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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.

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



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Global Consensus Standardization for Health Technologies

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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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Foreword

Medical conditions, physical location of the patient, and treatment regimens often require test results to be obtained quickly, so appropriate medical care can be administered expeditiously. Laboratory medicine professionals are challenged by the increasing demands for providing faster turnaround of test results, without compromising accuracy. The need to provide test results at greater convenience to, and increased efficiency for, the patient/caregiver without compromising cost-effectiveness is also recognized.

With the introduction of portable devices capable of producing results within seconds or minutes, point-of-care testing (POC—also referred to as “near-patient testing” or “bedside testing”), has been evolving as one way to meet these demands. Because of the potentially serious consequences of inaccurate test results, it is essential that results are accurate and reliable.

One of the challenges facing the healthcare community is acceptance of the idea that clinical coagulation testing, traditionally performed by and under the supervision of trained laboratory professionals, may be performed by personnel not trained in clinical laboratory practice or by patients/caregivers in the home. However, it is the responsibility of the manufacturer to provide test systems capable of delivering accurate results when used properly. Professionals in laboratory medicine should support high-quality point-of-care coagulation testing (POC-CT) services. POC-CT has been, and will continue to be implemented in different sites within the hospital, e.g., operating room, emergency room, intensive care unit, postsurgical recovery room, hemodialysis unit, ambulatory care site, and the patient’s home. The selection of patients for patient self-testing (PST) is the responsibility of the treating physician.

This document provides information to users on how to proceed in the evaluation, implementation, and monitoring of POC-CT, and deals only with the use of POC-CT in monitoring of anticoagulant therapy. It does not address issues related to the use of POC-CT in the evaluation of patients with suspected bleeding disorders. The guideline was written under the assumption that most users may not be laboratory professionals and provides important definitions, procedures, and recommendations. The format is designed to be easy to follow for the lay user.

This document relates closely to NCCLS documents EP18—*Quality Management for Unit-Use Testing* and AST2—*Point-of-Care In Vitro Diagnostic (IVD) Testing*. Please refer to these documents for additional information.

A Note on Terminology

NCCLS, as a global leader in standardization and harmonization, is firmly committed to achieving global harmonization wherever possible. Harmonization is a process of recognizing, understanding, and explaining differences while taking steps to achieve worldwide uniformity. NCCLS recognizes that medical conventions in the global metrological community have evolved differently in the United States, Europe, and elsewhere; that these differences are reflected in NCCLS, ISO, and CEN documents; and that legally required use of terms, regional usage, and different consensus timelines are all obstacles to harmonization. In light of this, NCCLS recognizes that harmonization of terms facilitates the global application of standards and is an area of immediate attention. Implementation of this policy must be an evolutionary and educational process that begins with new projects and revisions of existing documents.

In order to align the terminology used in H49-A with ISO, the term “trueness” is used in this document when referring to the closeness of the agreement between the average value from a large series of measurements to a true value of a measurand. The term “accuracy,” in its metrological sense, refers to the closeness of the agreement between the result of a (single) measurement and a true value of a measurand, thus comprising both random and systematic effects.

All terms and definitions will be reviewed again for consistency with international use, and revised appropriately during the next scheduled revision of this document.

The Subcommittee on Point-of-Care Coagulation Testing appreciates the opinions of manufacturers and users of POC-CT devices. We encourage all to participate in the consensus process by submitting written comments on content and format to the NCCLS Executive Offices. The subcommittee will consider all comments when it revises this guideline for the next edition.

Key Words

Calibration, point-of-care testing, quality assurance, quality control, safety

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.