CLINICAL AND LABORATORY STANDARDS INSTITUTE®

June 2004

AUTO07-A

Laboratory Automation: Data Content for Specimen Identification; Approved Standard

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.

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.

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 managed according to the consensus process by a committee of experts.

Appeals Process

When it is believed that an objection has not been adequately considered and responded to, the process for appeals, documented in the CLSI Standards Development Policies and Processes, is followed.

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 additional 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: +1.610.688.0100
F: +1.610.688.0700
www.clsi.org
standard@clsi.org

Laboratory Automation: Data Content for Specimen Identification; Approved Standard

Volume 24 Number 20

Randy R. Davis
Suzanne H. Butch, M.A., M.T.(ASCP), S.B.
David Chou, M.D.
Stanley D. Cooper, Ph.D.
Jeff Quint, Ph.D.
Robert O. Rainer, M.D.
John J. Roberts, J.D.
Eugene, J. Youkilis, Ph.D.

Abstract

CLSI document AUTO07-A—*Laboratory Automation: Data Content for Specimen Identification; Approved Standard* was developed to standardize the way specimens are identified. With the consolidation of healthcare facilities and clinical laboratory testing sites for a given healthcare enterprise, specimen processing may be achieved at a variety of sites. This standard allows for specimens from a given enterprise to be processed in a central location. The specimen identification must be able to not only be linked to the patient, but also to the requesting facility. This standard describes the format for specimen numbering that will enable specimens to be processed by independent sites and still be linked to the patient and the requesting facility. The standard is an extension of CLSI document AUTO2—*Laboratory Automation: Bar Codes for Specimen Container Identification,* which defines location and format of the label and the bar code.

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

Suggested Citation

CLSI. *Laboratory Automation: Data Content for Specimen Identification; Approved Standard.* CLSI document AUTO07-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2004.

Previous Edition:
November 2003

Reaffirmed:
July 2010

Archived:
January 2017

Contents

Foreword

One of the enabling technologies that makes automation of clinical testing possible is an inexpensive, reliable way to identify individual specimens as unique entities. The most common method for accomplishing this identification is through the use of bar codes. While there has been a recent effort to provide a bar-code standard for use with clinical instruments, there still remain many aspects of specimen identification that may require standards to ensure that the specimen bar-code identification method will be useful not only in automated systems but also in all laboratory testing settings. For example, the informational content of the bar code must be clearly understood by the information system generating or reading the bar code, but because of the current diversity of patient data, the informational content of bar codes has not yet been specified. In addition, there are a number of emerging technologies that may replace the current linear bar-code method as the specimen identification system of choice. Examples include two-dimensional bar codes and radio frequency tagging.

Automation topics for the standardization of identifiers for specimen container identification covered in this document include:

- bar-code label characteristics (size, white space, number of characters, resolution, etc.);
- scanner characteristics (scan rate, focal length, scan length, symbology decoding, etc.);
- label placement tolerance;
- manufacturer-supplied, bar-code-labeled tubes (symbology, unique identification requirements, etc.);
- method to identify specimen type; and
- relationship between specimen, container, and carrier.

These specifications are also intended to complement the following interrelated NCCLS standards developed by other automation subcommittees and to support overall operational goals for future development in laboratory instrumentation and automation:

AUTO1—*Laboratory Automation: Specimen Container/Specimen Carrier;*
AUTO2—*Laboratory Automation: Bar Codes for Specimen Container Identification;*
AUTO3—*Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems;*
AUTO4—*Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements;* and
AUTO5—*Laboratory Automation: Electromechanical Interfaces.*

Key Words

Bar code, content, label, symbol

Mission Statement of the Area Committee on Automation and Informatics

The mission of the Area Committee on Automation and Informatics is:

"…to identify the need for, set priorities for, and manage and coordinate the development of compatible standards and guidelines that address, in a prospective manner, the design and integration of automated clinical laboratory systems worldwide. In addition, the area committee will foster communication of the issues and developments worldwide."

Attributes of Standards for Laboratory Automation Systems

It was agreed by the Area Committee on Automation and Informatics that all of the laboratory automation system standards should share the following attributes:

- **Prescriptive** – Essential requirements should be prescriptive, and should define only those features essential for compatibility of instruments, devices, and laboratory automation systems.

