CLINICAL AND LABORATORY STANDARDS INSTITUTE®

3rd Edition

POCT04

Essential Tools for Implementation and Management of a Point-of-Care Testing Program

This guideline provides direction to users of *in vitro* diagnostic devices outside the medical laboratory on how to ensure reliable results that are comparable to those obtained from medical laboratory instruments.

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

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POCT04, 3rd ed.
June 2016
Replaces POCT04-A2

Essential Tools for Implementation and Management of a Point-of-Care Testing Program

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Abstract

Clinical and Laboratory Standards Institute guideline POCT04—*Essential Tools for Implementation and Management of a Point-of-Care Testing Program* provides users of *in vitro* diagnostic devices outside the medical laboratory with information and recommendations for good laboratory practice and for producing reliable test results regardless of where the test is performed. Point-of-care testing (POCT), also known as bedside testing or near-patient testing, is intended to provide more rapid test results than can be achieved in central or satellite laboratory settings. This option is particularly important in critical care areas, such as the intensive care unit, emergency rooms, burn units, emergency transport vehicles, and operating rooms, as well as in skilled nursing facilities and hospices. POCT has also been used to expedite treatment decisions and provide convenience for the patient or client.

Clinical and Laboratory Standards Institute (CLSI). *Essential Tools for Implementation and Management of a Point-of-Care Testing Program*. 3rd ed. CLSI guideline POCT04 (ISBN 1-56238-938-6 [Print]; ISBN 1-56238-939-4 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2016.

Suggested Citation

CLSI. *Essential Tools for Implementation and Management of a Point-of-Care Testing Program*. 3rd ed. CLSI guideline POCT04. Wayne, PA: Clinical and Laboratory Standards Institute; 2016.

Previous Editions:
March 1995, June 1999, August 2006

ISBN 1-56238-938-6 (Print)
ISBN 1-56238-939-4 (Electronic)
ISSN 1558-6502 (Print)
ISSN 2162-2914 (Electronic) Volume 36, Number 9

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Foreword

In response to pressures from outside and within, the health care community is re-evaluating the best way to deliver services in a complex system. Part of this examination concerns the delivery of laboratory services to patients and clients.

Medical conditions, physical location of the patient or client, and treatment regimens often need laboratory test results quickly so that appropriate medical care may be administered. Laboratory professionals are challenged by the increasing demands for faster turnaround of results, but at the same time are faced with limitations such as cost constraints in providing these services.

The development of portable testing instruments capable of producing results within minutes has provided one way to meet these demands. Point-of-care testing (POCT), also referred to as near-patient testing or bedside testing, augments dipsticks and other noninstrumented testing systems such as occult blood testing. Because of the enormous consequences stemming from unreliable test results, it is vital that results continue to be trustworthy and of high quality as these tests are transferred from the medical laboratory to the point of care.

POCT is often performed by personnel not trained in medical laboratory practice, and faces similar regulatory and quality management issues as laboratory-based testing. These concerns apply both within and outside the traditional laboratory community. The manufacturer is responsible for providing test systems capable of delivering reliable results when used properly by the testing personnel. Once the decision to offer POCT is made, professionals in laboratory medicine should be involved in supporting and assessing the results of these services.

POCT has been, and will continue to be, implemented in a wide variety of locations. Each hospital, nursing home, emergency service provider, insurance company, home health care delivery network, etc., is responsible for assessing its POCT needs. This guideline provides information on how to assess those needs and how to evaluate and implement POCT.

This guideline provides useful information to locations desiring to perform POCT, written with the assumption that primary users will be nonlaboratory health care personnel. Therefore, this guideline provides definitions, procedures, and recommendations that are both educational and practical. In addition, the format is designed to be user friendly and easy to follow.

Overview of Changes

Several changes have been made in this edition; chief among them is the introduction of the concept of quality management based on risk assessment (see Subchapter 2.2.3) for POCT sites. This guideline also contains updated recommendations regarding infection control and patient and testing personnel safety (see Subchapter 2.3).

NOTE: The content of this guideline is supported by the CLSI consensus process, and does not necessarily reflect the views of any single individual or organization.

Key Words

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

Essential Tools for Implementation and Management of a Point-of-Care Testing Program

Chapter 1: Introduction

This chapter includes:

- Guideline's scope and applicable exclusions
- Background information pertinent to the guideline's content
- Standard precautions information
- "Note on Terminology" that highlights particular use and/or variation in use of terms and/or definitions
- Terms and definitions used in the guideline
- Abbreviations and acronyms used in the guideline

1.1 Scope

Many potential sites are eligible for point-of-care testing (POCT). To achieve producing patient test results comparable with those from the medical laboratory, this guideline provides essential tools for implementing and managing POCT in both clinical and nonclinical settings. Depending on the location, individuals who may perform POCT and for whom this guideline is intended include:

- Nurses and physicians in acute care units in hospitals and emergency rooms
- Cardiac perfusionists in operating rooms
- Visiting home nurses
- Emergency medical technicians
- Nurses in clinics, schools, and colleges
- Pharmacists and pharmacy technicians in pharmacies
- Non–health care professionals at various employment settings, such as drug rehabilitation centers, law enforcement facilities, public screening sites, insurance companies, and physician office laboratories (POLs)

This guideline does not cover patient self-testing and the handling of results generated in this manner. Additionally, this guideline only applies to tests that involve the collection of patient specimens. Thus, examination devices such as breath analyzers, transcutaneous meters, and continuous glucose monitoring devices are outside the scope of this guideline.