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 NCCLS consensus process.
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Laboratory Automation: Specimen Container/Specimen Carrier; Approved Standard

Abstract

Laboratory Automation: Specimen Container/Specimen Carrier; Approved Standard (NCCLS document AUTO1-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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Laboratory Automation: Specimen Container/Specimen Carrier; Approved Standard

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Williamsburg Community Hospital (VA)
Winchester Hospital (MA)

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Matrix of NCCLS Laboratory Automation Standards

The laboratory automation standards documents, AUTO1, 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 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 NCCLS Laboratory Automation Standards

This matrix cross-links sections from NCCLS documents, AUTO1, AUTO2, AUTO3, AUTO4, and AUTO5.

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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:

- **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.

- **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. 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 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/.  
XVIII
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 AUTO1-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--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.

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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
than two for the multiple containers per carrier. Instrument and automation technology designers are allowed the flexibility in their design process.

The standards suggested here support the current JCCLS five-place rack configuration for those manufacturers who have adopted the JCCLS standard, without precluding the development of future designs.

2 Scope

The overall objective of this document is to establish standards for two components essential to successful automated specimen handling: the specimen container and specimen carrier. The first goal is to establish standard dimensions for specimen collection containers, so use and processing of the specimen can be optimized by laboratory automation systems. The second goal is to determine standard carrier attributes for both single-container and multiple-container carriers to facilitate optimized, automated specimen handling.

Many other kinds of containers are utilized in laboratory practice, including urine collection bottles or blood culture bottles. These containers are not usually placed directly onto laboratory transport systems, and are therefore outside the scope of this effort. Specimens (such as those used for drug-abuse testing), collected in larger containers may be transferred to smaller containers for use on the laboratory automation system (LAS).

This standard fits into the series of interrelated NCCLS automation standards (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).

3 Definitions

Some of the computer-, automation-, or robotics–related terms used in the five interrelated NCCLS automation documents can be found in ANSI X3.172, ANSI X3.182-1990, ASTM D966, ASTM E1013, ASTM F149, ASTM F1156, IEEE 100, IEEE 610, IEEE 1007, and HL7 Version 2.4:

ACK, $n - 1$) A data field name for a general acknowledgment message as specified in the HL7 protocol (HL7 V2.4); 2) A communication control character transmitted by a receiver as an affirmative response to a sender (ASTM).

ADT, $n - 1$) An abbreviation for admission, discharge, or transfer; 2) A data field in a hospital information system denoting admission, discharge, or transfer.

Aliquot, $n$ – 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 sample 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.

b Some of these definitions are found in NCCLS document NRSCL8—Terminology and Definitions for Use in NCCLS Documents. For complete definitions and detailed source information, please refer to the most current edition of that document.
Analyzer, n – An instrument and/or specimen processing and handling device that performs measurements on patient specimens of quantitative, clinically relevant analytes; NOTE: A portion of a patient’s specimen is consumed in the analytic process.

ANSI, n - 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, n – 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.

Audit trail, n – An electronic log of transactions, detailing all events which have occurred in the laboratory automation system, including date and time of these events, which operator was responsible or directs processes, and any additional details.

Automated, adj – A characterization applied when all analytical processes, including sample and reagent uptake, sample/reagent interaction, chemical/biological analysis, result calculation, and result readout are mechanized. NOTE: These are usually controlled by a set of stored, modifiable instructions.

Automated instrument, n – A laboratory instrument that may or may not be connected to a laboratory information system (LIS), hospital information system (HIS), and/or laboratory automation system (LAS), which performs measurements on a patient’s sample; NOTE: These instruments may have specific hardware and/or software modifications that allow interface to a laboratory automation system.

Automation system, n - An automation system refers to a variety of possible systems that can include some of the following types: automated instruments, laboratory information systems (LIS), laboratory automation systems (LAS), hospital information systems (HIS), and front-end processing devices.

Bar code, n – 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 (ASTM F1156); 3) An identification code consisting of a pattern of vertical bars whose width and spacing identifies the item marked; NOTE: The code is meant to be read by an optical input device, such as a bar-code scanner. Applications include retail product pricing labels, identification of library documents, and railroad boxcar identification. (IEEE 610.2)

Bar length, n - The length of the bars in the bar code.

Bottom of cap, n - 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, n - The portion of the container/test tube farthest from the cap (see Point of reference).

Bottom of tube, n - See Bottom of container.

Carrier, n - See Specimen carrier.

Character, n - 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)*; 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)*

**Clinical laboratory automation, n** - The integration of laboratory personnel and preanalytical, analytical, and postanalytical processes and information systems.

**Clinical laboratory automation systems, n** - An assemblage of components that mechanically and electronically transfers, analyzes, and processes information and material related to clinical diagnostic testing of patient specimens, controls, calibrators, standards, and images.

**Closed-container sampling//Closed-tube sampling, v** – The action of aspirating a sample from a container/tube with the closure in place, requiring the sample probe to pierce the closure of the container/sample container.

**Closed-tube sampling, v** - See Closed-container sampling.

**Container//Tube//Test tube, n** - See Specimen collection container.

**Cycle time components, n** – The identified time segments of the process of moving from one sample to the next, including: presentation of specimen along transportation system to docking site at instrument; identification/recognition that the correct specimen is in place; either direct aspiration from specimen container by probe, or transfer of specimen container to instrument, aspiration, and return of specimen container to specimen carrier/transportation system; departure of completed specimen container; movement into position of next specimen container.

**Decapping, v** – The removal of a closure from a specimen container.

**Delimiter, n** – 1) A symbol used to separate items in a list; 2) *In software data management,* a bit, character, or set of characters used to denote the beginning or end of a group of related bits, characters, words, or statements. For example, the ampersand "&" in the character string "& APPLE &." *(IEEE 610.5, 610.12)*

**Device, n** – *In Automation,* a unit to prepare specimens for analysis, or to handle specimens after they have been analyzed by another instrument, e.g., automated centrifuges, automated aliquoters, automated storage and retrieval.
Directions of the specimen, Transportation system, Instrument or Specimen processing and handling device interfaces, *n* - The orthogonal axes; **NOTE**: a) These axes are demonstrated in Figure 1.

