CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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AUTO02-A2

Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard—Second Edition

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.

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.

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

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Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard—Second Edition

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Abstract

Clinical and Laboratory Standards Institute document AUTO02-A2—*Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard—Second Edition* defines the way bar-coded sample identification labels are applied to clinical specimen containers. It documents the form, placement, and content of bar-code labels on specimen container tubes that are used on clinical laboratory analyzers. However, due to the current diversity of patient data, the informational content that is used to identify the specimen has not been specified. This specification will also meet the requirement for laboratory automation systems. It enables the production of reliable bar-coded symbols that are readable by any complying clinical laboratory analyzer and automation system.

Clinical and Laboratory Standards Institute (CLSI). *Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard—Second Edition*. CLSI document AUTO02-A2 (ISBN 1-56238-589-5). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2005.

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Contents

Matrix of CLSI/NCCLS Laboratory Automation Standards

The laboratory automation standards AUTO1, AUTO02, AUTO3, AUTO4, and AUTO5 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 that 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 [e.g., (1)5.4, (5)5.4.1.3].

The 'first digit' (in parentheses) represents one of the five automation documents [e.g., (1)5.4 is from AUTO1; (5)5.4.1.3 is from AUTO5].

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 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 HS1—*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 healthcare service's path of workflow (i.e., 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 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

AUTO02-A2 addresses the quality system essentials (QSEs) indicated by an "X." For a description of the other documents listed in the grid, please refer to the Related CLSI/NCCLS Publications section on the following page.

Documents & Records	Organization	Personnel	Equipment	Purchasing & Inventory	Process Control	Information Management	Occurrence Management	Assessment	Process Improvement	Service & Satisfaction	Facilities & Safety
GP2			X AUTO1 H38		X	AUTO3 AUTO4 AUTO5					GP18 M29

Adapted from CLSI/NCCLS document HS1—*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.

AUTO02-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/NCCLS Publications 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
			H18					

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

Related CLSI/NCCLS Publications*

AUTO1-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 automaton systems.

AUTO3-A **Laboratory Automation: Communications With Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard (2000).** This document provides standards to facilitate accurate and timely electronic exchange of data and information between the automated laboratory elements.

AUTO4-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.

AUTO5-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.

AUTO7-A **Laboratory Automation: Data Content for Specimen Identification; Approved Standard (2004).** This document provides specifications for the content of linear bar codes on specimen container tubes in the clinical laboratory and for use on laboratory automation systems.

GP2-A4 **Clinical Laboratory Technical Procedure Manuals; Approved Guideline—Fourth Edition (2002).** This document provides guidance on development, review, approval, management, and use of policy, process, and procedure documents in the laboratory testing community. (See related publication GP21-A2.)

GP2-A4-C **NCCLS Procedure Manual Toolkit.** These templates enable one to establish a starting point for creating one's own laboratory-specific procedure manual. The templates allow the user to enter information into a "boiler plate" file where the parameters are preformatted—headers and footers are set. The user can simply open the template and fill in the blanks. A few samples are proved so that the user has a visual representation of the various sections of the completed procedure.

GP18-A **Laboratory Design; Approved Guideline (1998).** This guideline provides a foundation of information about laboratory design elements that can be used to help define the issues being considered when designing a laboratory.

H18-A3 **Procedures for the Handling and Processing of Blood Specimens; Approved Guideline—Third Edition (2004).** This document includes criteria for preparing an optimal serum or plasma sample and for the devices used to process blood specimens.

H38-P **Calibration and Quality Control of Automated Hematology Analyzers; Proposed Standard (1999).** This document addresses calibration and quality control strategies for multichannel hematology analyzers; assignment of values to calibrator materials; calibration using stabilized blood controls; internal quality control; pair difference analysis; and use of the weighted moving average ($\overline{x}_B$) method.

