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Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition

This document provides a model for medical laboratories that will assist with implementation and maintenance of an effective quality management system.

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

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Advancing Quality in Health Care Testing

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Abstract

Clinical and Laboratory Standards Institute document GP26-A4—*Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition* provides the necessary background information and infrastructure to develop a quality management system that will meet health care quality objectives and be consistent with the quality objectives of laboratory services. This guideline provides a structure for a comprehensive, systematic approach to build quality into the laboratory's processes, assess the laboratory's performance, and implement quality improvements.

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Foreword

The increasing awareness of the costly personal and economic impact of medical errors has focused a spotlight on quality management in health care services. In the present environment of limited resources, quality cannot be taken for granted by those who fund, receive, and provide laboratory services. Our historical perspective—of quality control and quality assurance as defining quality—needs to be superseded by a more global view of internationally accepted quality activities applied to a laboratory's scope of work.

This document revises a model, first published in 1999 by the National Committee for Clinical Laboratory Standards (NCCLS), that assists laboratories with implementation and maintenance of an effective quality management system (QMS). This model is based on and contains the QMS requirements specified by international, national, and accreditation organizations for laboratory services.[1-12]

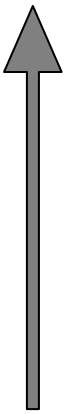
The driving force behind the original version of this guideline was the publication in 1995 of a model[13] that provided blood banks and transfusion services with a simple way to categorize all the many regulatory and accreditation requirements applicable to them, such as the Clinical Laboratory Improvement Amendments of 1988, the Food and Drug Administration Good Manufacturing Practice, The Joint Commission, the College of American Pathologists, and AABB. Persons in hospital-based blood banks and transfusion services quickly saw the applicability of the quality system model to the other medical laboratory disciplines for all the regulatory and accreditation requirements for which laboratories were accountable at the time. New requirements for laboratories, such as those in the international medical laboratory standard ISO 15189,[1] have been included in their respective portions of the model. As additional requirements are published in the future, they will continue to be incorporated into subsequent editions of this guideline.

It is true that other interpretations can be made of QMS requirements. However, this consensus document is intended as a sound, practical, and user-friendly interpretation that can be easily implemented in any laboratory. This guideline will assist an interested laboratory that seeks to obtain accreditation to relevant standards.

GP26 is a practical guide for medical laboratories that provide quality-based services. It can be used along with other quality-related documents to design the system foundation necessary to achieve total quality management.

A hierarchy defining stages of quality[14] synthesized from the concepts of acknowledged quality experts[15,16] is described in Table 1. An analogy for the stages of quality is a ladder. A laboratory can best obtain the next higher stage by mastering the preceding one, ultimately reaching the top rung. The shaded row in Table 1 indicates the level of laboratory quality for which this guideline presents a model for achievement.

Table 1. Stages of Quality. The QMS (shaded) is a major level in the health care quality hierarchy and forms the basis for this document.[14]



Stage	Activities Performed
Total Quality Management	Management approach centered on sustained high quality, by focusing on long-term success through customer satisfaction
Quality Cost Management	Measurement system for the economic aspects of the "cost of quality"
Quality Management System	**Systematic process-oriented approach to meeting quality objectives**
Quality Assurance	Planned and systematic activities to provide confidence that an organization fulfills requirements for quality
Quality Control	Operational process control techniques to fulfill quality requirements for regulatory compliance and accreditation[17]

An integrated QMS provides an opportunity to deliver consistent, high-quality, and cost-effective laboratory services. Where governmental and accreditation compliance apply, having a QMS will simplify this process.

Although some laboratories are working successfully at the level of a QMS (the shaded cells in Table 1), in much of the world, many laboratories are operating at or below the stage of quality assurance. The need to upgrade to a QMS approach has become evident from worldwide reports that describe medical errors in present-day health care systems,[18-20] and from reports of the cost of both good and poor quality on laboratory operations.[21] The best contribution a laboratory can make to reduce errors that can or may cause harm is to understand and document its processes, train staff to perform processes competently, identify problematic processes, and improve processes where problems exist.

