CLINICAL AND LABORATORY STANDARDS INSTITUTE®

August 2008

GP29-A2

Assessment of Laboratory Tests When Proficiency Testing Is Not Available; Approved Guideline—Second Edition

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.

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

Clinical and Laboratory Standards Institute

Setting the standard for quality in clinical laboratory testing around the world.

The Clinical and Laboratory Standards Institute (CLSI) is a not-for-profit membership organization that brings together the varied perspectives and expertise of the worldwide laboratory community for the advancement of a common cause: to foster excellence in laboratory medicine by developing and implementing clinical laboratory standards and guidelines that help laboratories fulfill their responsibilities with efficiency, effectiveness, and global applicability.

Consensus Process

Consensus—the substantial agreement by materially affected, competent, and interested parties—is core to the development of all CLSI documents. It does not always connote unanimous agreement, but does mean that the participants in the development of a consensus document have considered and resolved all relevant objections and accept the resulting agreement.

Commenting on Documents

CLSI documents undergo periodic evaluation and modification to keep pace with advancements in technologies, procedures, methods, and protocols affecting the laboratory or health care.

CLSI's consensus process depends on experts who volunteer to serve as contributing authors and/or as participants in the reviewing and commenting process. At the end of each comment period, the committee that developed the document is obligated to review all comments, respond in writing to all substantive comments, and revise the draft document as appropriate.

Comments on published CLSI documents are equally essential, and may be submitted by anyone, at any time, on any document. All comments are addressed according to the consensus process by a committee of experts.

Appeals Process

If it is believed that an objection has not been adequately addressed, the process for appeals is documented in the CLSI Standards Development Policies and Process document.

All comments and responses submitted on draft and published documents are retained on file at CLSI and are available upon request.

Get Involved—Volunteer!

Do you use CLSI documents in your workplace? Do you see room for improvement? Would you like to get involved in the revision process? Or maybe you see a need to develop a new document for an emerging technology? CLSI wants to hear from you. We are always looking for volunteers. By donating your time and talents to improve the standards that affect your own work, you will play an active role in improving public health across the globe.

For further information on committee participation or to submit comments, contact CLSI.

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

GP29-A2
Vol. 28 No. 21
ISBN 1-56238-673-5
Replaces GP29-A
ISSN 0273-3099
Vol. 22 No. 26

Assessment of Laboratory Tests When Proficiency Testing Is Not Available; Approved Guideline—Second Edition

Volume 28 Number 21

Stephen J. Sarewitz, MD
Harvey George, PhD
W. Gregory Miller, PhD
Daniel W. Tholen, MS
Paul Valenstein, MD

Abstract

Clinical and Laboratory Standards Institute document GP29-A2—*Assessment of Laboratory Tests When Proficiency Testing Is Not Available; Approved Guideline—Second Edition* offers methods to assess test performance when formal proficiency testing (PT) programs (also known as external quality assessment [EQA] programs) are not available. The guideline includes 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.

Clinical and Laboratory Standards Institute (CLSI). *Assessment of Laboratory Tests When Proficiency Testing Is Not Available; Approved Guideline—Second Edition*. CLSI document GP29-A2 (ISBN 1-56238-673-5). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2008.

Suggested Citation

CLSI. *Assessment of Laboratory Tests When Proficiency Testing Is Not Available; Approved Guideline—Second Edition.* CLSI document GP29-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2008.

Proposed Guideline
July 2001

Approved Guideline
December 2002

Approved Guideline—Second Edition
August 2008

ISBN 1-56238-673-5
ISSN 0273-3099

Committee Membership

Area Committee on Quality Systems and Laboratory Practices

Sheila M. Woodcock, MBA, FCSMLS(D)
Chairholder
QSE Consulting
Rose Bay, Nova Scotia, Canada

Carl D. Mottram, BA, RRT, RPFT, FAARC
Co-Vice Chairholder
Mayo Clinic
Rochester, Minnesota

Albert Rabinovitch, MD, PhD
Co-Vice Chairholder
NovoMetrics, Inc.
Mountain View, California

Eric Arendash, MT(ASCP)
Centers for Medicare & Medicaid Services
Philadelphia, Pennsylvania

Lucia M. Berte, MA, MT(ASCP)SBB, DLM; CQA(ASQ) CQMgr
Laboratories Made Better!
Broomfield, Colorado

Theresa Billups, MBA, MT(ASCP)DLM
Remel, Inc.
Lake Charles, Louisiana

Margaret M. Grimes, MD
Medical College of Virginia Campus
Richmond, Virginia

Devery Howerton, PhD
Centers for Disease Control and Prevention
Atlanta, Georgia

Peter L. Minetti, CQA, CQE, CQMgr(ASQ)
Fujirebio Diagnostics, Inc.
Malvern, Pennsylvania

Bruce D. Tually, BAppSc, MAppSc
Hunter Area Pathology Service
New South Wales, Australia

