CLINICAL AND LABORATORY STANDARDS INSTITUTE®

December 2005

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.

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

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AUTO02-A2
Vol. 25 No. 29
Replaces AUTO2-A
Vol. 20 No. 19

ISBN 1-56238-589-5
ISSN 0273-3099

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

Volume 25 Number 29

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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.

Suggested Citation

CLSI. *Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard—Second Edition.* CLSI document AUTO02-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2005.

Proposed Standard
December 1998

Approved Standard
October 2000

Approved Standard—Second Edition
December 2005

ISBN 1-56238-589-5
ISSN 0273-3099

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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].

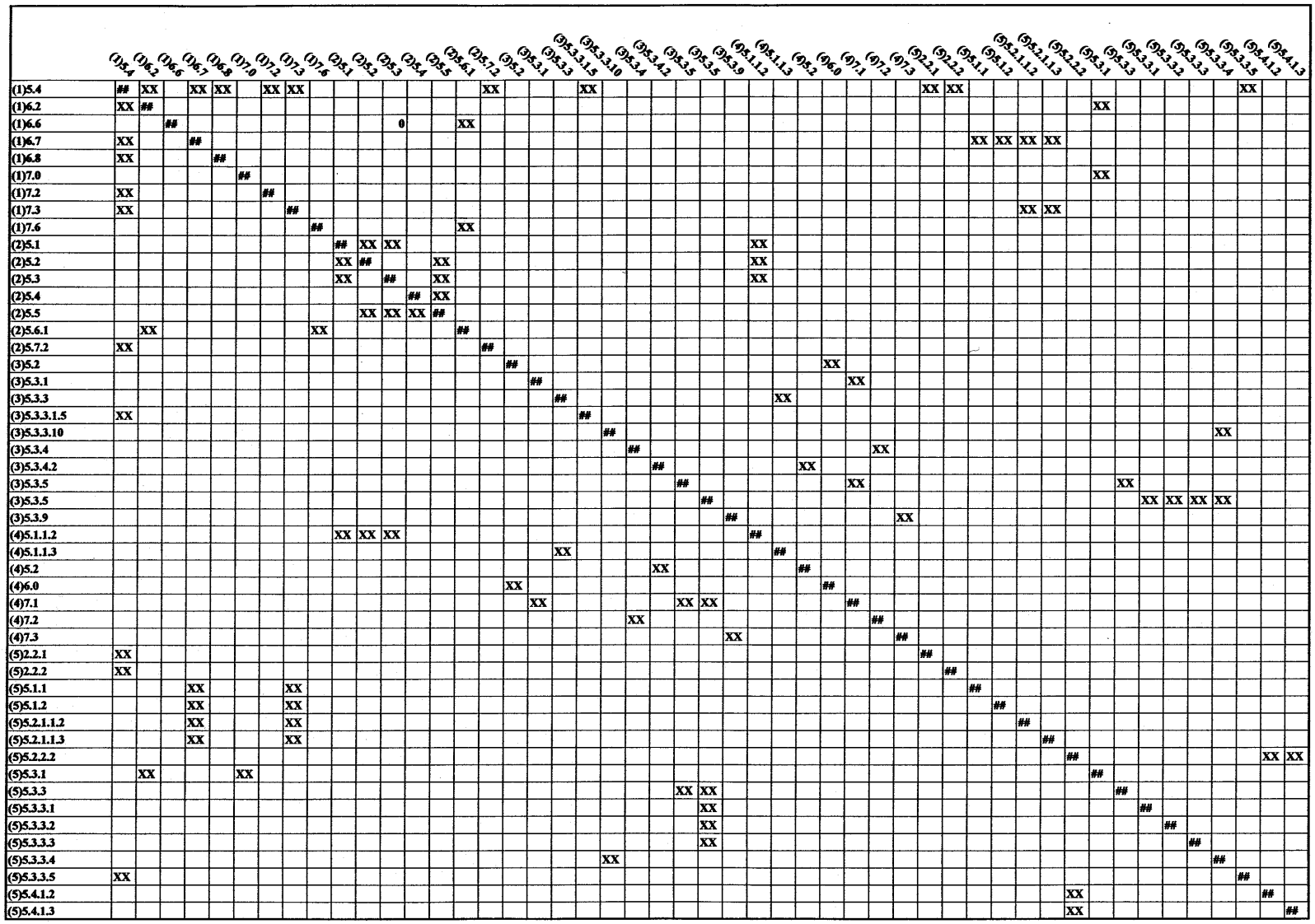
The 'remaining digits' represent the specific section of that document.

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.

Matrix of CLSI/NCCLS Laboratory Automation Standards

This matrix cross-links sections from CLSI/NCCLS documents AUTO1, AUTO02, AUTO3, AUTO4, and AUTO5.



Preface to Laboratory Automation Standards

Background

In late 1996, CLSI agreed to undertake the complex and challenging task of managing an effort to develop standards for clinical laboratory automation, based upon the urgent request of many leading individuals and institutions in the field. Standardization was needed to overcome difficulties and unnecessary costs incurred by laboratories and manufacturers in their efforts to integrate and simplify laboratory functions using technology.