The foundation of a QMS, with operations under control, provides a platform for continuous improvement and further transition up the quality hierarchy. If a laboratory implements the QMS model described in this guideline, the following outcomes are greatly enhanced:

- Ability to reduce or eliminate error
- Likelihood of meeting customer expectations
- More effective and efficient operations
- Potential for successful governmental and accreditation assessments
- Sustainable attainment of quality objectives

GP26-A4 introduces 12 building blocks of quality (referred to as quality system essentials [QSEs]) to create the management foundation needed to support the laboratory's path of workflow, from a request for a laboratory service through providing the laboratory report.

With leadership commitment to building a QMS, a platform for continuous improvement and further progress toward overall Total Quality Management is established.

Overview of Changes From GP26-A3

This document combines and replaces the previous edition of the approved guideline, GP26-A3, published in 2004, and the second edition of CLSI document HS01, also published in 2004. Several changes were made in this edition including the following:

- Reunification of the information about the QSEs with the information about the laboratory's path of workflow

- Alignment with any new or changed international, national, and accreditation requirements for laboratories since the last version of this guideline

- Additional examples of documents and forms that can be used or modified as needed for implementing a laboratory QMS

Key Words

Examination processes, path of workflow, postexamination processes, preexamination processes, quality, quality assurance, quality control, quality cost management, quality indicators, quality management, quality management system, quality system essentials, total quality management

Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition

1 Scope

The quality management system (QMS) model described in this guideline can be used in laboratories around the world including, but not limited to:

- Medical laboratories
- Public health laboratories
- Research laboratories
- Veterinary laboratories
- Food laboratories
- Environmental laboratories

The 12 quality system essentials (QSEs) described in this guideline are universal and applicable to any size laboratory, whether simple or complex, in any laboratory discipline. This guideline is intended for use by laboratory directors, managers, supervisors, quality managers, and others responsible for implementing, maintaining, and evaluating the laboratory's QMS.

2 Introduction

The goal of an efficient and effective laboratory is to provide consistently accurate results in a timely manner with the most judicious use of resources. The complexity of laboratory services emphasizes the need for a systematic approach to provide this high level of service. A laboratory QMS is a systematic approach that describes, documents, implements, measures, and monitors the effectiveness of laboratory work operations in meeting international, national, regional, local, and organizational requirements and promotes the efficient use of resources. The ultimate objective of all this activity is to meet the expectations of the laboratory's customers.

This document is organized into five major sections. **Section 4 introduces a model for a laboratory QMS that is based on, includes, and categorizes the QMS requirements specified by international, national, and accreditation organizations for laboratory services.**[1-12] The model was derived by sorting the individual reference requirements into groups of like kind—ie, identifying all the requirements for a subject such as laboratory equipment or personnel and arranging them in the sequential order of how they occur in the laboratory. The resulting groups of requirements were recognized as fundamental building blocks of quality and were given the title of QSEs. See the "Additional important note" in Section 3.1.

Section 5 further describes the 12 QSEs and discusses the key components of each, as determined from the referenced requirements. Information is provided about laboratory processes that ensure work operations are functioning as intended to meet customer, international, national, accreditation, local, and organizational requirements, and support for the highest level of service.

Section 6 describes the laboratory's path of workflow—defined as the sequential processes in laboratory activities that transform a request for service into laboratory information. Each laboratory—whether large and complex or of narrower scope—needs to understand how work flows through it so that processes can be designed and procedures documented that will build the required level of quality into laboratory work (ie, meet the requirements) and reduce the potential for errors that could cause harm or waste resources. This guideline includes specific laboratory examples.

Section 7 suggests a sequence of activities for implementing the QMS model described in this guideline. Guidance for important features of these activities is provided. Numerous examples to help meet requirements are provided in the appendixes, which can be customized for different sizes, scopes, and specialties of laboratories.