Advisors

Eileen Carreiro-Lewandowski, CLS(NCA)
University of Massachusetts
N. Dartmouth, Massachusetts

Kay M. Creed
Bon Secours Health Partners Laboratories
Richmond, Virginia

Dennis J. Ernst, MT(ASCP)
Center for Phlebotomy Education
Ramsey, Indiana

Steven I. Gutman, MD, MBA
FDA Ctr. for Devices/Rad. Health
Rockville, Maryland

Stephen J. Sarewitz, MD
Valley Medical Center
Renton, Washington

Jennifer Schiffgens, MBA, MT(ASCP)
California Pacific Medical Center
San Francisco, California

Daniel W. Tholen, MS
A2LA
Traverse City, Michigan

Staff

Clinical and Laboratory Standards Institute
Wayne, Pennsylvania

Lois M. Schmidt, DA
Vice President, Standards Development and Marketing

Jennifer K. McGeary, MT(ASCP), MSHA
Staff Liaison

Melissa A. Lewis
Editor

Acknowledgment

CLSI gratefully acknowledges the following individuals for their help in preparing the approved-level, second edition of this guideline:

Stephen J. Sarewitz, MD
Valley Medical Center
Renton, Washington

Harvey George, PhD
MA Dept. of Public Health Laboratories
Jamaica Plain, Massachusetts

W. Gregory Miller, PhD
Virginia Commonwealth University
Richmond, Virginia

Daniel W. Tholen, MS
A2LA
Traverse City, Michigan

Paul Valenstein, MD
Trinity Health
Ann Arbor, Michigan

Contents

Foreword

Proficiency testing (PT), also known as external quality assessment (EQA), is an important part of quality management in the clinical laboratory. PT complements internal quality control (QC) to help ensure patient test results are valid.[1] Many agencies and associations, governmental and nongovernmental, offer PT for numerous analytes. In many cases, accrediting bodies and governmental agencies that oversee clinical laboratories require participation in a formal PT program.

However, formal PT programs are not available for a substantial number of laboratory tests; the reasons vary. Some analytes are unstable, precluding the preparation of PT materials, or matrix effects may prevent reliable analysis. Some tests are performed in only a few laboratories, so it is not practical to develop a formal PT program. PT is not available for certain pathogenic microorganisms because of the hazards of transporting the organisms. In some parts of the world, competent PT programs may not be available or may not be affordable.

This document offers methods to assess test performance when PT is not available. These methods are termed "alternative assessment procedures," or AAPs.[a] The document addresses a variety of tests, including quantitative analyses of blood, microbiological cultures, morphologic analyses, and *in vivo* tests. The options for some of these tests are necessarily rather limited.

Overview of Changes

This document replaces the first edition approved guideline, GP29-A, which was published in 2002. Principal among the changes in this edition are revised/harmonized terminology (see Section 2.1), updated examples of tests for which PT is not available, and examples of government comparison programs. References were updated throughout.

Key Words

Alternative assessment procedure, external quality assessment, proficiency testing

[a] Neither PT nor the procedures described in this document are adequate *by themselves* to comprehensively validate a test method.

Assessment of Laboratory Tests When Proficiency Testing Is Not Available; Approved Guideline—Second Edition

1 Scope

This document offers methods to assess test performance when proficiency testing (PT), or external quality assessment (EQA), is not available. The guidelines in this document apply to clinical laboratory tests performed in the traditional laboratory setting, as well as point-of-care testing, and testing in clinics' laboratories. The subcommittee believes assessment procedures (either PT or alternative assessment procedures [AAPs]) to validate ongoing performance are important for all laboratory tests. However, the scope of the document does not include home testing (ie, patient self-testing). Quality assessment programs for home testing have been described.[2]

This document makes no distinction between "regulated" and "nonregulated analytes" as defined in the United States under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88).[3,4] The subcommittee believes assessment procedures (either PT or AAPs) to validate ongoing performance are important for all laboratory tests.

This document suggests general approaches and provides examples, but does not prescribe specific assessment procedures for individual analytes. The responsibility for selecting specific assessment procedures lies with the individual clinical laboratory.

The document may be useful for managers, supervisors, and laboratory personnel in traditional laboratories, as well as personnel performing point-of-care and bedside testing.

2 Terminology

2.1 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 2.2. 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."[5-8] PT is the term currently in use in many countries, including the United States.

2.2 Definitions

accepted reference value – value that serves as an agreed-upon reference for comparison and which is derived as a theoretical or established value based on scientific principles; an assigned value based on experimental work of some national or international organization; or a consensus value based on collaborative experimental work under the auspices of a scientific or engineering group (ISO 5725-1, ISO Guide 30).[9,10]

accuracy (of measurement) – closeness of the agreement between a measured quantity value and a true quantity value of a measurand (VIM07).[11]

analyte – component represented in the name of a measurable quantity (ISO 17511)[8]; **NOTE:** In the type of quantity "mass of protein in 24-hour urine," "protein" is the analyte. In "amount of substance of