CLINICAL AND LABORATORY STANDARDS INSTITUTE®

December 2000

AUTO01-A

Laboratory Automation: Specimen Container/ Specimen Carrier; Approved Standard

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.

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

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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.

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Laboratory Automation: Specimen Container/Specimen Carrier; Approved Standard

Volume 20 Number 29

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Abstract

Laboratory Automation: Specimen Container/Specimen Carrier; Approved Standard (CLSI document AUTO01-A) was developed for those engaged in the design and manufacture of specimen collection containers used for specimen handling in the healthcare and clinical laboratory environments, and for those engaged in the design and manufacture of clinical laboratory instrumentation and clinical laboratory automation systems. This document is intended to *lead* design and manufacturing toward standardized products for a wider variety of instruments and automated laboratory systems.

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Contents

Matrix of NCCLS Laboratory Automation Standards

The laboratory automation standards documents, AUTO01, AUTO2, 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 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 AUTO01; (5)5.4.1.3 is from AUTO5).

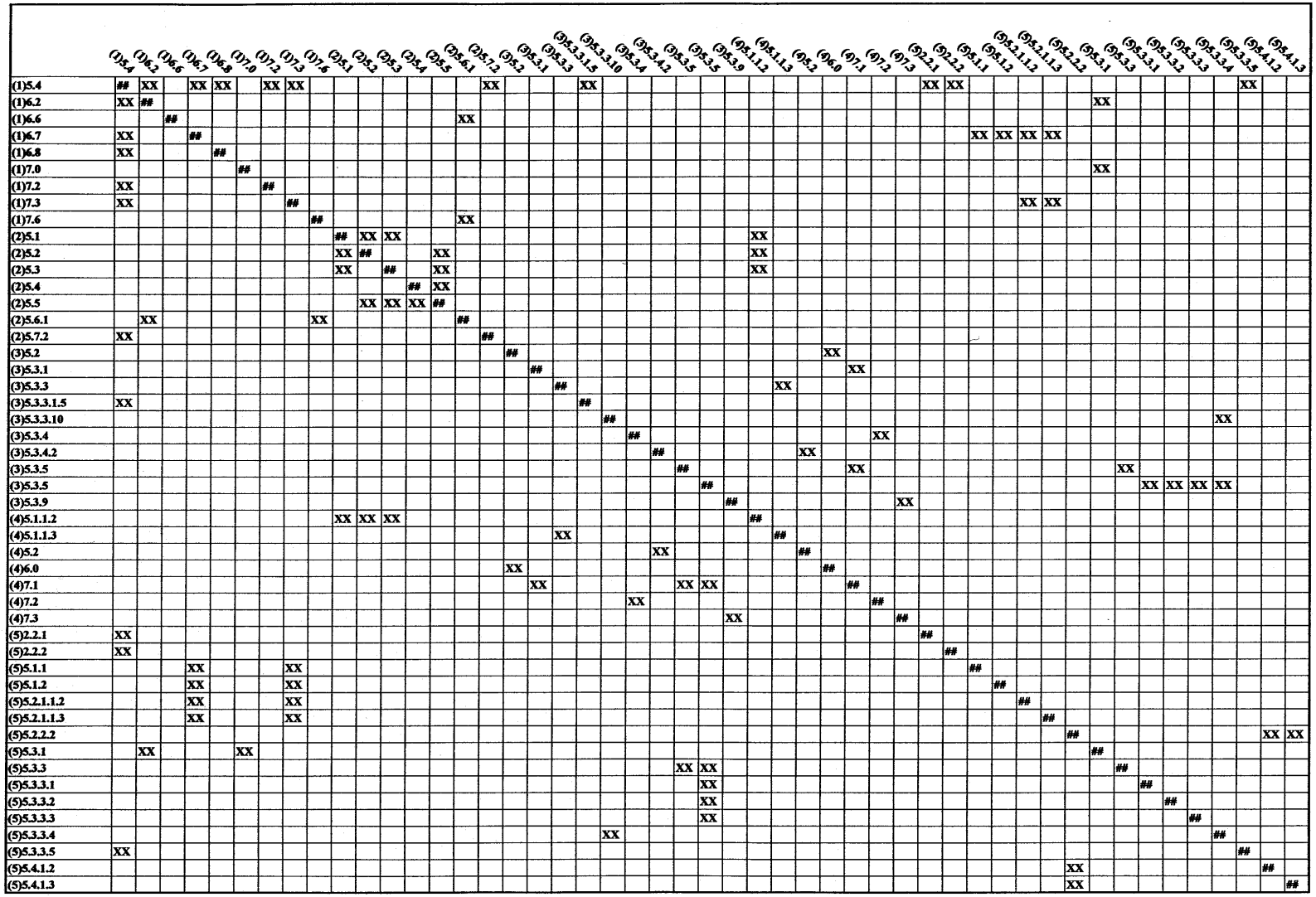
The ‘remaining digits’ represent the specific section of that document.

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 NCCLS Laboratory Automation Standards

This matrix cross-links sections from NCCLS documents, AUTO01, AUTO2, AUTO3, AUTO4, and AUTO5.



Preface to Laboratory Automation Standards

Background

In late 1996, NCCLS 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 had formed the Clinical Testing Automation Standards Steering Committee (CTASSC). The CTASSC approached NCCLS's leadership seeking collaboration, and believing that the desired standards could best be developed utilizing the unique voluntary consensus process, resources, and expertise of NCCLS 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.