Section 8 suggests that the QMS model can be applied to each health care service because the same 12 QSEs can support any service's respective path of workflow. The laboratory could be instrumental to a health care organization seeking improvement and customer satisfaction by developing QSE policies and processes and serving as an example to the other services for how to map, document, measure, monitor, and improve workflow.

To establish a complete QMS, policies, processes, and procedures for key activities in the laboratory's path of workflow need to be combined with policies, processes, and procedures for the QSEs.

3 Terminology

3.1 A Note on Terminology

CLSI, as a global leader in standardization, 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. CLSI 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 CLSI, International Organization for Standardization (ISO), and European Committee for Standardization (CEN) documents; and that legally required use of terms, regional usage, and different consensus timelines are all important considerations in the harmonization process. In light of this, CLSI's consensus process for development and revision of standards and guidelines focuses on harmonization of terms to facilitate the global application of standards and guidelines.

Additional important note:

Throughout this guideline, the phrase "the laboratory needs to" explains an action directly related to fulfilling requirements of international, national, and accreditation organizations.[1-12] By taking the actions described in this guideline, the laboratory will fulfill requirements; means by which the requirements are met are left to the discretion of the laboratory unless otherwise specified.

The phrase "the laboratory should" describes a recommendation provided in laboratory literature, a statement of good laboratory practice, or a suggestion for how to meet a requirement.

3.2 Definitions

accident – an undesirable or unfortunate happening that occurs unintentionally.

accreditation – procedure by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks (modified from ISO/IEC 17000).[22]

analytical measuring interval – a set of values of quantities of the same kind that can be measured by a given measuring instrument or measuring system with specified instrumental uncertainty, under defined conditions (ISO/IEC Guide 99)[23]; **NOTE:** It is sometimes called the analytical measurement range, which is "the range of analyte values that a method can directly measure on the specimen without any dilution, concentration, or other pretreatment not part of the usual assay process."[24]

Path of Workflow

A path of workflow is the description of the necessary processes to deliver the particular product or service that the organization or entity provides. A laboratory path of workflow consists of the sequential processes: preexamination, examination, and postexamination and their respective sequential subprocesses. All laboratories follow these processes to deliver the laboratory's services, namely quality laboratory information.

GP26-A4 addresses the clinical laboratory path of workflow processes indicated by an "X." For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Preexamination				**Examination**			**Postexamination**	
Examination ordering	Sample collection	Sample transport	Sample receipt/processing	Examination	Results review and follow-up	Interpretation	Results reporting and archiving	Sample management
X	X	X	X	X	X	X	X	X
				C42	C42	C42	C42	
C46	C46	C46	C46	C46	C46	C46	C46	
					C50	C50		
					EP27	EP27		
	GP33		GP33	GP33			GP33	
	H26			H26				H26
					I/LA20			
K2Q	K2Q MM13	K2Q MM13	K2Q MM13	K2Q	K2Q	K2Q	K2Q	K2Q MM13

Related CLSI Reference Materials*

C03-A4 **Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline—Fourth Edition (2006).** This document provides guidelines on water purified for clinical laboratory use; methods for monitoring water quality and testing for specific contaminants; and water system design considerations.

C24-A3 **Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline—Third Edition (2006).** This guideline provides definitions of analytical intervals, planning of quality control procedures, and guidance for quality control applications.

C28-A3c **Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition (2010).** This document contains guidelines for determining reference values and reference intervals for quantitative clinical laboratory tests.

C29-A2 **Standardization of Sodium and Potassium Ion-Selective Electrode Systems to the Flame Photometric Reference Method; Approved Standard—Second Edition (2000).** This document contains recommendations on the expression of the results of ion-selective electrode measurement of sodium and potassium ion activities in undiluted serum, plasma, or whole blood in clinical practice.

C37-A **Preparation and Validation of Commutable Frozen Human Serum Pools as Secondary Reference Materials for Cholesterol Measurement Procedures; Approved Guideline (1999).** This guideline details procedures for the manufacture and evaluation of human serum pools for cholesterol measurement.