As a result of discussions at an annual meeting of the International Conference on Automation, Robotics, and Artificial Intelligence Applied to Analytical Chemistry and Laboratory Medicine (ICAR) in 1994, an interested group of individuals formed the Clinical Testing Automation Standards Steering Committee (CTASSC). The CTASSC approached CLSI's leadership seeking collaboration, and believing that the desired standards could best be developed utilizing the unique voluntary consensus process, resources, and expertise of CLSI and its member organizations. It was expected that cooperation would also be necessary with other complementary standards-developing bodies, such as ASTM, IEEE, and HL7.

The original shared vision was to take advantage of market forces within the industry and of the benefits of implementing prospective standards in the context of market forces and industry support, so that customers (laboratories) and vendors could enjoy products that function together, and buyers and suppliers could agree on a format for laboratory automation systems.

CLSI accepted the challenge and committed to the following:

- CLSI's voluntary consensus process would be utilized to ensure balance, fairness, and broad review of documents by all institutions affected by the effort.

- The project would be global in scope and participation.

- Sources and mechanisms for funding would be identified to ensure that the projects would be given high priority to achieve timely completion.

CLSI surveyed the interest of all institutions likely to be affected by the proposed standards effort, and confirmed high interest in providing both expertise and financial support. CLSI presented the proposal at several meetings in the United States, Japan, and Europe to increase awareness of the activity and to invite broad, global participation. Based upon favorable response to the proposals, the CLSI Board of Directors authorized the creation of a new Area Committee on Automation and Informatics, chaired by Dr. Rodney S. Markin, with Mr. Paul J. Mountain serving as its Vice-Chairholder.

Mission Statement

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."

Subcommittee Activities

Based upon the recommendations of the new area committee, the Board authorized establishment of five subcommittees to manage the development of the following documents:

- **AUTO1—*Specimen Container/Specimen Carrier*** contains standards for the design and manufacture of specimen containers and carriers used for collecting and processing samples, such as blood and urine, for testing on laboratory automation systems.

- **AUTO02—*Bar Codes for Specimen Container Identification*** provides specifications for linear bar codes on specimen containers for use on laboratory automation systems.

- **AUTO3—*Communications With Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems*** facilitates accurate and timely electronic exchange of data and information among automated instruments, laboratory automation systems, and other information systems.

- **AUTO4—*Systems Operational Requirements, Characteristics, and Informational Elements*** 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—*Electromechanical Interfaces*** provides guidance for the standardization of electromechanical interfaces between instruments and/or specimen processing and handling devices and automation systems in the automated laboratory.

The five subcommittees began their efforts in the spring of 1997, with goals to develop proposed standards suitable for publication and review by the end of 1999 consistent with the formal CLSI consensus process, and to advance them to the approved consensus stage in 2000.

Validation of Designs, Systems, and Software

The five laboratory automation standards are tools to help in the design, development, and implementation of laboratory automation systems (LAS) for the clinical laboratory. Each standard may be used fully or in part, whether or not the intent is to design a completely automated or semiautomated system. These standards provide specifications that can be adhered to and verified during various phases of development for each LAS project. Adherence to standards alone does not ensure valid system design. Design validation confirms that the medical devices (LAS) meet user needs and intended use. Software validation is also a required component of the design validation of a medical device.[a] Also refer to CLSI/NCCLS document GP19—*Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring.*

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.

[a] A good source of information on these and related subjects, plus other medical device regulations, can be found on FDA/CDRH web pages, available at: http://www.fda.gov/cdrh/.

- **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 that 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 five interrelated automation standards are a system of related documents that are available separately or packaged in a manner similar to CLSI Specialty Collections.

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 CLSI 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 is 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.

Special Recognition of Global Participation

The CLSI Board of Directors wishes to give special recognition and thanks to several organizations that have taken leadership roles in the development of these standards, including the Japanese Committee for Clinical Laboratory Standards (JCCLS), the Japanese Society for Clinical Chemistry (JSCC), and the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). These and other organizations have helped shape the global scope of these documents.

CLSI can only succeed in fulfilling its responsibilities with the cooperation of other organizations and individuals. In view of the economic and quality benefits expected by laboratory practitioners and manufacturers upon implementation of standardization in automation, broad participation and cooperation was sought and obtained, and is gratefully acknowledged. CLSI will continue to achieve a position of worldwide leadership and influence in the development and harmonization of global standards for the healthcare community.

