CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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AUTO03-A2

Laboratory Automation: Communications With Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard—Second Edition

This document provides standards to facilitate accurate and timely electronic exchange of data and information between the automated laboratory elements.

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

Clinical and Laboratory Standards Institute

Setting the standard for quality in medical 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 medical laboratory standards and guidelines that help laboratories fulfill their responsibilities with efficiency, effectiveness, and global applicability.

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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.

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

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Laboratory Automation: Communications With Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard—Second Edition

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Abstract

Clinical and Laboratory Standards Institute document AUTO03-A2—*Laboratory Automation: Communications With Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard—Second Edition* provides standards to facilitate accurate and timely electronic exchange of data and information between the automated laboratory elements. This will allow and encourage scalable, open systems, and extendibility and interoperability of the automated laboratory elements. Implementation of this standard will contribute to the development of a shared vision of future clinical laboratory automation communications.

Clinical and Laboratory Standards Institute (CLSI). *Laboratory Automation: Communications With Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard—Second Edition.* CLSI document AUTO03-A2 (ISBN 1-56238-707-3). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2009.

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Matrix of CLSI Laboratory Automation Standards

The CLSI laboratory automation standards AUTO01,[1] AUTO02,[2] AUTO03, AUTO04,[3] and AUTO05[4] are interdependent with respect to their implementation in automated laboratory systems. The matrix describes the engineering relationships between the standards elements in each of the five documents. This matrix is provided so designers and engineers, as well as users and customers, understand the relationships between the different standards' components in an automated system. The matrix format allows the users of one document to easily identify other standard elements, which relate to the standard elements in the document or documents from which they may be working, to design a system correctly.

How to Read the Matrix (See the matrix on the next page.)

The numbers listed on the horizontal (X) and vertical (Y) axes contain multiple-digit numbers [eg, (1)5.4, (5)5.4.1.3].

The 'first digit' (in parentheses) represents one of the five automation documents [eg, (1)5.4 is from AUTO01; (5)5.4.1.3 is from AUTO05].

The 'remaining digits' represent the specific section of that document.

The symbol XX represents the direct 'engineering relationship' between two sections.

The symbol ## represents the section's 'self'; when it has been lined up with itself on the other axis.

The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management 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. The approach is based on the model presented in the most current edition of CLSI/NCCLS document HS01—*A Quality Management System Model for Health Care.* The quality management system approach applies a core set of "quality system essentials" (QSEs), basic to any organization, to all operations in any health care service's path of workflow (ie, operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager's guide. The QSEs are

Documents and Records	Equipment	Information Management	Process Improvement
Organization	Purchasing and Inventory	Occurrence Management	Customer Service
Personnel	Process Control	Assessment—External and Internal	Facilities and Safety

AUTO03-A2 addresses the QSEs 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.

Documents and Records	Organization	Personnel	Equipment	Purchasing and Inventory	Process Control	Information Management	Occurrence Management	Assessments—External and Internal	Process Improvement	Customer Service	Facilities and Safety
			AUTO01 AUTO02		AUTO02 AUTO04	X AUTO04 AUTO05					
GP19	GP19	GP19	GP19	GP19	GP19 LIS01 LIS02 M29	GP19 LIS01 LIS02	GP19		GP19	GP19	GP19 M29

Adapted from CLSI/NCCLS document HS01—*A Quality Management System Model for Health Care*.

Path of Workflow

A path of workflow is the description of the necessary steps to deliver the particular product or service that the organization or entity provides. For example, CLSI/NCCLS document GP26—*Application of a Quality Management System Model for Laboratory Services* defines a clinical laboratory path of workflow, which consists of three sequential processes: preexamination, examination, and postexamination. All clinical laboratories follow these processes to deliver the laboratory's services, namely quality laboratory information.

AUTO03-A2 addresses the clinical laboratory path of workflow steps 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 LIS01 LIS02	

Adapted from CLSI/NCCLS document HS01—*A Quality Management System Model for Health Care*.

Related CLSI Reference Materials*

AUTO01-A **Laboratory Automation: Specimen Container/Specimen Carrier; Approved Standard (2000).** This document provides standards for the design and manufacture of specimen containers and carriers used for collecting and processing liquid samples, such as blood and urine, for clinical testing in laboratory automation systems.

AUTO02-A2 **Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard—Second Edition (2005).** This document provides specifications for use of linear bar codes on specimen container tubes in the clinical laboratory and for use on laboratory automation systems.

AUTO04-A **Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements; Approved Standard (2001).** This document describes operational requirements, characteristics, and required information elements of clinical laboratory automation systems. This information is used to determine the status of a clinical specimen within the clinical laboratory automation system, as well as the status of the actual components of the clinical laboratory automation system.

AUTO05-A **Laboratory Automation: Electromechanical Interfaces; Approved Standard (2001).** This document provides standards for the development of an electromechanical interface between instruments and specimen processing and handling devices used in automated laboratory testing procedures.

GP19-A2 **Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline—Second Edition (2003).** This document identifies important factors that designers and laboratory managers should consider when developing new software-driven systems and selecting software user interfaces. Also included are simple rules to help prepare validation protocols for assessing the functionality and dependability of software.

LIS01-A2 **Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems; Approved Standard—Second Edition (2008).** This document describes the electronic transmission of digital information between clinical laboratory instruments and computer systems.

LIS02-A2 **Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems; Approved Standard—Second Edition (2004).** This document covers the two-way digital transmission of remote requests and results between clinical laboratory instruments and information systems.

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.

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

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