



POCT14-A

Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline

This document provides guidance to users and manufacturers of point-of-care coagulation devices for monitoring heparin and warfarin anticoagulant therapy, and to ensure reliable results comparable to those obtained by routine clinical laboratory testing.

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Clinical and Laboratory Standards Institute
950 West Valley Road, Suite 2500
Wayne, PA 19087 USA
P: 610.688.0100
F: 610.688.0700
www.clsi.org
standard@clsi.org

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Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline

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J. Heinrich Joist, M.D., Ph.D.
Jack E. Ansell, M.D.
George G. Despotis, M.D.
Frank LaDuca, Ph.D.
Richard A. Marlar, Ph.D.
Ginette Y. Michaud, M.D.
David L. Phillips
Paula J. Santrach, M.D.

Abstract

Point-of-care coagulation testing (POC-CT), also known as “bedside testing” or “near-patient testing,” is intended to provide test results more rapidly than can be achieved in hospital or reference laboratory settings. This is important in intensive care units, emergency rooms, operating rooms, and outpatient clinics, where it may help to expedite treatment decisions. POCT allows coagulation testing in the home environment, including patient self-testing (PST), thus providing increased access and convenience for the patient and/or caregiver and improving quality of care.

The guideline provides users of POC-CT systems with information and suggestions for good clinical testing practice and for producing reliable test results regardless of where or by whom the test is performed. This document deals with POC-CT performed for monitoring heparin and warfarin therapy.

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Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline

1 Scope

This document deals only with the use of POC-CT in monitoring of anticoagulant therapy with unfractionated heparin (hereafter called “heparin”) and warfarin. It does not address issues related to the use of POC-CT in the evaluation of patients with suspected hemostatic disorders or use of other anticoagulants. There are many potential sites for POC-CT, such as hospitals, physicians’ offices, and patients’ homes. Those performing POC-CT may include healthcare professionals and patient caregivers, as well as patients.

2 Introduction

Advances in technology and the development of microtechniques and portable test instruments have made it possible to move medical testing closer to the patient. Point-of-care coagulation testing (POC-CT), is intended to provide test results more rapidly, efficiently, and conveniently than can be achieved in the clinical laboratory. This is particularly important in intensive care units, emergency rooms, operating rooms, and outpatient clinics where it may help expedite treatment decisions. POC-CT may also provide greater access to testing for the patient and/or caregiver, whether in the clinic or home setting. POC-CT may also reduce errors due to incorrect or delayed test result transmission to the patient/caregiver and thus improve overall quality of care. The guideline provides information and suggestions for good medical testing practice to produce accurate test results regardless of where, and by whom, testing is performed.

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)¹; **NOTE:** See **Measurand**.

Activated clotting time, ACT – A global coagulation test which is particularly sensitive to abnormalities in the intrinsic blood coagulation pathway and the anticoagulant activity of heparin; **NOTE:** The ACT is a measurement of the time in seconds required for a clot to form in a native (i.e., nonanticoagulated) blood specimen which has been exposed to a contact activator of the intrinsic phase blood coagulation pathway.

Activated partial thromboplastin time, APTT – A global coagulation test used for the evaluation of the intrinsic and common coagulation pathway and for monitoring therapy with unfractionated heparin and certain other anticoagulants; **NOTE:** The APTT is the time in seconds required for a fibrin clot to form in a plasma sample after an optimal amount of calcium chloride, a partial thromboplastin reagent (phospholipid), and a contact factor activating agent have been added to the sample.

Anticoagulant – An agent, natural or pharmacological, that inhibits clotting of blood or plasma.

Antithrombin, AT (formerly Antithrombin III) – A plasma protein which, when activated by heparin or heparin-like molecules containing a specific pentasaccharide sequence such as glucosaminoglycans on endothelial cells, is a potent, irreversible inhibitor of activated, procoagulant serine proteases such as thrombin and Factor Xa.

APTT (POC) – The APTT performed using a point-of-care (POC) test system.

Bias – The difference between the expectation of the test results and an accepted reference value (ISO 3534-1).²

Blood specimen – The discrete portion of blood taken for examination, study, or analysis of one or more quantities or characteristics to determine the character of the whole.

Arterial – Blood obtained by arterial puncture or from an individual arterial line, catheter, or extracorporeal circuit.

Capillary – Blood obtained by skin puncture.

Venous – Blood obtained by venipuncture or from an indwelling line or catheter.

Calibration – Set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards (VIM93)¹; **NOTE:** According to the U.S. Code of Federal Regulations, calibration is the process of testing and adjustment of an instrument, kit, or test system, to provide a known relationship between the measurement response and the value of the substance being measured by the test procedure (US CFR 493 February 28, 1992).³

Cardiopulmonary bypass, CPB – A procedure used to sustain organ perfusion with oxygenated blood during cardiac surgery.