- *Z*: Vertical Travel of Sample Probe or Sampling Device
- *X*: Specimen Travel Direction in Horizontal Plane
- *Y*: Direction in Horizontal Plane Perpendicular to Specimen Travel

**Figure 1. Physical Frame of Reference in a Three-Dimensional Space (X-Y-Z)**

- *X*-direction, *n* - The direction that a specimen travels along a transportation system; **NOTE**: b) Specimens would move along the X dimension as, for example, in transportation from station to station in a laboratory (see Figure 2A).

**Figure 2A. X Direction**
• Y–direction, \( n \) - The horizontal direction perpendicular to specimen travel along a transportation system; **NOTE**: c) Specimens could move in the Y dimension away from a transport system to be placed onto an instrument for analysis (see Figure 2B). The sample probe would move in the Y dimension as it moves out from the instrument or specimen processing and handling device to a position directly over the specimen container.

![Figure 2B. Y Direction](image)

• Z–direction, \( n \) - The vertical dimension; **NOTES**: d) Specimens could be lifted in the Z dimension off a transport system for transfer between locations; e) The center line of a container should be controlled, so it is in the Z dimension; a specimen centering device would be referenced to the Z dimension; a sample probe would follow the Z dimension as it moves downward into a specimen container to aspirate serum, blood, etc. for analysis (see Figure 2C); f) Rotation about the Z dimension may be used to locate and read the bar-code label on a specimen container or to assess the quality of a specimen in terms of turbidity, hemolysis, icterus, etc.

![Figure 2C. Z Direction](image)
Directions of the sample, Transportation system, Instrument or Specimen processing handling device and interfaces, n - See Directions of the specimen, etc.

Direct track sampling, n – The process in which aspiration of a sample occurs directly from the specimen container while it is on the transportation system, whereby the instrument probe extends to reach the specimen container on the transportation system; NOTE: The integrity of this process requires reliable agreement between the transportation system and the instrument and specimen processing and handling devices regarding point of reference (POR) to guide movement of the probe to the specimen.

Docking site, n – 1) The location of the physical interface between two components of a system; 2) In Automation, the interface between the transportation system and the instrument and/or the specimen processing and handling devices where the specimen container arrives for sampling to occur.

Encoding, n – 1) A system of assigning numeric values to characters; 2) A means of producing a unique combination of bits (a code) in response to an analog signal. (IEEE-1007 9)

ENQ, n - ASCII character denoting the word “enquiry,” which requests establishment of the communication phase; NOTE: Part of the ASTM E1381 12 and E1394 13 protocols.

EOT, n - ASCII character denoting “end of transmission,” indicating the end of a communication phase; NOTE: Part of the ASTM E1381 12 and E1394 13 protocols.

ERR, n – An HL7 error segment (HL7 V2.4 19).

Filler, n – A person or service that produces the observations requested by the placer.

Flection, n – The point at which the vertical (straight) walls of the specimen container bend to form the base.

Health Level 7, n – 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.

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

High-level protocol, n - A protocol describing the content of messages passed between systems.

HIS, n – Abbreviation for Hospital Information System.

HISB, n – Abbreviation for Healthcare Informatics Standards Board.

HL7, n – Abbreviation for Health Level 7.10,11

Hospital information system, HIS, n – A data management system which usually supports functions external to the laboratory, e.g., admission, discharge, and transfer (ADT) functions.

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

IFCC, n – Abbreviation for International Federation of Clinical Chemistry.

Instrument, n – An analytical unit which uses samples to perform chemical or physical assays (e.g., chemistry analyzer, hematology analyzer).
Inventory, n – The materials available on an instrument used to support the operation of that instrument.

ISO 8859, n – Acronym for the International Standards Organization’s eight-bit character encoding that is also called code page1252, Western European, or Latin1.


JCCLS, n - Abbreviation for Japanese Committee for Clinical Laboratory Standards.

JIS, n – Abbreviation for Japan Industry Standard.

JSCC, n - Abbreviation for Japanese Society for Clinical Chemistry.

Label, n – 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. (ASTM D966 3); 4) In computer software, a name or identifier assigned to a computer program statement to enable other statements to refer to that statement; 5) One or more characters within or attached to a set of data, that identify or describe the data. (IEEE 610.12 8)

Laboratory automation system, LAS, n - A system of information and hardware technology that allows the operation of the clinical laboratory process without significant operator intervention; NOTE: Typical functionality includes information system control of the instruments through direct LAS interfacing, including any technology that manipulates the specimen (i.e., centrifuge); transportation of the specimen; result evaluation, repeat testing, reflex testing; and quality assessment and results reporting.

Laboratory equipment control interface specification, LECIS, n – A high-level protocol that defines message content for standard behaviors or interactions for remote control of analytical instruments and devices (ASTM E1989 14).

Laboratory information system, LIS, n - The information system that is responsible for management of data regarding patient specimen identification, tests requested, results reported, quality control testing, and other aspects of sample analysis; NOTES: a) The LIS interfaces directly with the LAS to communicate patient, visit, container, test orders, specimen status, and results about specific testing to be done; b) Instrument or specimen processing and handling devices may be interfaced with the LIS or the LAS to direct specific testing and to retrieve results for reporting; c) The LIS is frequently also interfaced to a clinical information system for use by physicians and other medical personnel.

Latin 1, n – A specific, eight-bit, character encoding system, also known as ISO 8859, code page1252, or Western European.

LECIS, n – Acronym for Laboratory Equipment Control Interface Specification (ASTM E1989 14).

Location, n – A physical place within the laboratory, with a unique identifier (e.g., refrigerator shelf number, instrument buffer ID, track identifier). (See Figure 3.)

Logical observations identifiers names and codes, LOINC, n - A systematic approach to formal names and codes for laboratory results and clinical variables with numeric, coded, or narrative text values developed by a consortium of laboratories, system vendors, hospitals, and academic institutions.

Low-level protocol, $n$ – A protocol describing the electrical and mechanical connections of the physical layer of communication between systems and the software protocol definition.

Medical information bus, $n$ – A communication service designed for ICU, OR, and ER bedside devices (IEEE).