- **Prospective** – Standards should describe the desired and necessary attributes which will enable and enhance the connectivity of laboratory automation system components in the future; the creation of a laboratory automation system from components should not be constrained by obsolete or inadequate technology which may be in current use.

- **Inclusive** – Current technology with widespread use should not be excluded unless it impedes connectivity; in some instances, a future date for discontinuation of a technology may be recommended to encourage upgrades, providing sufficient time for interested laboratories or suppliers to comply with new requirements.

- **Explanatory** – In cases where exclusions are recommended that are not obvious, or where consensus is not achieved, the documents should include a brief rationale and, possibly, a description of opposing viewpoints.

- **Differentiating** – In view of the complexity of the tasks, documents should differentiate between imperative prescriptions ("must" verbal forms) and discretionary recommendations ("should" verbal forms).

- **Enabling of Innovation** – The concept of "prescriptive, essential requirements" should be employed to ensure that performance requirements rather than design specifications are utilized to the extent possible.

- **Consistent** – Each document should be written to be "self-sufficient" with respect to the scope of its individual effort. The five documents are interrelated and interdependent, and presented in a consistent style using cross-references and a common glossary of terms (definitions) giving the appearance of a collection of documents.

The clinical laboratory automation standards effort has attempted to engage the broadest possible worldwide representation in committee deliberations. Consequently, it was reasonable to expect that controversies existed and issues remained unresolved at the time of publication of the initial proposed-level documents. A mechanism for resolving such controversies through the subcommittees and the Area Committee on Automation and Informatics was employed during the review and comment process.

The NCCLS voluntary consensus process is dependent upon broad distribution of documents for review and comment and upon the expertise of reviewers worldwide whose comments add value to the effort. At the end of the comment period, each subcommittee was obligated to review all comments and to respond in writing to all which are substantive. Where appropriate, modifications were made to the respective document, and all comments, along with the subcommittee's responses, are included in the Summary of Comments and Committee Responses at the end of each document.

SAMPLE

Laboratory Automation: Data Content for Specimen Identification; Approved Standard

1 Scope

This document will define a format for specimen identification in a logical manner that allows systems with different and varying capabilities to utilize a common structured format. Different identification techniques will allow varying amounts of data to be transported with the specimens. Each of these techniques will expand on the basic required information.

2 Introduction

With the consolidation of healthcare facilities, emergence of laboratory automation centers, and the use of reference laboratories, proper identification of patient samples requires standardization of the data content used to identify the specimen.

Healthcare facilities are consolidating, and clinical laboratory testing for a given healthcare enterprise may be achieved at a variety of sites, allowing samples for a given enterprise to be processed in a central location. The specimen identification must be able to not only link to the patient, but also to the requesting facility. Reference laboratories face the same demands and usually have to reidentify the samples with something that is compatible with their operating systems.

A consolidated healthcare system may operate several laboratory information systems, each of which independently issues specimen numbers. As a result, specimen numbers issued from one computer may collide with those issued by another system. This standard provides a means for systems to independently issue specimen numbers in a manner to avoid collisions, so specimen numbers created by one system can be accepted on another. This standard does not provide for a means to exchange order or patient information. It is expected that interfaces between computer systems will provide such linkage of the specimen number to this data. Every attempt has been made to ensure that this standard is forward compatible within the scope of existing standards, including International Society of Blood Transfusion and NCCLS document AUTO2—*Laboratory Automation: Bar Codes for Specimen Container Identification* and to conservatively project the available future technologies.

3 Definitions

Some of the computer-, automation-, or robotics–related terms used in the five interrelated NCCLS automation documents (AUTO1 through AUTO5) can be found in ANSI X3.172[1], ANSI X3.182-1990[2], ASTM F149-92b(2003)[3], IEEE 100,[4] IEEE 610,[5] IEEE 1007[6], and HL7 Version 2.5[7]:

Aliquot – *In Automation,* a portion of a specimen placed in a separate container to facilitate concurrent testing or to hold in reserve for future use; **NOTES:** a) The portion of the specimen is typically removed from the original specimen after initial processing, such as centrifugation, to obtain serum or plasma samples, and is considered to be chemically identical to all other subdivisions of an original specimen of serum, plasma, urine, cerebral spinal fluid (CSF), etc.; b) It may be necessary to identify the aliquot as an individual specimen distinct from the original specimen in a collection container labeled with a unique identifier that may be linked to or associated with the primary collection container.

