tests. Many variables, including anticoagulant volume and concentration, type of tube additive, duration and temperature of specimen storage, and surface of containers used for specimen collection and storage, may affect plasma-based coagulation test results. The reliability and accuracy of molecular test results also depend upon a variety of specimen collection, transport, and storage factors. The molecular testing in this document refers to DNA testing only.

The document is directed toward laboratory and/or clinical personnel responsible for obtaining and preparing patient specimens and for plasma-based coagulation and molecular hemostasis testing. It is also aimed at manufacturers of products involved in specimen collection, storage, preparation, and testing of plasma-based or molecular hemostasis assays. This document does not address whole blood clotting tests, platelet function tests, or point-of-care testing. H21-A5 does not provide general guidelines for the performance of coagulation testing. Performance guidelines for specific coagulation assays are addressed in other CLSI documents, such as those for PT and APTT assays (ie, H47[1]) and fibrinogen assay (ie, H30[2]).

2 Introduction

A procedural guideline for the collection, transport, and processing of specimens for plasma-based coagulation and molecular hemostasis tests is necessary, as many preanalytical variables may affect test results (eg, concentration and volume of anticoagulant or additive; specimen and sample storage time and temperature). Because important diagnostic and therapeutic decisions are based on the results of hemostasis assays, a procedural guideline for the collection, transport, and processing of specimens for the general performance of plasma-based coagulation and molecular hemostasis assays is warranted.

3 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 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.[3] 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 CLSI document M29.[4]

4 Definitions

activated partial thromboplastin time (APTT) – the time, in seconds, required for a fibrin clot to form in a plasma sample after appropriate amounts of calcium chloride, and a partial thromboplastin reagent (phospholipid plus a contact activator), are mixed with the sample; **NOTE:** The APTT measures the intrinsic and common coagulation pathways.