MEDIX, $n$ – A data model for medical data interchange between diverse systems (IEEE).

Message, $n$ - The body of text information concerning orders for, or results of, diagnostic studies, tests, or clinical observations transmitted at one time between two systems.

MSA, $n$ - An HL7 abbreviation for message acknowledgment segment (HL7 V2.4 10).

MSH, $n$ - An HL7 abbreviation for message header segment (HL7 V2.4 10).

OBR, $n$ – An HL7 abbreviation for observation request.

Observation request, OBR, $n$ – A segment used to transmit information specific to an order for a diagnostic study or observation, physical exam, or assessment, and define the attributes of a particular request for diagnostic services (e.g., laboratory, EKG) or clinical observation (e.g., vital signs or physical exam) (HL7 V2.4 10).

Observation/Result segment, OBX, $n$ – A segment used to transmit a single observation or observation fragment, and representing the smallest indivisible unit of a report; NOTE: Its principal mission is to carry information about observations in report messages (HL7 V2.4 10).

OBX, $n$ – An HL7 abbreviation for observation/result segment.

Open-container sampling//Open-tube sampling, $v$ – The action of aspirating a sample from a specimen container from which the closure has previously been removed; NOTE: The sample probe contacts the surface of the specimen without other physical barriers.

Open-tube sampling, $v$ – See Open-container sampling.

ORC, $n$ – An abbreviation for an HL7 common order segment (HL7 V2.4 10).

PID, $n$ – In Automation, an HL7 abbreviation for HL7 patient identification segment (HL7 V2.4 10).

Pitch, $n$ – The center distance between two specimen containers in a carrier or between two sequential specimen container carriers.

Placer, $n$ – In Automation, a person or service that requests observations; NOTE: An example would be the physician, the practice, the clinic, or ward service that orders a test, x-ray, vital signs, etc.

Point of reference//Point in space, POR, $n$ – The intersection of the xy plane and an infinite line in the ‘z’ direction. NOTE: The POR is the reference from which all positioning and alignment of specimen containers is measured.

Process control, $n$ – A method of managing the process required to produce a result from a patient specimen and to handle/manipulate/transport the specimen, as applied to the NCCLS standards, under the control or supervision of software that controls instruments/devices and automation hardware.
**Process instruments, n – In Automation**, components of an automated laboratory comprising the automated devices that perform a multitude of pre- and postanalytical tasks, and perform nonanalytical tasks on specimens, containers, carriers, and similar processes.

PV1, n – An HL7 abbreviation for a patient visit segment (HL7 V2.4\(^1\)).

PV2, n – An HL7 abbreviation for a patient visit with additional information (HL7 V2.4\(^1\)).

**Quiet zone, n – In Automation**, the white (blank) space on a bar code immediately preceding the first bar and immediately following the last bar.

**Recap, v –** To replace the closure on a specimen container, either with the original closure or with a new replacement closure.

**Robotic arm, n –** A device capable of moving a specimen container, specimen carrier, or another object in the X, Y, and Z directions; **NOTE:** Unless this device is an integral part of the LAS system, it is considered an instrument for the purpose of this standard.

**ROL, n –** An HL7 abbreviation for a role segment.

**Role segment, n – In Automation**, a segment containing the data necessary to revise the records of the person(s) involved, as well as their functional involvement in the activity being transmitted (HL7 V2.4\(^1\)).

**Sample/(Specimen), n –** A portion or aliquot withdrawn from a container for the actual test; **NOTES:** In Automation, a) Samples are typically not placed in containers that will have to be uniquely identified, but may go directly into the instrument or specimen processing and handling device test stream or may be placed in sample cups unique to the instrument or specimen processing and handling device; b) The identification (ID) of the specimen is typically assured by computer linkage of the pipetting or aspiration step to the identification (ID) of the container from which it was obtained, or by a separate numbering system for the sample cups that is internal to the analytical instrument or specimen processing and handling device.

**Sample carrier, n –** See Specimen carrier.

**Sample container, n –** See Specimen collection container.

**Sample-positioning system, n –** See Specimen-positioning system.

**Sample probe, n –** See Specimen probe.

**Service envelope, n – In Automation**, the space around the transportation system and instruments that may be accessed periodically for maintenance or repair of equipment; **NOTE:** A transportation system and analytic instruments should not have mutually impinging service envelopes.

**Shift-JIS-code, n –** The Japan Industry Standard multibyte encoding system; **NOTE:** The codes are numerically shifted from the codes used by the JIS standard X0208\(^1\); hence the name.

**SNOMED®, n –** 1) The Systematized Nomenclature of Medicine, a copyrighted work of the College of American Pathologists; 2) A reference terminology that makes health care knowledge more accessible and usable whenever and wherever it is needed; 3) Includes clinical findings, conclusions and assessments, laboratory test results, diagnoses, living organisms, biological functions, drugs, chemicals, body structures, specimens, occupations, physical agents, activities and forces, general modifiers, and

**Specimen, n** – The discrete portion of a body fluid or tissue taken for examination, study, or analysis of one or more quantities or characteristics, to determine the character of the whole; **NOTE:** The substance may still be referred to as a specimen if it has been processed from the obtained specimen; thus, examples of specimens include whole blood and serum or plasma prepared from whole blood; saliva; cerebrospinal fluid; feces; urine; fingernail clippings; hair clippings; tissue samples, even if embedded in a paraffin block; etc.

**Specimen carrier//Sample carrier//Carrier, n** - A device that holds the specimen container; **NOTE:** The specimen carrier interfaces mechanically with the transportation system to move the specimen from location to location, and may carry one specimen container or many specimen containers (see Figure 3).

**Specimen collection container//Specimen container//Sample container//Container, n** – The tube that holds a patient specimen; **NOTE:** The container typically consists of a glass or plastic closed-end tube with a removable closure on the opposite end (see Figure 3).

![Figure 3. Relationship Among Specimen Container, Specimen Carrier, Tray, and Locations](image_url)

**Specimen-positioning system//Sample-positioning system, SPS, n** - A device to position a specimen container within acceptable tolerances of a POR.