C39-A **A Designated Comparison Method for the Measurement of Ionized Calcium in Serum; Approved Standard (2000).** This document provides a designated comparison method to standardize the measurement of ionized calcium made by ion-selective electrode (ISE) potentiometry. This system can be used to assign ionized calcium concentrations to a commercially available, serum-based material to improve the traceability and transferability of results for the measurement of ionized calcium in the clinical laboratory.

C42-A **Erythrocyte Protoporphyrin Testing; Approved Guideline (1996).** This document contains recommendations for the measurement, reporting, and interpretation of erythrocyte protoporphyrin using hematofluorometric and extraction measurement methods.

C43-A2 **Gas Chromatography/Mass Spectrometry Confirmation of Drugs; Approved Guideline—Second Edition (2010).** This document provides guidance on establishing uniform practices necessary to produce quality data for quantitation and identification of a drug or drug metabolite using the gas chromatography/mass spectrometry method. Specific quality assurance criteria for maintaining and documenting optimal instrument performance are also presented.

C44-A **Harmonization of Glycohemoglobin Measurements; Approved Guideline (2002).** This document describes an established program to harmonize glycohemoglobin (GHB) testing results among laboratories to a common, outcomes-based reference system and includes recommendations for the clinical application of harmonized GHB testing results.

C45-A **Measurement of Free Thyroid Hormones; Approved Guideline (2004).** This document addresses analytical and clinical validation of free (nonprotein-bound) thyroid hormone (FTH) measurement procedures.

C46-A2 **Blood Gas and pH Analysis and Related Measurements; Approved Guideline—Second Edition (2009).** This document provides clear definitions of the quantities in current use, and provides a single source of information on appropriate specimen collection, preanalytical variables, calibration, and quality control for blood pH and gas analysis and related measurements.

C50-A **Mass Spectrometry in the Clinical Laboratory: General Principles and Guidance; Approved Guideline (2007).** This guideline provides a general understanding of mass spectrometry and the principles that dictate its application in the clinical laboratory. It includes guidance, references, and quality assurance markers that will assist with the implementation and correct operation of a mass spectrometry (MS) system for its many applications. Information on maintaining optimum performance, approaches to ensuring accurate and precise mass measurement, verification of methods, quality control of assays within and between instruments, instrument troubleshooting, sample preparation, interpretation of results, and limitations of the technology is included.

* CLSI documents are continually reviewed and revised through the CLSI consensus process; therefore, readers should refer to the most current editions.

Related CLSI Reference Materials (Continued)

C53-A **Characterization and Qualification of Commutable Reference Materials for Laboratory Medicine; Approved Guideline (2010).** This document provides information to help material manufacturers in the production and characterization of commutable reference materials, as well as to assist assay manufacturers and laboratorians in the appropriate use of these materials for calibration and trueness assessment of *in vitro* diagnostic medical devices.

EP05-A2 **Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition (2004).** This document provides guidance for designing an experiment to evaluate the precision performance of quantitative measurement methods; recommendations on comparing the resulting precision estimates with manufacturers' precision performance claims and determining when such comparisons are valid; as well as manufacturers' guidelines for establishing claims.

EP06-A **Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline (2003).** This document provides guidance for characterizing the linearity of a method during a method evaluation; for checking linearity as part of routine quality assurance; and for determining and stating a manufacturer's claim for linear range.

EP07-A2 **Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition (2005).** This document provides background information, guidance, and experimental procedures for investigating, identifying, and characterizing the effects of interfering substances on clinical chemistry test results.

EP09-A2-IR **Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition (Interim Revision) (2010).** This document addresses procedures for determining the bias between two clinical methods, and the design of a method comparison experiment using split patient samples and data analysis.

EP10-A3 **Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures; Approved Guideline—Third Edition (2006).** This guideline provides experimental design and data analysis for preliminary evaluation of the performance of a measurement procedure or device.

EP12-A2 **User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline—Second Edition (2008).** This document provides a consistent approach for protocol design and data analysis when evaluating qualitative diagnostic tests. Guidance is provided for both precision and method-comparison studies.