NCCLS accepted the challenge and committed to the following:

- NCCLS'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.

NCCLS 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. NCCLS 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 NCCLS Board of Directors authorized the creation of a new Area Committee on Automation, chaired by Dr. Rodney S. Markin, with Mr. Paul S. Mountain serving as its vice-chairholder.

Mission Statement

The mission of the Area Committee on Automation 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."

Preface to Laboratory Automation Standards (Continued)

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:

- **AUTO01—*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.

- **AUTO2—*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 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 NCCLS 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 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 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: http://www.fda.gov/cdrh/.

Preface to Laboratory Automation Standards (Continued)

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

Preface to Laboratory Automation Standards (Continued)

Special Recognition of Global Participation

The NCCLS Board of Directors wishes to give special recognition and thanks to several organizations which 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 (IFCC). These and other organizations have helped shape the global scope of these documents.

NCCLS 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. NCCLS will continue to achieve a position of world leadership and influence in the development and harmonization of global standards for the healthcare community.

Recognition of the Efforts of Other Standards Organizations

NCCLS 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 Committee E31
Health Level 7 (HL7)
International Organization for Standardization Technical Committee 212 (ISO/TC 212)
Institute of Electrical and Electronics Engineers, Inc. (IEEE)
International Federation of Clinical Chemistry (IFCC)
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 NCCLS in meeting this need through the efforts of the Area Committee on Automation. To achieve standardization and ensure that automation projects do not compete with other NCCLS 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 included on the inside front cover of this document.

Foreword

NCCLS document AUTO01-A--*Laboratory Automation: Specimen Container/Specimen Carrier; Approved Standard* represents the efforts of the Area Committee on Automation and the Subcommittee on Specimen Container/Specimen Carrier to standardize specimen containers used for collecting and processing of biological specimens (e.g., blood, plasma, serum, whole blood, and urine) used in clinical laboratory automation systems. This standard also addresses the design and manufacture of specimen carriers used to transport specimen containers within clinical laboratory automation systems.

Differences were recognized and considered among the wide array of manufacturers of specimen containers and carriers that already exist in this field. Previous specimen carrier standardization efforts by the Japanese Committee for Clinical Laboratory Standards (JCCLS) were evaluated as well.

This document includes specifications for both containers used for primary specimen collection (with closure removed) and for containers that might be used as secondary (sample) containers within laboratory automation systems. Dimensions for primary-specimen-collection containers (with closure in place) are also included.

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

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

Automation, blood collection tubes, carriers, containers, laboratory automation, racks, standards, tubes, vacuum blood collection tubes

Laboratory Automation: Specimen Container/Specimen Carrier; Approved Standard

1 Introduction

Over the years, clinical laboratories have evolved from smaller laboratories or subsections of laboratories X each dedicated to a particular discipline (e.g., chemistry). Many laboratory areas were then consolidated, and testing from many sections was combined so that several large-scale instruments became responsible for the majority of testing (core laboratory concept). Recently, this consolidation has evolved to support the development of islands of automation, where several similar instruments can be physically connected and/or controlled and supported by a few technologists. Further consolidation may result in the implementation of total laboratory automation systems.

This evolutionary process has yielded laboratory instruments, support equipment, and automation systems designed to meet the competitive pressures of the market place; however, these products were designed without attempts to make them compatible with each other. The designs and functionalities of these systems have been primarily proprietary, with little consideration for the incorporation of competitors' technologies.

As part of the larger effort to develop overall standards for laboratory automation systems, this document includes standards for specimen collection containers and for the single-container and multiple-container specimen carriers that transport them on and within automated laboratory instruments and systems.

The rationale for determining the specifications for specimen containers can be stated as follows:

Efforts were made to develop a minimum number of container configurations, so automation and/or instrument designers, manufacturers, and vendors could limit the scope of specimen-handling issues. Many containers currently on the market can help define the specifications. Originally, the specifications for the containers included a much narrower range of sizes. However, in subsequent meetings and after comments from manufacturers, the specifications were modified to accommodate a larger array of individual specimen and sample containers or related products. Wider specifications include an array of containers currently manufactured and used around the world. The specifications for container sizes allow for overlapping dimensions between the different nominal tube lengths. This overlap may preclude, in some instances, autodetection of a closure on a container and might require that the number of containers used on or within a specific automation system be restricted by the vendor of the technology.

The rationale for determining specimen-carrier specifications can be stated as follows:

There are two philosophical and design approaches to the transportation of specimen containers: a) single-container-per-specimen carrier; and b) multiple-containers-per-specimen carrier. The single-container-per-specimen carrier appears to be the favored approach of laboratory automation vendors, while the multiple-containers-per-specimen carrier appears to be favored by *in vitro* diagnostics (IVD) vendors. Both the subcommittee and area committee support the use of either approach.

Some of the tenets of the Area Committee on Automation are: a) to preclude the creation of any standard that would inhibit the innovation and creativity of instrument and automation technology designers; and b) to preclude endorsement of a specific product. The rationale for the single container per carrier is simple and easy to understand. The rationale for multiple containers per carrier was based primarily upon the work of JCCLS. The current JCCLS proposed standard for multiple containers per carrier specifies a five-position rack with a 22-mm pitch between specimen containers, an overall length of 110 mm, and a maximum height of 70 mm. By definition, the number of specimen containers per carrier can be no less