**Specimen probe//Sample probe, n** – A part of an instrument or specimen processing and handling device that aspirates fluid from a specimen and delivers it to the instrument for analysis; **NOTE:** The sample probe can also be called sample proboscis, nozzle, needle, or sampling mechanism.
Stay clear zone, \textit{n} - \textit{In Automation}, the area between the instrument or specimen processing and handling device and the automation hardware that must remain clear of any physical device, ensuring that there is adequate access by the user or service person to either system.

Symbol, \textit{n} – \textit{In Automation}, a combination of bar-code characters, including start/stop characters, quiet zones, data elements, and check characters which form a complete scanning entity.

Test mnemonics, \textit{n} - Short, understandable contractions for test names.

Top of container//Top of tube, \textit{n} – The open end of the container/test tube, closest to the cap.

Top of tube, \textit{n} - See Top of container.

Tray, \textit{n} – A holder for one or more carriers (optional). (See Figure 3.)

Tube//Test tube, \textit{n} – See Specimen collection container.

Unicode, \textit{n} - A fixed-width, 16-bit worldwide character encoding system that was developed and is maintained by the Unicode Consortium, supporting all national languages; \textbf{NOTE}: The Unicode Consortium is a nonprofit computer industry organization.

X–direction, \textit{n} - See Directions.

Y–direction, \textit{n} - See Directions.

Z–direction, \textit{n} - See Directions.

4 Standard Precautions

Because it is often impossible to know what might be infectious, all human blood specimens are to be treated as infectious and handled according to “standard precautions.” Standard precautions are new guidelines that combine the major features of “universal precautions and body substance isolation” practices. Standard precautions cover the transmission of any pathogen and thus are more comprehensive than universal precautions which are intended to apply only to transmission of blood-borne pathogens. Standard precaution and universal precaution guidelines are available from the U.S. Centers for Disease Control and Prevention (Guideline for Isolation Precautions in Hospitals. Infection Control and Hospital Epidemiology. CDC. 1996;Vol 17:1:53-80.), [MMWR 1987;36(suppl 2S):2S-18S] and (MMWR 1988;37:377-382, 387-388). For 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, refer to NCCLS document M29—Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue.

5 Specifications for Containers

The following section provides the specifications for containers used for automated laboratory applications, either as primary collection containers, or as secondary containers prepared by the automated systems from primary containers. Four nominal sizes are specified as 13 x 75 mm, 13 x 100 mm, 16 x 75 mm, and 16 x 100 mm.
5.1 **Container Body**

Container body material shall be glass or plastic, compatible with collection and other processing of specimens for clinical laboratory testing.

5.2 **Container Design**

Container design is parallel-wall and usually round-bottom. Flat-bottom tubes or tubes with chamfered bottoms are allowable within the dimensional tolerances specified. (Parallel assumes sufficient taper or conicity for molding or other production methods.)

5.3 **Closure Configurations**

5.3.1 The following types of closures are allowed (see Appendix A). It is assumed that automation system devices, such as decapping or aliquotting components that do not require decapping (direct sampling systems with or without closure-piercing capabilities), may require selection of one of the following closure configurations:

(a) plug closure with or without shields;
(b) film seal closure;
(c) plug closure integrated with outer guard; or
(d) screw-cap closure.

5.4 **Tube Dimensions and Tolerances**

5.4.1 The total length of container with closure in place is listed as follows:

- 13 x 75 mm: less than or equal to 93.0 mm
- 13 x 100 mm: less than or equal to 120.0 mm
- 16 x 75 mm: less than or equal to 93.0 mm
- 16 x 100 mm: less than or equal to 120.0 mm

5.4.2 The total length of container with closure removed is listed as follows:

- 13 x 75 mm: 63.0 to 79.0 mm
- 13 x 100 mm: 88.0 to 105.0 mm
- 16 x 75 mm: 63.0 to 79.0 mm
- 16 x 100 mm: 88.0 to 105.0 mm

5.4.3 The exposed container body length with closure in place is listed as follows:

- 13 x 75 mm: greater than or equal to 55.0 mm
- 13 x 100 mm: greater than or equal to 78.0 mm
- 16 x 75 mm: greater than or equal to 55.0 mm
- 16 x 100 mm: greater than or equal to 78.0 mm

5.4.4 The specimen container outer diameter, measured at 10 mm from the tube’s open end, is listed as follows:

- 13 x 75 mm: 11.5 to 14.0 mm
- 13 x 100 mm: 11.5 to 14.0 mm
5.4.5 The minimum outer diameter of container at the flection at the bottom of the tube is listed as follows:

- 13 x 75 mm: 11.1 mm
- 13 x 100 mm: 11.1 mm
- 16 x 75 mm: 13.9 mm
- 16 x 100 mm: 13.9 mm

5.4.6 The outer diameter of the container closure is listed as follows:

- 13 x 75 mm: less than or equal to 19.5 mm
- 13 x 100 mm: less than or equal to 19.5 mm
- 16 x 75 mm: less than or equal to 19.5 mm
- 16 x 100 mm: less than or equal to 19.5 mm

5.4.7 The height of point of flection of container is listed as follows:

- 13 x 75 mm: less than or equal to 6.5 mm
- 13 x 100 mm: less than or equal to 6.5 mm
- 16 x 75 mm: less than or equal to 8.0 mm
- 16 x 100 mm: less than or equal to 8.0 mm

5.4.8 Minimum Open Cylinder – Refer to the current edition of NCCLS document AUTO5--Laboratory Automation: Electromechanical Interfaces.

5.4.9 The dimension for container wall thickness is not specified in order to allow for development of specialized or “micro” containers. Such containers may have limited applications.

5.4.10 For a recommended bar-code “READ” zone, measured from the bottom of the container, refer to the current edition of NCCLS document AUTO2--Laboratory Automation: Bar Codes for Specimen Container Identification.

5.4.11 For a recommended bar-code label placement zone, measured from the bottom of the container, refer to the current edition of NCCLS document AUTO2--Laboratory Automation: Bar Codes for Specimen Container Identification.