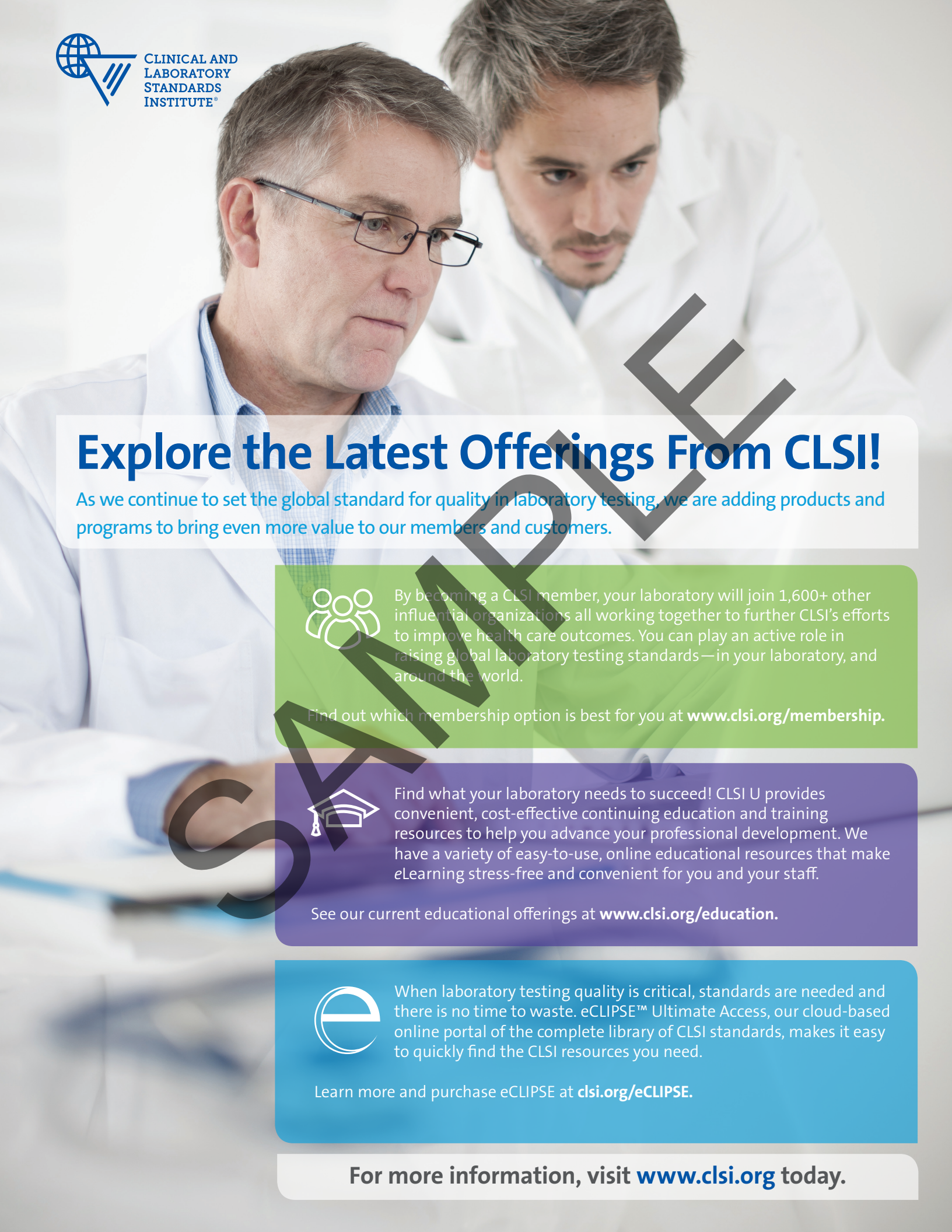
LIS1-A **Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems (2003).** This specification describes the electronic transmission of digital information between clinical laboratory instruments (those that measure one or more parameters from one or multiple samples) and computer systems (those that are configured to accept instrument results for further processing, storage, reporting, or manipulation).

* Proposed-level documents are being advanced through the Clinical and Laboratory Standards Institute consensus process; therefore, readers should refer to the most current editions.

Related CLSI/NCCLS Publications (Continued)

LIS2-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. It enables any two such systems to establish a logical link for communicating text to send result, request, or demographic information in a standardized and interpretable form.

M29-A3 **Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition (2005).** Based on U.S. 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.



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