ANSI – Acronym for American National Standards Institute; **NOTE:** *In Automation,* the Microsoft Windows ANSI character set is composed of ISO 8859/x plus additional characters.

ASTM – Abbreviation for ASTM International, the official name of the organization formerly known as the American Society for Testing and Materials; **NOTE:** ASTM has developed various high- and low-level communications protocols.

Bar code – **1)** An array of parallel rectangular bars and spaces that creates a symbology representing a number or alphanumeric identifier; **2)** An array of rectangular lines and spaces that are arranged in a predetermined pattern following unambiguous rules and representing data that are referred to as characters; **3)** An identification code consisting of a pattern of vertical bars whose width and spacing identifies the item marked; **NOTES:** a) The code is meant to be read by an optical input device, such as a bar-code scanner; b) Applications include retail product pricing labels, identification of library documents, and railroad boxcar identification. (IEEE 610.2[5])

Bar length – The length of the bars in the bar code.

Bottom of cap – The farthest point from the top of the container/test tube that the cap reaches; **NOTE:** This point may be inside the tube.

Bottom of container//Bottom of tube – The portion of the container/test tube farthest from the cap.

Bottom of tube – See **Bottom of container.**

Character – **1)** The smallest abstract element of a writing system or script; **NOTE:** A character refers to an abstract idea rather than to a specific shape; **2)** A code element; **3)** A member of a set of elements upon which agreement has been reached and that is used for the organization, control, or representation of information; **NOTE:** Characters may be letters, digits, punctuation marks, or other symbols, often represented in the form of spatial arrangement of adjacent or connected strokes or in the form of other physical conditions in the data media; **4)** A letter, digit, or other symbol that is used as part of the organization, control, or representation of data; **NOTE:** A character is often in the form of a spatial arrangement of adjacent or connected strokes. (ASTM F149-92b (2003)[3]); **5)** *In data transmission*, one of a set of elementary symbols which normally include both alpha and numeric codes plus punctuation marks and any other symbol which may be read, stored, or written and is used for organization, control, or representation of data; **6)** *In computers,* a letter, digit, or other symbol used to represent information. (IEEE 610.1, 610.5, 610.12[5])

Container//Tube//Test tube – See **Specimen collection container.**

Health Level 7 (HL7) – The highest level (application) communications model for open systems interconnection (OSI); **NOTE:** Level 7 supports security checks, participant identification, availability checks, exchange mechanism negotiations, and data exchange structuring.[7]

Healthcare Informatics Standards Board (**HISB)** – An organization that coordinates activities of all standards developers in the healthcare informatics area of ANSI organizations.

IEEE – Abbreviation for Institute of Electrical and Electronics Engineers, Inc.

JIS – Abbreviation for Japan Industry Standard.

Label – **1)** The display of written, printed, or graphic matter upon the immediate container of any article; **2)** *In Automation*, the paper and attached adhesive coating on which the bar code and other human readable information is printed; **3)** A piece of paper or other material to be affixed to a container or article, on which is printed a legend, information concerning the product, or addresses. It may also be printed directly on the container;[8] **4)** *In computer software,* a name or identifier assigned to a computer
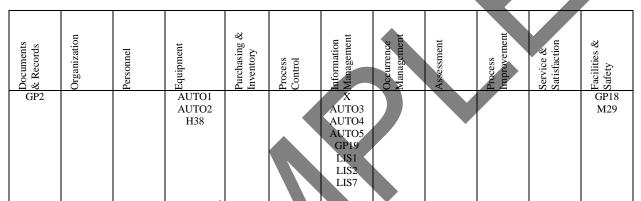
The Quality System Approach

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 QSEs are:

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

AUTO07-A addresses the QSEs indicated by an "X." For a description of the other NCCLS documents listed in the grid, please refer to the Related 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			AUTO1 AUTO2 H38			X AUTO3 AUTO4 AUTO5 GP19 LIS1 LIS2 LIS7					GP18 M29

Adapted from NCCLS document HS1—*A Quality 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, GP26-A2 defines a clinical laboratory path of workflow which consists of three sequential processes: preanalytic, analytic, and postanalytic. All clinical laboratories follow these processes to deliver the laboratory's services, namely quality laboratory information.

AUTO07-A addresses the clinical laboratory path of workflow steps indicated by an "X." For a description of the other NCCLS documents listed in the grid, please refer to the Related NCCLS Publications section on the following page.