6 Specifications for a Multiple-Specimen Container Carrier

6.1 The minimum number of specimens in a multiple-specimen container carrier shall be two. The maximum number of specimens carried in a multiple-specimen carrier is not specified. Multiple-specimen carrier capacity can be instrument- or system-dependent. (NOTE: For subcommittee rationale, please see Comment 2 in the Appendix, Summary of Comments and Subcommittee Responses.)

6.2 The multiple-specimen carrier may accommodate all four container dimensions specified in Section 5.4, i.e., 13 x 75 mm, 13 x 100 mm, 16 x 75 mm, and 16 x 100 mm.

6.3 The length of the carrier and the number of specimen containers are not specified, except that pitch (specified in Section 6.5) should be maintained when multiple-specimen container carriers are positioned “end to end.” Length tolerance is +/- 0.2 mm.
6.4 The width of the carrier is 22 mm ± 0.2 mm\(^c\) (NOTE: For subcommittee rationale, please see Comment 3 in the Appendix, Summary of Comments and Subcommittee Responses.)

6.5 The pitch is 22 mm ± 0.2 mm\(^c\) for a multiple-specimen-container carrier. The pitch will be on both the x and y directions (see Appendix B). (NOTE: For subcommittee rationale, please see Comment 3 in the Appendix, Summary of Comments and Subcommittee Responses.)

6.6 A mechanism for carrier identification or a bar-code slot shall be provided on at least one side of the carrier.

6.7 The carrier will support self-centering of containers with a ±1.0-mm tolerance. Containers are carried in a vertical orientation with an angle from vertical tolerance of not more than one degree off center in the carrier.

6.8 Carriers intended for centrifugation shall withstand a minimum acceleration of 3,000 g\(_n\) on the longitudinal axis. (NOTE: For subcommittee rationale, please see Comment 4 in the Appendix, Summary of Comments and Subcommittee Responses.)

6.9 The force required to insert or remove containers from carriers is not specified.

7 Specifications for a Single-Specimen Container Carrier

7.1 The number of specimen containers carried is one.

7.2 The single-specimen carrier accommodates all of the container dimensions specified in Section 5.4, i.e., 13 x 75 mm, 13 x 100 mm, 16 x 75 mm, and 16 x 100 mm. All four container configurations need not be accommodated interchangeably in one holder or automation system.

7.3 The carrier will support self-centering of containers with a ±1.0-mm tolerance. Containers are carried in a vertical orientation with an angle from vertical tolerance of not more than one degree off center in the carrier.

7.4 The width or diameter of the carrier is not specified.

7.5 The entire bar-code read zone specified for containers must be visible for holders gripping the tube at the bottom only.

7.6 When individual specimen carriers are not uniquely identified, symmetrical bar-code read slots must be provided on both sides of specimen carriers that grip the length of the tube.

7.7 The force required to insert or remove tubes from carriers is not specified.

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\(^c\) For transport only; not for storage and retrieval.
References


Additional References


Appendix A. Examples of Container and Closure Configurations

Figure A1. Shown with plug closure (see Section 5.3.1).

Figure A2. Shown with film seal closure (see Section 5.3.1).

Figure A3. Shown with plug closure integrated with outer guard (see Section 5.3.1).

Figure A4. Shown with screw-cap closure (see Section 5.3.1).

Dimensions:  

a. Total length of container with closure in place (see Section 5.4.1)  
b. Total length of container with closure removed (see Section 5.4.2)  
c. Outer diameters of container (see Sections 5.4.4 and 5.4.5)  
d. Outer diameter of container closure (see Section 5.4.6)
Appendix B. Illustration of X, Y Pitch Orientation of the Multiple-Specimen Container Carrier

The pitch allowed is 22 mm ± 0.2 mm. Equivalent x and y dimensions are maintained only if pitch and carrier width are the same.
Summary of Comments and Subcommittee Responses

AUTO1-P: Laboratory Automation: Specimen Container/Specimen Carrier; Proposed Standard

Section 5.4

1. Comments were submitted with proposed changes for tube dimensions and tolerances (as seen in the table on the next page) for the following reasons:

(a) The proposals are feasible as far as tube manufacturing is concerned.

(b) Uniquely specified tube dimensions and tolerances should simplify the relevant systems and parts commonly used in the clinical laboratories, as well as make them more convenient and eventually less expensive.

(c) However, the tube dimensions and tolerances specified in AUTO1-P do not seem to facilitate laboratory automation. Since AUTO1-P includes almost all of the currently available tubes, it is less likely to change the current status in the clinical laboratory.

(d) Tube users and manufacturers are not required to change their tubes right now. As it is the aim of all other laboratory automation standards, AUTO1-P should also stipulate to the users and manufacturers what they will be required to do within the next five years. They then can change their tube dimensions gradually within the five-year period.