Coagulation test system – A device used to measure the rate of clotting of blood or plasma.

Common blood coagulation pathway – The activation of Factor X by Tissue Factor/VIIa complex and/or Factor IXa, followed by activation of Factor II and conversion of fibrinogen to fibrin.

Competency assessment – Evaluation of a person's ability to perform a test including all aspects of testing, from specimen collection to result reporting.

Contact activator – A particulate (e.g., kaolin, celite, silica) or soluble (e.g., ellagic acid) substance which activates the "contact phase of coagulation," involving Hageman Factor (Factor XII), Prekallikrein, and HMW Kininogen, thereby initiating the intrinsic phase blood coagulation pathway (i.e., activation of Factors XI and IX).

The Quality System Approach

NCCLS subscribes to a quality system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents through a gap analysis. The approach is based on the model presented in the most current edition of NCCLS HS1—*A Quality System Model for Health Care*. The quality system approach applies a core set of “quality system essentials (QSEs),” basic to any organization, to all operations in any healthcare service’s path of workflow. The QSEs provide the framework for delivery of any type of product or service, serving as a manager’s guide. The quality system essentials (QSEs) are:

Documents & Records	Equipment	Information Management	Process Improvement
Organization	Purchasing & Inventory	Occurrence Management	Service & Satisfaction
Personnel	Process Control	Assessment	Facilities & Safety

POCT14-A addresses the quality system essentials (QSEs) indicated by an “X.” For a description of the other NCCLS documents listed in the grid, please refer to the Related NCCLS Publications section on the following page.

Documents & Records	Organization	Personnel	Equipment	Purchasing & Inventory	Process Control	Information Management	Occurrence Management	Assessment	Process Improvement	Service & Satisfaction	Facilities & Safety
					X AST2 EP18				GP29		

Adapted from NCCLS document HS1—*A Quality System Model for Health Care*.

Path of Workflow

A path of workflow is the description of the necessary steps to deliver the particular product or service that the organization or entity provides. For example, GP26-A2 defines a clinical laboratory path of workflow which consists of three sequential processes: preanalytic, analytic, and postanalytic. All clinical laboratories follow these processes to deliver the laboratory’s services, namely quality laboratory information.

POCT14-A addresses the clinical laboratory path of workflow steps indicated by an “X.” For a description of the other NCCLS documents listed in the grid, please refer to the Related NCCLS Publications section on the following page.

Patient Assessment	Preanalytic				Analytic		Postanalytic	
	Test Request	Specimen Collection	Specimen Transport	Specimen Receipt	Testing Review	Laboratory Interpretation	Results Report	Post-test Specimen Management
X		X H3 H4 H21			X H47		X	

Adapted from NCCLS document HS1—*A Quality System Model for Health Care*.

Related NCCLS Publications*

- AST2-A** **Point-of-Care *In Vitro* Diagnostic (IVD) Testing; Approved Guideline (1999).** This document contains guidelines for users of *in vitro* diagnostic (IVD) devices outside the clinical laboratory to produce reliable results comparable to those obtained in the clinical laboratory.
- EP18-A** **Quality Management for Unit-Use Testing; Approved Guideline (2002).** This guideline recommends a quality management system for unit-use devices that will aid in the identification, understanding, and management of sources of error and help to ensure correct results. It is targeted for those involved in the supervision of laboratory-testing quality management, and it addresses issues related to specimen collection through reporting of test results.
- GP29-A** **Assessment of Laboratory Tests When Proficiency Testing is Not Available; Approved Guideline (2002).** This document offers methods to assess test performance when proficiency testing (PT) is not available; these methods include examples with statistical analyses. This document is intended for use by laboratory managers and testing personnel in traditional clinical laboratories as well as in point-of-care and bedside testing environments.
- H3-A5** **Procedure for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth Edition (2003).** This document provides procedures for the collection of diagnostic specimens by venipuncture, including line draws, blood culture collection, and venipuncture in children. It also includes recommendations on order of draw.
- H4-A5** **Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard—Fifth Edition (2004).** This document provides a technique for the collection of diagnostic blood specimens by skin puncture, including recommendations for collection sites and specimen handling and identification. Specifications for disposable devices used to collect, process, and transfer diagnostic blood specimens obtained by skin puncture are also included.
- H21-A4** **Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays; Approved Guideline—Fourth Edition (2003).** 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.
- 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.

* Proposed- and tentative-level documents are being advanced through the NCCLS consensus process; therefore, readers should refer to the most recent editions.



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950 West Valley Road, Suite 2500, Wayne, PA 19087 USA

P: 610.688.0100 Toll Free (US): 877.447.1888 F: 610.688.0700

E: customerservice@clsi.org www.clsi.org

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