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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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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.

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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.

Related CLSI Reference Materials*

C28-A2 **How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline—Second Edition (2000).** This document provides guidance for determining reference values and reference intervals for quantitative clinical laboratory tests.

GP2-A5 **Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition (2006).** This document provides guidance on development, review, approval, management, and use of policy, process, and procedure documents in the medical laboratory community.

H1-A5 **Tubes and Additives for Venous Blood Specimen Collection; Approved Standard—Fifth Edition (2003).** 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.

H3-A6 **Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Sixth Edition (2007).** This document provides procedures for the collection of diagnostic specimens by venipuncture, including line draws, blood culture collection, and venipuncture in children.

H30-A2 **Procedure for the Determination of Fibrinogen in Plasma; Approved Guideline—Second Edition (2001).** This document provides general guidelines for performing the fibrinogen assay in the clinical laboratory. It also includes reporting of results and *in vivo* and *in vitro* conditions that may alter results.

H47-A **One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test; Approved Guideline (1996).** This document provides guidelines for performing the PT and APTT tests in the clinical laboratory, for reporting results, and for identifying sources of error.

H51-A **Assays of von Willebrand Factor Antigen and Ristocetin Cofactor Activity; Approved Guideline (2002).** This guideline describes the following: appropriate test specimens; reagents and materials; methods of platelet agglutination and ELISA; preparation of reference curves; determination of reference intervals; quality control procedures; result interpretation; and sources of error for assays of von Willebrand factor antigen and ristocetin cofactor activity. A brief description of von Willebrand disease and its various subtypes is included, as well as a list of references to more comprehensive reviews of this commonly inherited and rarely acquired bleeding disorder.

M29-A3 **Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition (2005).** 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.

MM1-A2 **Molecular Diagnostic Methods for Genetic Diseases; Approved Guideline—Second Edition (2006).** This document provides guidance for the use of molecular biological techniques for clinical detection of heritable mutations associated with genetic disease.

MM5-A **Nucleic Acid Amplification Assays for Molecular Hematopathology; Approved Guideline (2003).** This guideline addresses the performance and application of assays for gene rearrangement and translocations by both polymerase chain reaction (PCR) and reverse-transcriptase polymerase chain reaction (RT-PCR) techniques and includes information on specimen collection, sample preparation, test reporting, test validation, and quality assurance.

MM13-A **Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods; Approved Guideline (2005).** This document provides guidance related to proper and safe biological specimen collection and nucleic acid isolation and purification. These topics include methods of collection, recommended storage and transport conditions, and available nucleic acid purification technologies for each specimen/nucleic acid type.

* Proposed-level documents are being advanced through the Clinical and Laboratory Standards Institute consensus process; therefore, readers should refer to the most current editions.