(e) It would make more sense to specify the tube’s outer diameter at the position corresponding to the top of the rack, where the container is usually held, i.e., approximately 50 mm from the top of the tube. If the tube’s outer diameter is defined at this position, it would help the tube stand as vertically as possible.
A proposal of the tube dimensions and tolerances and a comparison with those which are specified in AUTO1-P.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Type*</th>
<th>Alternate proposal</th>
<th>AUTO1-P</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.4.1 The total length of container with closure in place</td>
<td>100 mm</td>
<td>≤ 110.0 mm</td>
<td>≤ 120.0 mm</td>
</tr>
<tr>
<td></td>
<td>75 mm</td>
<td>≤ 85.0 mm</td>
<td>≤ 93.0 mm</td>
</tr>
<tr>
<td>5.4.2 The total length of container with closure removed</td>
<td>100 mm</td>
<td>100.0 ± 2.0 mm</td>
<td>88.0 ~ 105.0 mm</td>
</tr>
<tr>
<td></td>
<td>75 mm</td>
<td>75.0 ± 2.0 mm</td>
<td>63.0 ~ 79.0 mm</td>
</tr>
<tr>
<td>5.4.3 The exposed container body length with closure in place</td>
<td>100 mm</td>
<td>≥ 86.0 mm</td>
<td>≥ 78.0 mm</td>
</tr>
<tr>
<td></td>
<td>75 mm</td>
<td>≥ 61.0 mm</td>
<td>≥ 55.0 mm</td>
</tr>
<tr>
<td>5.4.4 The specimen container outer diameter, measured at 10 mm from the tube’s open end</td>
<td>16 mm</td>
<td>(No specifications)</td>
<td>15.0 ~ 17.0 mm</td>
</tr>
<tr>
<td></td>
<td>13 mm</td>
<td>(No specifications)</td>
<td>11.5 ~ 14.0 mm</td>
</tr>
<tr>
<td>5.4.4 The specimen container outer diameter, measured at 50 mm from the tube’s open end</td>
<td>16 mm</td>
<td>15.3 ± 0.2 mm †</td>
<td>(No specifications)</td>
</tr>
<tr>
<td></td>
<td>13 mm</td>
<td>12.2 ± 0.2 mm †</td>
<td>(No specifications)</td>
</tr>
<tr>
<td>5.4.5 The minimum outer diameter of container at the flection at the bottom of the tubes</td>
<td>16 mm</td>
<td>14.0 mm</td>
<td>13.9 mm</td>
</tr>
<tr>
<td></td>
<td>13 mm</td>
<td>11.0 mm</td>
<td>11.1 mm</td>
</tr>
<tr>
<td>5.4.6 The outer diameter of the container closure</td>
<td>16 mm</td>
<td>≤ 18.0 mm</td>
<td>≤ 19.5 mm</td>
</tr>
<tr>
<td></td>
<td>13 mm</td>
<td>≤ 18.0 mm</td>
<td>≤ 19.5 mm</td>
</tr>
<tr>
<td>5.4.7 The height of point of flection of container</td>
<td>16 mm</td>
<td>6.5 ~ 8.0 mm</td>
<td>≤ 8.0 mm</td>
</tr>
<tr>
<td></td>
<td>13 mm</td>
<td>5.0 ~ 6.5 mm</td>
<td>≤ 6.5 mm</td>
</tr>
</tbody>
</table>

* One type of length or diameter is referred to in this column, which implies that the values should be applied to the tubes irrespective of the values of the type not referred to.

† The average diameter may be subject to change. The manufacturability of specimen containers should be considered to a greater extent.

- The subcommittee and area committee retained the tolerances and dimensions as stated at the current time. Tube manufacturers will need to consider narrowing their specifications for tube dimensions and tolerances in the near future. The area committee will monitor data over the next two to three years.
Section 6.1

2. According to AUTO1-P, the number of specimen containers on a rack would not be specified. However, regarding the basic concept of standardization, the number of samples on a rack should be stated, because the number of samples is the basic figure for the transportation line design. This figure influences both the physical design and the sample management software design in the transportation line.

When we consider the purpose of standardization—to realize less costly and more flexible laboratory automation systems, any sample transportation line according to this standard can be connected without special mechanisms. For example, if we connect two types of transportation lines which are using very different racks, we would need to use a high-cost robotic mechanism and transfer samples from one rack to the other. But this will cause financial and throughput performance problems. So, the standard should contribute to standardization of the rack design and transportation line design. Therefore, because it is a key factor in rack design, the number of samples on a rack should be clearly stated in the standard.

When we consider the standard number of samples on a rack, five would be most advantageous. There are two major reasons for this:

The first one considers the appropriate number for manual processing. There are two kinds of processing in a typical laboratory, i.e., large-volume processing and spontaneous, small-volume processing. The former takes place in the morning and the latter takes place during night shift or on holidays. Laboratory technicians should handle samples on a rack before setting samples on LAS or taking out samples from LAS. A larger number such as five or ten would be preferred for the number of samples on a rack regarding large-volume, manual processing. Small numbers (less than five) would be preferred for small-volume processing. Five would be the most appropriate for both types of processing. Moreover, when counting samples, five-sample grouping on a rack would be simple.

The second reason considers automatic processing. For basic processing on LAS, such as centrifuge, decapping, aliquoting, etc., it is necessary to process several samples at once to have higher throughput. When the system requires over a thousand samples per hour as the throughput, ten samples processing at once is necessary. But this kind of mechanism is very big and very expensive. This high throughput is usually required in very large laboratories, such as large central laboratories or large commercial laboratories. When the system requires 300 to 500 samples per hour as the throughput, two or five samples processing at once is necessary. This kind of throughput is necessary in typical core hospital laboratories.

So, if transportation lines can transfer five samples at once to processing machines, a more effective and advantageous system will be in place.

- This has been an ongoing discussion for the subcommittee, resulting in the area committee’s recommendation ‘not to specify’ the maximum number of specimen containers in a multiple-specimen container carrier. The Area Committee on Automation decided not to limit the carriers to five per rack, thus allowing manufacturers to have flexibility when developing their automated systems. With the recommendation of the area committee, the Subcommittee on Specimen Container/Specimen Carrier solicited comments and data during the six-month review period regarding the need to recommend a five-carrier rack. At the current time, there are no data to justify this recommendation. Over the next two to three years, NCCLS will continue to monitor automated technology and review comments in order to gather data regarding the need to reconsider an alternative recommendation.
Sections 6.4 and 6.5

3. Comments were submitted related to ‘pitch’ and 'width' in AUTO1-P, and stated that the document did not specify specimen container and specimen carrier in a comprehensive enough manner to promote laboratory automation standardization. Also included were data from several manufacturing companies surveyed to support the comment. The commentor felt that the specifications regarding the minimum pitch of 22 mm +/- 0.2 mm were not helpful for system design, and requested that AUTO1-P’s rack specification be reconsidered during the approved-level review process.

For instance, only a few features are specified for the specimen carriers in AUTO1-P, which does not seem to facilitate system or instrument design standardization. The pitch for both x and y directions is specified only as "22 mm or wider." Of course, this would allow a lot of different "standard" racks to exist, which may still make the interfaces between the instruments/devices and the racks complicated and expensive. On the other hand, this specification does not allow most currently existing racks to survive, which cannot be readily understood.

Manufacturers were recently surveyed, and it was determined that none of their racks comply with the AUTO1-P specifications, except for one. This implies that not only Japanese users but most users worldwide will be confused if they have to change their racks to comply with this NCCLS standard, knowing that the standard won't promote uniquely defined racks due to loose tolerance limits in rack dimensions.

