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Assessment of Laboratory Tests When Proficiency Testing is Not Available; Approved Guideline

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 NCCLS consensus process.

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Assessment of Laboratory Tests When Proficiency Testing is Not Available; Approved Guideline

Abstract

NCCLS document GP29-A—*Assessment of Laboratory Tests When Proficiency Testing is Not Available; Approved Guideline* 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.

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Assessment of Laboratory Tests When Proficiency Testing is Not Available; Approved Guideline

Volume 22 Number 26

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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 to help assure that patient test results are valid. In many cases, 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 that 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.

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.

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

Key Words

Alternative assessment procedure, external quality assessment, proficiency testing

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 deserves immediate attention. Implementation of this policy must be an evolutionary and educational process that begins with new projects and revisions of existing documents.

In the context of this guideline, it is necessary to point out that several terms are used differently in the USA and other countries, notably those in Europe.

Also, in order to align the usage of terms to 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 and to an accepted reference value. 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.

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

The Quality System Approach

NCCLS subscribes to a quality system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents through a gap analysis. The approach is based on the model presented in the most current edition of NCCLS HS1—*A Quality System Model for Health Care.* The quality system approach applies a core set of "quality system essentials (QSEs)," basic to any organization, to all operations in any healthcare service's path of workflow. The QSEs provide the framework for delivery of any type of product or service, serving as a manager's guide. The quality system essentials (QSEs) are:

Documents & Records	Equipment	Information Management	Process Improvement
Organization	Purchasing & Inventory	Occurrence Management	Service & Satisfaction
Personnel	Process Control	Assessment	Facilities & Safety

GP29-A addresses the following quality system essentials (QSEs):

Documents & Records	Organization	Personnel	Equipment	Purchasing & Inventory	Process Control	Information Management	Occurrence Management	Assessment	Process Improvement	Service & Satisfaction	Facilities & Safety
								X			

Adapted from NCCLS document HS1— *A Quality System Model for Health Care*.

Assessment of Laboratory Tests When Proficiency Testing is Not Available; Approved Guideline

1 Introduction

Proficiency testing (PT), also known as external quality assessment (EQA), is a valuable element in clinical laboratory quality management.[1] Many agencies and associations, governmental and non-governmental, offer PT for numerous analytes. However, for a variety of reasons, PT is not available for a substantial number of laboratory tests. This document offers guidance to clinical laboratories in the development of alternative quality assessment procedures (AAPs) when PT is not available.

2 Scope

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 and physician offices. The scope of the document does not include home testing (i.e., 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 U.S. under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88).[3] The subcommittee believes that 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.

3 Standard Precautions

Because it is often impossible to know what might be infectious, all human blood specimens are to be treated as infectious and handled according to "standard precautions." Standard precautions are new guidelines that combine the major features of "universal precautions and body substance isolation" practices. Standard precautions cover the transmission of any pathogen and thus are more comprehensive than universal precautions which are intended to apply only to transmission of blood-borne pathogens. Standard precaution 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;Vol 17;1:53-80), (MMWR 1987;36[suppl 2S]2S-18S), and (MMWR 1988;37:377-382, 387-388). For specific precautions for preventing the laboratory transmission of blood-borne infection from laboratory instruments and materials and for recommendations for the management of blood-borne exposure, refer to NCCLS document M29—*Protection of Laboratory Workers from Occupationally Acquired Infections*.

4 Definitions and Abbreviations[b]

4.1 Definitions

Accepted reference value – A 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

[b] Some of these definitions are found in NCCLS document NRSCL8—*Terminology and Definitions for Use in NCCLS Documents.* For complete definitions and detailed source information, please refer to the most current edition of that document.