Recognition of the Efforts of Other Standards Organizations

CLSI would like to acknowledge and thank the volunteers who are active participants in the related work of other standards organizations for their contributions to the laboratory automation program. Their effective leadership and outstanding volunteer service during the development and successful completion of the automation standards is greatly appreciated. This special recognition includes volunteers who are participants in the following standards organizations:

American National Standards Institute (ANSI) Health Informatics Standards Board (HISB)
ASTM (formerly American Society for Testing and Materials) Committee E31
Health Level 7 (HL7)
Institute of Electrical and Electronics Engineers, Inc. (IEEE)
International Federation of Clinical Chemistry and Laboratory Medicine (IFCC)
International Organization for Standardization Technical Committee 212 (ISO/TC 212)
Japanese Association of Healthcare Information Systems (JAHIS)
Japanese Committee for Clinical Laboratory Standards (JCCLS)
Japanese Society for Clinical Chemistry (JSCC)

Recognition of Laboratory Automation Fund Contributors

Many of the large instrument and automation system vendors and the users of the technology recognized the clear need to develop standards for clinical laboratory automation and information systems, and actively supported CLSI in meeting this need through the efforts of the Area Committee on Automation and Informatics. To achieve standardization and ensure that automation projects do not compete with other CLSI projects for resources, a Laboratory Automation Development Fund was created. We express our appreciation to all organizations that have supported this important program.

A list of Laboratory Automation Development Fund contributors is listed on pg. xiii of this document.

Acknowledgements

CLSI gratefully acknowledges the following sponsors of this project:

American Association for Clinical Chemistry (AACC)

American Society for Clinical Laboratory Science (ASCLS)

A & T Corporation

Abbott Diagnostics

ARUP Laboratories

Auto Lab Systems

Bayer Diagnostics

Beckman Coulter Corporation

Becton Dickinson and Company

Children's Hospital Medical Center (Cincinnati, OH)

Chiron Diagnostics Corporation

Clinical Laboratory Management Association (CLMA)

College of American Pathologists (CAP)

Compunet Clinical Labs

CRS Robotics

Dade Behring Inc.

Dean Medical Center

Duke University

Enterprise Analysis Corporation

Food and Drug Administration (FDA)

HBO & Company

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Trillium GmbH

Triple G Corporation

UMD of New Jersey University Hospital

University Hospitals Lab Services Foundation

University of Nebraska Medical Center

Wuesthoff Health Systems

Wellmont Health Systems

York Hospital

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 in automated systems. 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 been specified in this standard. 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 bar codes 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 CLSI/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;*
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.*

This document replaces the first approved edition, AUTO2-A, which was published in 2000. Several changes have been made in this edition; chief among them is the addition of recommendations for noncylindrical collection systems and devices (see Section 7). The tables in Appendix B have been removed; information on code 128 character density is now available from most bar-code printer/reader vendors.

Key Words

Bar code, label, symbol

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

1 Scope

This standard ensures that identification of specimen container bar codes will be effective in automated laboratory systems and for sample handling in automated instrumentation. The standard uses Code 128, a bar-code symbology which accommodates many different languages and recommended phasing out all other types of symbologies by the year 2003. In addition, the placement of the label has been recommended to be 9 mm from the bottom and 10 mm from the top of the specimen container with no more than three labels, including the manufacturer's label.

The bar code used for specimen container identification which is referred to in this document may be any one of three SAC attribute fields defined in CLSI/NCCLS document AUTO3—*Laboratory Automation: Communications With Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems,* Section 6.3.3. These fields may depend on the application and include the attributes, container identifier, or primary (parent) container identifier. In some applications, the specimen identification used must be unique to a single container. It is also important to note that the maximum field length as defined in Section 6.3.3 of CLSI/NCCLS document AUTO3 may not be possible. The field size will be limited by the bar-code characteristics and the specimen container sizes used in the specific application.

2 Introduction

As automation becomes more prevalent in the clinical laboratory, standards for bar coding also become necessary. Bar coding aids in information transfer, enhances productivity, and is necessary for automation technologies. It is the intention of this document to provide standards as they apply to specimens contained in test tubes.

This specification is intended to apply to all clinical settings where specimens are collected from patients for examination or analysis in healthcare laboratory operations. It is complementary to and extends the bar code standards created by the Health Industry Business Communication Council (HIBCC). This standard provides requirements that include the symbology, print-quality measurement, module width, symbol size, placement and orientation of the label, data form, and content of bar codes for specimen container identification.

The values stated in metric units (mm) are the preferred units of measure. The values given in parentheses are provided for information only.

3 Standard Precautions

Because it is often impossible to know what might be infectious, all patient and laboratory specimens are treated as infectious and handled according to "standard precautions." Standard precautions are guidelines that combine the major features of "universal precautions and body substance isolation" practices. Standard precautions cover the transmission of all infectious agents and thus are more comprehensive than universal precautions which are intended to apply only to transmission of blood-borne pathogens. Standard and universal precaution guidelines are available from the U.S. Centers for Disease Control and Prevention (Garner JS, Hospital Infection Control Practices Advisory Committee. Guideline for isolation precautions in hospitals. *Infect Control Hosp Epidemiol*. 1996;17(1):53-80). For specific precautions for preventing the laboratory transmission of all infectious agents from laboratory instruments and materials and for recommendations for the management of exposure to all infectious disease, refer to the most