Reconsideration of AUTO1-P is requested, at least in terms of rack specifications according to the following proposal, when the approved standard is published:

It is proposed that Sections 6.4 and 6.5 be replaced by one of the following descriptions.

Proposal 1:

Section 6.4: The width of the carrier is 22 mm +/- 0.2 mm.
Section 6.5: The pitch is 22 mm +/- 0.2 mm for a multiple-specimen carrier.

Proposal 2:

Section 6.4: The minimum width of the carrier is 20 mm +/- 0.2 mm.
Section 6.5: The minimum pitch is 20 mm +/- 0.2 mm for a multiple-specimen carrier.

The reason is as follows:

It is described in Section 6.4, "The minimum width of the carrier is 22 mm +/- 0.2 mm," and in Section 6.5, "The minimum pitch is 22 mm +/- 0.2 mm or greater for a multiple-specimen carrier. The pitch shall be on both the x and y directions (see Appendix B)." This implies that AUTO1-P does not specify the pitch in either of the x or the y direction in a unique manner, and the pitch can range from 22 mm to even 30 mm or wider, even if all racks (multispecimen container carriers) comply with AUTO1-P. However, as wide a variation in the pitch as several or more millimeters does not seem to facilitate compatibility between systems/instruments nor that of laboratory automation. A standardized pitch would facilitate laboratory automation only if the dimensions are uniquely specified. On the other hand, AUTO1-P will exclude most currently existing racks from the market, which will certainly hamper most users, not only of total laboratory automation, but also users of typical clinical analyzers. Therefore, these descriptions should be revised in accordance with one of the proposals.
• This topic has been discussed extensively over the past two years and a special ‘note’ was added to the proposed-level document to solicit more input and data. After the six-month review period, the subcommittee again held extensive discussions based on the data provided and agreed to accept the proposals to change the ‘width’ and ‘pitch’ of the multiple-specimen carrier to 22 mm +/- 0.2 mm. Appendix B has also been revised.

Section 6.8

4. We would propose that Section 6.8 should be replaced by the following paragraph.

Carriers intended for centrifugation shall withstand a minimum acceleration of 2,000 gn on the longitudinal axis.

The reason is as follows:

It is specified in Section 6.8, "Carriers intended for centrifugation shall withstand a minimum acceleration of 3,000 gn on the longitudinal axis." However, there are few racks (multispecimen container carriers) in existence which can withstand an acceleration of 3,000 gn. At least there are only a few racks that have been proven capable of withstanding such a high acceleration. On the other hand, most methods do not require as high of an acceleration as 3,000 gn. Therefore, this specification does not seem appropriate, nor does it facilitate global standardization of laboratory automation. The acceleration of 2,000 gn seems sufficient and practical.

We would appreciate the corresponding area committee and subcommittee taking our comments into consideration, and revising the standard so that it facilitates clinical laboratory automation.

• After review of the current data collected, the subcommittee agreed that the centrifugation speed remain at 3,000 gn. The subcommittee decided to italicize the words ‘intended for centrifugation’ for clarification.

Section 7.2

5. The section can be confusing. Proposed modification would be to replace the first sentence with: "The single-specimen carrier accommodates all of the container dimensions specified in Section 5.4 per configuration (e.g. 13 x 75mm, 13 x 100mm, 16 x 75mm and 16 x 100mm).” No changes are proposed to the second sentence.

• The text has been revised to replace ‘configurations’ with ‘dimensions.’

Section 7.4

6. A comment should be added to this regarding maintaining the pitch (similar to Sections 6.3 and 6.4). In addition, should the sentence read "width and length?" Diameter assumes circular shape to the carrier. This also allows for similar interpretation to the multiple-specimen carrier.

• The subcommittee has made no change. The pitch is not relevant on a single-specimen container carrier; it is a design issue.
Summary of Delegate Voting Comments and Subcommittee Responses

AUTO1-A: Laboratory Automation: Specimen Container/Specimen Carrier; Approved Standard

1. If it is possible to insert the following underlined text into the subcommittee’s response to Comment 2 located in the “Summary of Comments and Subcommittee Responses,” we would greatly appreciate it.

“At the current time, there are no data to justify this recommendation. The management team of the Area Committee on Automation thanks our Japanese colleagues, including JCCLS and JAIMI, for their efforts. NCCLS will continue to monitor automated technology and any comments with an objective to gain more data over the next two or three years for the need to reconsider an alternative recommendation.”

Comment 2 refers to Section 6.1, which states “The minimum number of specimens in a multiple-specimen container carrier shall be two. The maximum number of specimens carried in a multiple-specimen container carrier is not specified. Multiple-specimen container carrier capacity can be instrument- or system-dependent. (NOTE: For the subcommittee’s rationale, please see Comment 2 in the Summary of Comments and Subcommittee Responses.)”

The five-place specimen container carrier vs. the multiple-place specimen container carrier has been a controversial topic for discussions held at both the subcommittee and area committee levels. At the final meeting in January 2000, it was agreed that, by recommending the “multiple-place specimen container carrier,” AUTO1 does not preclude the use of that carrier, and it allows a multiplicity of other carrier configurations that contain more than one specimen. In addition, no data were presented to justify a five-carrier rack. The area committee agreed that the document would contain text explaining the subcommittee’s rationale for its recommended specifications (which is currently presented as the response to Comment 2).

Because these discussions were primarily with Japanese colleagues, the previous draft contained the underlined text described above. After discussions with the management team, it was decided to remove the references to any specific organization or country to genericize the response.

2. This standard seems unnecessary. There already is standardization among tube manufacturers and automated systems and a document of this nature may inhibit the creation of new and innovative ideas.

We recently went through the process of acquiring laboratory automation and a split in volume has changed the need for upfront lab automation. The person who reviewed these documents was heavily involved in the evaluations and I feel that person’s opinion on the subject is valuable. Our concern is that because it takes so long for changes to happen in the US, having documents/guidelines that may inhibit the process is only another ball on the chain of progress.