EP14-A2 **Evaluation of Matrix Effects; Approved Guideline—Second Edition (2005).** This document provides guidance for evaluating the bias in analyte measurements that is due to the sample matrix (physiological or artificial) when two measurement procedures are compared.

EP15-A2 **User Verification of Performance for Precision and Trueness; Approved Guideline—Second Edition (2006).** This document describes the demonstration of method precision and trueness for clinical laboratory quantitative methods utilizing a protocol designed to be completed within five working days or less.

EP17-A **Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline (2004).** This document provides guidance for determining the lower limit of detection of clinical laboratory methods, for verifying claimed limits, and for the proper use and interpretation of the limits.

EP18-A2 **Risk Management Techniques to Identify and Control Laboratory Error Sources; Approved Guideline—Second Edition (2009).** This guideline describes risk management techniques that will aid in identifying, understanding, and managing sources of failure (potential failure modes) and help to ensure correct results. Although intended primarily for *in vitro* diagnostics, this document will also serve as a reference for clinical laboratory managers and supervisors who wish to learn about risk management techniques and processes.

EP21-A **Estimation of Total Analytical Error for Clinical Laboratory Methods; Approved Guideline (2003).** This document provides manufacturers and end users with a means to estimate total analytical error for an assay. A data collection protocol and an analysis method that can be used to judge the clinical acceptability of new methods using patient specimens are included. These tools can also monitor an assay's total analytical error by using quality control samples.

EP25-A **Evaluation of Stability of *In Vitro* Diagnostic Reagents; Approved Guideline (2009).** This document provides guidance for establishing shelf-life and in-use stability claims for *in vitro* diagnostic reagents such as reagent kits, calibrators, and control products.

Related CLSI Reference Materials (Continued)

GP02-A5 **Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition (2006).** This document provides guidance on development, review, approval, management, and use of policy, process, and procedure documents in the medical laboratory community.

GP05-A3 **Clinical Laboratory Waste Management; Approved Guideline—Third Edition (2011).** Based on US regulations, this document provides guidance on the safe handling and disposal of chemical, infectious, radioactive, and multihazardous wastes generated in the clinical laboratory. Although this document is a valuable resource for a wider audience, it is intended for use primarily in the United States.

GP09-A **Selecting and Evaluating a Referral Laboratory; Approved Guideline (1998).** This guideline provides an outline of reasons and criteria for choosing a referral laboratory. A checklist for evaluating potential referral laboratories is included to assist in the decision process.

GP10-A **Assessment of the Clinical Accuracy of Laboratory Tests Using Receiver Operating Characteristic (ROC) Plots; Approved Guideline (1995).** This document provides a protocol for evaluating the accuracy of a test to discriminate between two subclasses of subjects where there is some clinically relevant reason to separate them. In addition to the use of ROC plots, the importance of defining the question, selecting the sample group, and determining the "true" clinical state are emphasized.

GP17-A2 **Clinical Laboratory Safety; Approved Guideline—Second Edition (2004).** This document contains general recommendations for implementing a high-quality laboratory safety program, which are provided in a framework that is adaptable within any laboratory.

GP18-A2 **Laboratory Design; Approved Guideline—Second Edition (2007).** This document provides a foundation of information about laboratory design elements and guidance to help define the issues to be considered when designing a clinical laboratory.

GP21-A3 **Training and Competence Assessment; Approved Guideline—Third Edition (2009).** This document provides background information and recommended processes for the development of training and competence assessment programs that meet quality and regulatory objectives.

GP22-A3 **Quality Management System: Continual Improvement; Approved Guideline—Third Edition (2011).** This guideline considers continual improvement as an ongoing, systematic effort that is an essential component of a quality management system. A continual improvement program may consist of fundamental processes and common elements described in this guideline.

GP27-A2 **Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline—Second Edition (2007).** This guideline provides assistance to laboratories in using proficiency testing as a quality improvement tool.

