H21-A4
Vol. 23 No. 35
Replaces H21-A3
Vol. 18 No. 20

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

This document provides procedures for collecting, transporting, and storing blood; processing blood specimens; storage of plasma for coagulation testing; and general recommendations for performing the tests.

A guideline for global application developed through the NCCLS consensus process.

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H21-A4
ISBN 1-56238-521-6
Volume 23 Number 35 ISSN 0273-3099

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

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Abstract

NCCLS document H21-A4—*Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays; Approved Guideline—Fourth Edition* is an update of the previous edition published in 1998. The guideline provides procedures for the collection, transport, and processing of blood specimens for 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-A4 is primarily directed toward laboratory and/or clinical personnel responsible for obtaining patient specimens and preparing plasma for analysis by coagulation testing.

NCCLS. *Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays; Approved Guideline—Fourth Edition.* NCCLS document H21-A4 (ISBN 1-56238-521-6). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003.

Suggested Citation

(NCCLS. *Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays; Approved Guideline—Fourth Edition.* NCCLS document H21-A4 [ISBN 1-56238-521-6]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003.)

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

ISBN 1-56238-521-6
ISSN 0273-3099

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Acknowledgement

The NCCLS gratefully acknowledges the working group for their help in preparing the approved-level, fourth edition of this guideline.

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Contents

Foreword

NCCLS document H21-A4 is part of a series of guidelines involving methodology in blood coagulation testing. Because of the many variables that can affect coagulation test results, the Subcommittee on Coagulation concluded that it would be advantageous to provide a guideline which describes procedures for collection, storage, and preparation of blood or plasma before and during coagulation testing. This publication should increase the uniformity of coagulation testing and, thereby, reduce many variables that can affect the test results. Other publications in the series deal with specific coagulation assays such as the prothrombin time test, the activated partial thromboplastin time test, the fibrinogen assay, coagulation factor assays, and bleeding time test, as well as other assays.

The working group wishes to thank all commenters for their recommendations on the third-edition approved guideline (H21-A3). The Area Committee on Hematology urges users to submit comments related to experience in using H21-A4 to assure future editions reflect the "state of the art." Each comment will be carefully reviewed, and changes will be made where appropriate. NCCLS is dedicated to quality clinical laboratory services, and this guideline covers one of the many areas in which recommendations are being developed to help achieve this end.

This document replaces the third edition approved guideline, H21-A3, which was published in 1998. Several changes have been made in this edition; chief among them is the revised platelet count limit for the platelet poor plasma used in PT, APTT, and TT tests (Section 5.1). This guideline also contains revised recommendations regarding specimen storage (Section 5.2). The recommendations regarding the collection of coagulation specimens (Section 4.1) have been revised for consistency with NCCLS document H3—*Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard.*

Key Words

Activated partial thromboplastin time, citrate, coagulation, coagulation factors, control (plasma), fibrinogen, prothrombin time, sample storage, specimen collection, specimen transport, thrombin time

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

1 Scope

This guideline covers the procedures for the collection, transport, and processing of specimens for coagulation tests. Many variables, including anticoagulant amount and concentration, specimen and sample storage, and surface of containers, may affect test results. The document is directed toward laboratory and/or clinical personnel responsible for obtaining patient specimens and preparing plasma for analysis by coagulation testing. It is also aimed at manufacturers of products involved in specimen collection, storage, and preparation for coagulation testing. This document does not address whole blood clotting tests or point-of-care testing. In addition, H21-A4 provides general guidelines for performance of coagulation testing. Performance guidelines for specific coagulation assays are addressed in other NCCLS documents, such as those for PT and APTT assays (i.e., H47—*One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test*) and fibrinogen assay (i.e., H30—*Procedure for the Determination of Fibrinogen in Plasma*).

Standard Precautions

Because it is often impossible to know what might be infectious, all human blood specimens are to be 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 any pathogen and thus are more comprehensive than universal precautions which are intended to apply only to transmission of blood-borne pathogens. Standard precaution 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;Vol 17;1:53-80), (MMWR 1987;36[suppl 2S]2S-18S), and (MMWR 1988;37:377-382, 387-388). For specific precautions for preventing the laboratory transmission of blood-borne infection from laboratory instruments and materials and for recommendations for the management of blood-borne exposure, refer to the most current edition of NCCLS document M29—*Protection of Laboratory Workers from Occupationally Acquired Infections.*

2 Introduction

A procedural guideline for the collection, transport, and processing of specimens for coagulation tests is necessary, as many variables may affect test results (e.g., concentration and amount of anticoagulant, specimen and sample storage time and temperature, the surface of containers in which the specimen is obtained and stored). Because important diagnostic and therapeutic decisions are based on the results of coagulation tests, a procedural guideline for the collection, transport, and processing of blood specimens for the general performance of coagulation assays is warranted.

3 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, a partial thromboplastin reagent, and a wettable surface have been mixed with the sample; **NOTE:** The APTT measures the intrinsic and common coagulation pathways.