The reason that the members and constituents of CTASSC and the NCCLS Area Committee on Laboratory Automation moved forward with AUTO1 is, in fact, that the standard did seem necessary. There is no standardization among tube manufacturers either within their own product lines or between manufacturers of different product lines. Nor is it believed that this standard, which in fact defines a wide range, will inhibit the creation of new and innovative ideas. What the standard has done is place a relative stake in the ground by saying the specimen container must fall within a certain set of parameters so that it can interact with other components of laboratory automation, but does not endorse any single vendor of specimen
collection containers. This standard may also be modified with the introduction of new technology as we move forward.

3. The purpose of this document is to standardize specimen containers and specimen transport carriers in laboratory automation systems. It appears to accomplish this purpose, and in that capacity it meets a need and should be adopted. But I have two concerns. Adopting this standard will prolong the current situation in which laboratory automation is not suitable for pediatric hospitals because the automation hardware cannot handle the smaller specimen containers used in pediatrics. It will also prolong the current practice of drawing much more blood than necessary from adults. Instrument manufacturers have greatly reduced the volume of specimen and reagents actually used for testing. In the 1970s, a 12-test chemistry profile required three milliliters of serum. Today, the same profile requires 150 microliters or less. Pediatric specimen volumes have decreased in like manner, but adult specimen volumes have remained about the same as they were in 1970. There are good reasons to reduce the volumes of specimens drawn from adults as well as children. Instruments that use a few microliters of specimen per test nevertheless can't hold a certain tube in their specimen tray, can't read a bar code small enough to fit on it, and can't sample specimen out of it. Most of these instruments can accommodate 3-milliliter tubes, but the smallest tube proposed by this NCCLS standard is 13 x 75 mm and holds about 7 milliliters. If laboratory automation is standardized to this size tube, pediatric labs cannot be automated and adults will continue to part with too much blood for laboratory testing.

- The fundamental issue here appears to be blood volume for both pediatric and adult patients. Throughout the entire selection of automation standards (AUTO1 through AUTO5), reference is made to the conservation of specimen volume. The standards in AUTO1 are expressly intended to deal with the outside of the specimen collection container. In AUTO5, the support of the specimen containers with false bottoms as well as specimen cups that rest at the top of a larger vessel have been identified. The issue of practicality was discussed on all five automation projects. There was consensus that in order to make automation practical, whether for an adult or a pediatric patient, the outside of the specimen collection container needs to be defined with certain parameters. The specimen collection volume, however, and the level of specimen within a primary specimen-collection container or secondary specimen-collection container may be adjusted to deal with these issues, including microliter volumes. One of the innovation issues that the subcommittee discussed was the ability to embed, implant, or incorporate a three-milliliter tube into the shell of a 13 x 75 container, thereby minimizing the amount of blood drawn, yet allowing specimens to have enough surface area to accommodate a bar-code representation and fit into the automation technology platform. The management team of the area committee does not believe that automation will inhibit minimizing blood volume. However, the only mechanisms that will allow us to optimize the use of plasma or serum, from either adult or pediatric patients, is to standardize a process and allow machine manipulation of specimens, that are much more robust and uniform than manipulation by individual laboratorians.

4. Document is difficult to read and understand. Mostly definitions – not particularly helpful.

- The interrelated collection of automation documents was written and developed in a unique manner as compared to traditional NCCLS documents; primarily for engineers and developers of automation systems. Emphasis was put into developing an inclusive, consistent set of common terms used in computers, automation systems, and robotic technologies for clinical laboratory automation. As stated in the "Matrix of NCCLS Laboratory Automation Standards" section, the five standards are provided so that designers and engineers, as well as users and customers, understand the relationship between the different standards’ components for automated systems.
Related NCCLS Publications

AUTO2  Laboratory Automation: Bar Codes for Specimen Container Identification. This document provides specifications for use of linear bar codes on specimen tubes in the clinical laboratory and for use on laboratory automation systems.

AUTO3  Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems. The goal of this document is to facilitate accurate and timely electronic exchange of data and information between the automated laboratory elements.

AUTO4  Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements. 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  Laboratory Automation: Electromechanical Interfaces. 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-A2-C  NCCLS Procedure Manual Template. This computer template enables laboratorians to prepare consistent technical procedures in the NCCLS format. The template and its user manual, used along with the GP2-A3 guideline, provide a procedure format that is as easy to use as a word processing program. Procedures can be stored as individual files for easy retrieval and updating, or they can be networked through the local computer system for electronic distribution throughout the laboratory. The template format consists of tables for recording essential information for all procedures and an outline of key headings for incorporating procedure-specific details.


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-A  Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline (1995). The 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.

* 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)


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 ($\bar{x}_B$) method.

M29-A Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue; Approved Guideline (1997). A consolidation of M29-T2 and I17-P, 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.
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PUBLICATIONS
An NCCLS document is published as a standard, guideline, or committee report.

Standard A document developed through the consensus process that clearly identifies specific, essential requirements for materials, methods, or practices for use in an unmodified form. A standard may, in addition, contain discretionary elements, which are clearly identified.

Guideline A document developed through the consensus process describing criteria for a general operating practice, procedure, or material for voluntary use. A guideline may be used as written or modified by the user to fit specific needs.

Report A document that has not been subjected to consensus review and is released by the Board of Directors.

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The NCCLS voluntary consensus process is a protocol establishing formal criteria for:

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- the development and open review of documents
- the revision of documents in response to comments by users
- the acceptance of a document as a consensus standard or guideline.

Most NCCLS documents are subject to two levels of consensus—“proposed” and “approved.” Depending on the need for field evaluation or data collection, documents may also be made available for review at an intermediate (i.e., “tentative”) consensus level.

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Tentative A tentative standard or guideline is made available for review and comment only when a recommended method has a well-defined need for a field evaluation or when a recommended protocol requires that specific data be collected. It should be reviewed to ensure its utility.

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The comments of users are essential to the consensus process. Anyone may submit a comment, and all comments are addressed, according to the consensus process, by the NCCLS committee that wrote the document. All comments, including those that result in a change to the document when published at the next consensus level and those that do not result in a change, are responded to by the committee in an appendix to the document. Readers are strongly encouraged to comment in any form and at any time on any NCCLS document. Address comments to the NCCLS Executive Offices, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

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