GP29-A2 **Assessment of Laboratory Tests When Proficiency Testing Is Not Available; Approved Guideline—Second Edition (2008).** 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.

GP31-A **Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline (2009).** This guideline provides information about assessing instrument performance and function from the time of instrument purchase to the routine performance of clinical testing.

GP32-A **Management of Nonconforming Laboratory Events; Approved Guideline (2007).** This guideline provides an outline and the content for developing a program to manage a health care service's nonconforming events that is based on the principles of quality management and patient safety.

GP33-A **Accuracy in Patient and Sample Identification; Approved Guideline (2010).** This guideline describes the essential elements of systems and processes required to ensure accurate patient identification. The principles in this document may be applied to manual or electronic systems. Design considerations covered include criteria for accuracy, differences in inpatient vs outpatient settings that impact patient identification, language and cultural considerations, and standardization of processes across the health care enterprise.

Related CLSI Reference Materials (Continued)

GP35-A **Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality; Approved Guideline (2010).** This document provides guidance on development of quality indicators and their use in the medical laboratory.

H26-A2 **Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard—Second Edition (2010).** This document provides guidance for the validation, verification, calibration, quality assurance (QA), and quality control (QC) of automated multichannel hematology analyzers for manufacturers, end-user clinical laboratories, accrediting organizations, and regulatory bodies. In addition, end-user clinical laboratories will find guidance for establishment of clinically reportable intervals and for QA for preexamination and examination aspects of their systems.

HS11-A **A Model for Managing Medical Device Alerts (Hazards and Recalls) for Healthcare Organizations; Approved Guideline (2005).** This document provides a framework for healthcare delivery organizations to respond to externally generated notifications of medical device hazards and recalls while focusing on the quality constructs of process control, occurrence management, and process improvement.

I/LA20-A2 **Analytical Performance Characteristics and Clinical Utility of Immunological Assays for Human Immunoglobulin E (IgE) Antibodies and Defined Allergen Specificities; Approved Guideline—Second Edition (2009).** This document provides guidance for the design, analytical performance, standardization, quality assurance, and clinical application of laboratory assays used in the measurement of human IgE antibodies of defined allergen specificity.

K2Q **The Key to Quality (2007).** This comprehensive specialty portfolio, with tabs for quick references, showcases the implementation of all 12 quality system essentials. The portfolio includes essentials, examples, flow charts, cross-references, evaluations, and a CD-ROM based on the widely used QMS documents HS01, GP02, GP21, GP26, and ISO 15189.

M29-A3 **Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition (2005).** Based on US regulations, this document provides guidance on the risk of transmission of infectious agents by aerosols, droplets, blood, and body substances in a laboratory setting; specific precautions for preventing the laboratory transmission of microbial infection from laboratory instruments and materials; and recommendations for the management of exposure to infectious agents.

MM13-A **Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods; Approved Guideline (2005).** This document provides guidance related to proper and safe biological specimen collection and nucleic acid isolation and purification. These topics include methods of collection, recommended storage and transport conditions, and available nucleic acid purification technologies for each specimen/nucleic acid type.

MM17-A **Verification and Validation of Multiplex Nucleic Acid Assays; Approved Guideline (2008).** This guideline provides recommendations for analytic verification and validation of multiplex assays, as well as a review of different types of biologic and synthetic reference materials.

StatisPro **StatisPro™ (2010).** This feature-rich, easy-to-use method evaluation software can be used for establishing or verifying performance characteristics of a laboratory test method. This robust statistical tool can report on precision, linearity, bias (related to trueness), comparability, reference intervals, limits of detection, and limits of quantitation based on the most up-to-date CLSI guidelines.

X03-R **Implementing a Needlestick and Sharps Injury Prevention Program in the Clinical Laboratory; A Report (2002).** This document provides guidance for implementing safer medical devices that reduce or eliminate sharps injuries to laboratory personnel.

X04-R **Planning for Challenges to Clinical Laboratory Operations During a Disaster; A Report (2003).** This document provides guidance on steps to be taken by the clinical laboratory to be prepared in the event of an emergency.

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