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 clinical 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 clinical laboratory standards and guidelines that help laboratories fulfill their responsibilities with efficiency, effectiveness, and global applicability.

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CLSI documents undergo periodic evaluation and modification to keep pace with advancements in technologies, procedures, methods, and protocols affecting the laboratory or health care.

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

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NOTE: This document is no longer being reviewed as part of the CLSI consensus process. However, because of its usefulness to segments of the health care community, it is available for its informational content.

AUTO07-A
Vol. 24 No. 20
ISBN 1-56238-537-2
Replaces AUTO7-P
ISSN 0273-3099
Vol. 23 No. 30

Laboratory Automation: Data Content for Specimen Identification; Approved Standard

Volume 24 Number 20

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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.

CLSI. *Laboratory Automation: Data Content for Specimen Identification; Approved Standard*. CLSI document AUTO07-A (ISBN 1-56238-537-2). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2004.

Suggested Citation

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

Proposed Standard
November 2003

Approved Standard
June 2004

ISBN 1-56238-537-2
ISSN 0273-3099

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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.

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.