CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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GP27-A2

Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline—Second Edition

This guideline provides assistance to laboratories in using proficiency testing as a quality improvement tool.

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

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Abstract

Clinical and Laboratory Standards Institute document GP27-A2—*Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline—Second Edition* is intended for clinical laboratory managers and testing personnel in both the public and private sectors, from the bedside to large multidisciplinary testing facilities. This guideline approaches proficiency testing from a quality improvement perspective. It includes a suggested classification of unacceptable proficiency testing 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 objective evidence of laboratory competence for customers, accrediting bodies, and regulatory agencies, and it serves as a unique source of information that is not obtainable in any other way. This document provides guidance in using proficiency testing results, whether acceptable or unacceptable, to improve the quality of laboratory testing. Current accreditation requirements include integration of PT into the laboratory's quality improvement program; this guideline describes how that can be accomplished.

It is important to bear in mind the limitations of proficiency testing. Traditional PT schemes tend to address only the analytical process (examination procedures), not the pre- or postanalytical (pre- or post-examination) activities of the laboratory. Proficiency testing results are affected by variables not related to patient samples, including preparation of the sample, matrix effects, clerical functions, selection of statistical methods of evaluation, and peer group definition.[1-6] Furthermore, PT will not detect all analytical problems in the laboratory.

Accordingly, it is not appropriate to use proficiency testing as the sole means for evaluating the quality of a laboratory; proficiency testing is only one component of the determination of laboratory quality. A single unacceptable result does not necessarily indicate that a problem exists in the laboratory. In some studies, investigation fails to reveal the reason for 20 to 25% of unacceptable PT results.[7,8]

Note on Terminology

In many countries, the PT programs for clinical laboratories are called "external quality assurance" or "external quality assessment" (EQA) programs. The preferred term now is the latter, and is defined in Section 3. The recommendations in this document relate equally to PT and EQA. However, in this document, only the term "proficiency testing" will be used, for two reasons. First, the committee determined that the phrase "PT/EQA" was awkward. Second, CLSI has a policy to use international harmonized terminology where appropriate; currently, the generally accepted international terminology is "proficiency testing."[9-14] PT is the term currently in use in many countries.

Regulatory agencies and accreditation bodies both provide oversight of laboratories and should have processes for approval of PT programs. For simplicity, these organizations are referred to together as "oversight bodies."

Key Words

Corrective action, external quality assessment, proficiency testing, quality improvement

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1 Scope

The purpose of this document is to help clinical laboratories use proficiency testing (PT) as a quality improvement tool.[15-20] This guideline delineates a systematic approach to monitoring PT results, and to investigating and responding to unacceptable PT results, including a classification of the types of problems that cause PT failures. This document 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 is applicable to any setting in which clinical laboratory testing is performed, from bedside testing to large multispecialty laboratories. Laboratories may use a similar approach to monitor and investigate unacceptable results from internal quality control programs, as well as "split sample" quality control programs. Please refer to the most current editions of CLSI document C24—*Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions* for additional guidance for quality control applications, and CLSI/NCCLS document GP29—*Assessment of Laboratory Tests When Proficiency Testing Is Not Available*.

This guideline applies to both qualitative and quantitative laboratory testing, including detection and quantification of blood and fluid analytes, morphologic identification, and blood and tissue typing. Some of the discussions apply only to tests with quantitative results, whereas other discussions apply to tests with qualitative results.

The processes in this guideline can help laboratories prepare responses to regulatory and accrediting bodies. The processes include impact assessment, root cause analysis, and corrective action. However, laboratories are cautioned that oversight bodies may have additional requirements not covered in this document, and they may have differing interpretations of the requirements.

This document is intended for laboratories, but also could be used by oversight bodies and PT providers as guidance for reporting and interpreting performance. In addition to providing processes for tracking laboratory performance, this document includes guidance for other reviews of performance of different methods, such as reproducibility and bias, which should be performed by the providers of PT and by laboratory oversight bodies.

This guideline does not prescribe specific corrective or preventive actions that are appropriate for their specific root causes. The document applies to PT programs that test laboratory results, and does not apply to the use of PT for assessing the competence of individual analysts.[a]

2 Introduction

PT evaluates a laboratory's analytical performance in comparison to its peers, reference standards, and/or reference laboratories. It serves as an external validation of the quality of a laboratory's results, and also as a valuable self-monitoring tool. This can benefit the laboratory, its customers, and the oversight bodies.

The use of PT as an internal evaluation tool is not limited to investigation of unacceptable results. Monitoring trends in acceptable PT results allows the laboratory to identify potential, as of yet

[a] The recommendations in this document may not apply to programs for gynecological cytology that are approved for use to meet U.S. CLIA requirements (as of 2005).