CLINICAL AND LABORATORY STANDARDS INSTITUTE®

3rd Edition

QMS24

Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality

This guideline describes an approach for a complete proficiency testing (PT) process and provides assistance to laboratories in using PT as a quality improvement tool.

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

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Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality

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Abstract

Clinical and Laboratory Standards Institute guideline QMS24—*Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality* provides laboratories with a detailed description of important activities in the proficiency testing (PT) process and includes suggestions for how to improve this process from a quality management perspective. It includes a suggested classification of unacceptable PT results and specific examples of investigations of unacceptable results.

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Contents

Contents (Continued)

Foreword

Proficiency testing (PT) is a valuable tool in the quality improvement process. PT provides one measure of objective evidence of laboratory competence to customers and regulatory and accreditation organizations. It serves as a unique source of information not obtainable by other methods. QMS24 provides guidance to laboratories on designing a PT process and using PT results, whether acceptable or unacceptable, to improve the quality of laboratory testing. PT cannot be used as the sole means for evaluating the quality of a laboratory, as PT is only one component of laboratory quality management. Current accreditation requirements include integration of PT into the laboratory's quality improvement program, and this guideline describes how that can be accomplished.

Overview of Changes

This guideline replaces the second edition of GP27, published in 2007, and has been recoded as QMS24. Several changes were made in this edition, including:

- The terminology and definitions were updated and clarified.
- The scope of the guideline was expanded to include information published in CLSI document GP29, and to eliminate redundancy with that document.
- The entire guideline was reorganized and updated to be consistent with CLSI's quality system essentials, with a focus on using a process workflow for the PT process.
- A process flow chart was added that outlines development, implementation, and monitoring of the PT process.
- Additional information on opportunities for improvement for laboratories in longitudinal review of successful PT events was included.
- Additional information to assist laboratories in using PT to assess and improve laboratory quality was included.
- Chapters were added to provide an in-depth discussion of PT in specialized areas of the laboratory, such as molecular and gynecological cytology.

KEY WORDS

Alternative assessment procedure

Corrective action

External quality assessment

Proficiency testing

Quality assurance

Quality improvement

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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

Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality

1 Introduction

1.1 Scope

IMPORTANT NOTE:

Regulatory and accreditation organizations may have additional requirements extending beyond the guidance in QMS24.

The purpose of this guideline is to help medical laboratories use proficiency testing (PT) as a quality improvement tool.[1-6] This guideline presents a systematic approach for designing the PT process as a component of the laboratory QMS.

QMS24 is intended for clinical laboratory managers and analysts in both the public and private sectors, and is applicable to any setting in which clinical laboratory testing is performed, from bedside testing to large multispecialty laboratories. This guideline applies to both qualitative and quantitative laboratory testing, including detection and quantification of blood and fluid measurands and blood and tissue typing. Some discussions apply only to examinations with quantitative results, whereas other discussions apply to examinations with qualitative results.

REMINDER:

See CLSI document QMS11[7] for information on how to conduct a root cause analysis.

The processes described in this guideline can help laboratories design a PT process, monitor PT results, and investigate and respond to unacceptable PT results. Part of this response may include preparation of information for submission to regulatory or accreditation organizations. Laboratories are cautioned, however, that regulatory and accreditation organizations may have additional requirements not supported by the guidance in QMS24.

QMS24 also provides guidance for how to use PT as a tool to prevent problems through analysis of acceptable results, education of laboratory personnel, and monitoring of internal processes.

This guideline does not recommend specific corrective actions for specific root causes (see CLSI document QMS11[7]).

1.2 Background

NOTE:

PT serves as an external verification of a laboratory's results, and also as a valuable self-monitoring tool.

PT evaluates a laboratory's performance on various types of testing and examinations in comparison to peer group performance or a reference standard or method. Alternative assessment procedures (AAPs) may evaluate testing and examination performance against a reference laboratory or against clinical information. PT serves as an external verification of a laboratory's results, and also as a valuable self-monitoring tool. PT directly benefits the laboratory and, indirectly, its customers and regulatory and accreditation organizations.

The use of PT to improve the quality of laboratory performance is not limited to the investigation of unacceptable results. Monitoring