Preanalytic					Analytic		Postanalytic	
Patient Assessment	Test Request	Specimen Collection	Specimen Transport	Specimen Receipt	Testing Review	Laboratory Interpretation	Results Report	Post-test Specimen Management
				H18				

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

Related NCCLS Publications*

AUTO1-A   **Laboratory Automation: Specimen Container/Specimen Carrier; Approved Standard (2000).** This document contains standards for design and manufacture of specimen containers and specimen carriers used for collection and processing of specimens, such as blood and urine, for testing on laboratory automation systems.

AUTO2-A   **Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard (2000).** 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.

AUTO3-A   **Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard (2000).** The goal of this document is 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 provides standards of interest to operators for display of system status information such as specimen location, reagent supply, and warnings and alerts to support laboratory automation operations.

AUTO5-A   **Laboratory Automation: Electromechanical Interfaces; Approved Standard (2001).** This document provides guidance for the standardization of electromechanical interfaces between instruments and/or specimen processing and handling devices and automation systems in the automated laboratory.

GP2-A4-C   **The NCCLS Procedure Manual Toolkit.** The major concepts of document control outlined in GP2-A4 are presented in a user-friendly format that is easy to read—and, thanks to the *NCCLS Manual Toolkit*—implement. The *toolkit* includes a collection of eight Microsoft Word templates (one duplicated as an Excel spreadsheet) with appropriate samples. The templates enable the user to establish a starting point for creating laboratory-specific procedures. Each template is set up such that the information is entered into a "boiler plate" template with the parameters already formatted allowing for standardization in procedure format—simply open the template and fill in the blanks. The samples are there to provide the user with an idea of what the finished product will look like.

GP2-A4   **Clinical Laboratory Technical Procedure Manuals; Approved Guideline—Fourth Edition (2002).** This document provides guidance for the patient-testing community by addressing the design, preparation, maintenance, and use of paper or electronic technical procedure manuals.

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.

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.

H18-A2   **Procedures for the Handling and Processing of Blood Specimens; Approved Guideline—Second Edition (1999).** This guideline addresses multiple factors associated with handling and processing of specimens, and factors that can introduce imprecision or systematic bias into results.

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.

---

* Proposed- and tentative-level documents are being advanced through the NCCLS consensus process; therefore, readers should refer to the most recent editions.

Related NCCLS Publications (Continued)

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 the 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.

LIS2-A   **Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems (2003).** This standard covers the two-way digital transmission of remote requests and results between clinical instruments and computer systems. It enables any two such systems to establish a logical link for communicating text to send result, request, or demographic information in a standard and interpretable form.

LIS7-A   **Standard Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory (2003).** This specification identified 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 tubes that are used on clinical laboratory analyzers. It enables Laboratory Information System vendors to produce reliable bar-coded symbols that are readable by any complying clinical laboratory analyzer vendor.

M29-A2   **Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline— Second Edition (2001).** This document provides guidance on the risk of transmission of hepatitis viruses and human immunodeficiency viruses in any laboratory setting; specific precautions for preventing the laboratory transmission of blood-borne infection from laboratory instruments and materials; and recommendations for the management of blood-borne exposure.

Explore the Latest Offerings From CLSI!

As we continue to set the global standard for quality in laboratory testing, we are adding products and programs to bring even more value to our members and customers.

By becoming a CLSI member, your laboratory will join 1,600+ other influential organizations all working together to further CLSI's efforts to improve health care outcomes. You can play an active role in raising global laboratory testing standards—in your laboratory, and around the world.

Find out which membership option is best for you at **www.clsi.org/membership.**

Find what your laboratory needs to succeed! CLSI U provides convenient, cost-effective continuing education and training resources to help you advance your professional development. We have a variety of easy-to-use, online educational resources that make *e*Learning stress-free and convenient for you and your staff.

See our current educational offerings at **www.clsi.org/education.**

When laboratory testing quality is critical, standards are needed and there is no time to waste. eCLIPSE™ Ultimate Access, our cloud-based online portal of the complete library of CLSI standards, makes it easy to quickly find the CLSI resources you need.

Learn more and purchase eCLIPSE at **clsi.org/eCLIPSE.**

For more information, visit www.clsi.org today.

SAMPLE

**CLINICAL AND
LABORATORY
STANDARDS
INSTITUTE®**