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Vol. 20 No. 30

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Vol. 18 No. 18

Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard

This document provides standards to facilitate accurate and timely electronic exchange of data and information between the automated laboratory elements.

A standard for global application developed through the NCCLS consensus process.

NCCLS

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Abstract

NCCLS document AUTO3-A—*Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard* provides standards to facilitate accurate and timely electronic exchange of data and information between the automated laboratory elements. This will allow and encourage scalable, open systems, and extendibility and interoperability of the automated laboratory elements. Implementation of this standard will contribute to the development of a shared vision of future clinical laboratory automation communications.

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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.

	(1)5.4	(1)6.2	(1)6.6	(1)6.7	(1)6.8	(1)7.0	(1)7.2	(1)7.3	(1)7.6	(2)5.1	(2)5.2	(2)5.3	(2)5.4	(2)5.5	(2)5.6.1	(2)5.7.2	(3)5.2	(3)5.3.1	(3)5.3.3	(3)5.3.3.1.5	(3)5.3.3.10	(3)5.3.4	(3)5.3.4.2	(3)5.3.5	(3)5.3.5	(3)5.3.9	(4)5.1.1.2	(4)5.1.1.3	(4)5.2	(4)6.0	(4)7.1	(4)7.2	(4)7.3	(5)2.2.1	(5)2.2.2	(5)5.1.1	(5)5.1.2	(5)5.2.1.1.2	(5)5.2.1.1.3	(5)5.2.2.2	(5)5.3.1	(5)5.3.3	(5)5.3.3.1	(5)5.3.3.2	(5)5.3.3.3	(5)5.3.3.4	(5)5.3.3.5	(5)5.4.1.2	(5)5.4.1.3
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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.[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:

[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)

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

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

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

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

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

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

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

The 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

Clinical laboratory automation is defined as the integration of laboratory personnel and analytical, preanalytical, postanalytical, and computer systems to positively benefit the healthcare system, patient, and the laboratory's quality, economics, reliability, speed, and safety.

This standard addresses the communication of data between systems and provides information that is needed for developing automated laboratory systems. Recent standards developments have addressed messaging and data interchange, and test/result naming. Although some are used by a few instrument and Laboratory Information Systems (LIS) vendors, they have not been universally adopted, are only a small part of what will eventually be needed for true standard, compatible, device interconnectability, and lack a mechanism for validating vendor conformance.

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

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

An important aspect of the development of this and all NCCLS documents should be emphasized, and that is the consensus process. Within the context and operation of NCCLS, the term "consensus" means more than agreement. In the context of standard development, "consensus" is a process by which NCCLS, its members, and interested parties (1) have the opportunity to review and comment on any NCCLS publication; and (2) are assured that their comments are given serious, competent consideration.

Any standard dealing with laboratory automation will be continually evolving. Open communication and exchange of ideas and information can be used to modify the standard through the consensus process.

Key Words

Analytical instruments, automation, clinical laboratory automation, Laboratory Automation Systems (LAS), Laboratory Information Systems (LIS), process instruments

Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard

1 Introduction

This standard on information transfer and control for automated laboratory systems was developed by the NCCLS Subcommittee on Communications with Automation Systems.

Clinical laboratory automation is defined as the integration of laboratory personnel and analytical, pre- and postanalytical, and computer systems to positively benefit the healthcare system, patient, and the laboratory's quality, economics, reliability, speed, and safety. The goal of this document is to facilitate accurate and timely electronic exchange of data and information between the automated laboratory elements. This will allow and encourage scalable, open systems, and extendibility and interoperability of the automated laboratory elements. Implementation of this standard will contribute to the development of a shared vision of future clinical laboratory automation communications.

1.1 Scope

This standard provides a protocol for communications between Laboratory Automation Systems (LAS), Laboratory Information Systems (LIS), automated instruments (analyzers), and pre- and postanalytical automated devices. Although the primary venue for this standard is the clinical laboratory, in the future, elements of this standard may be applicable in the anatomic pathology, cytology, and related laboratories, as well as to nonclinical (analytical) laboratories. Additionally, although the focus of this standard is clinical laboratory automation, elements of the standard may apply to related (non-automated) areas such as small analyzers or point-of-care devices.

This standard fits into the series of interrelated NCCLS automation standards (AUTO1—*Laboratory Automation: Specimen Container/Specimen Carrier;* AUTO2—*Laboratory Automation: Bar Codes for Specimen Container Identification;* AUTO4—*Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements;* and AUTO5—*Laboratory Automation: Electromechanical Interfaces*).

1.2 Limitations

The focus of this standard is on the characteristics of the communications (low-level protocol) and the data to be transferred (high-level protocol). The low-level protocol was developed to meet the bandwidth and time characteristics required by automation. The high-level protocol defines specific messages and data to be transferred in automated communications.

It is recognized that there are old protocols in use in clinical laboratories that are not supported by this standard. The overall intent of this standard is to be prospective in nature and meet anticipated future needs for automation. Of necessity, therefore, the standard focuses on protocols that can meet the time and data characteristics for automation systems. Older (legacy) systems are not necessarily excluded, but are also not supported.

1.3 Terminology

Throughout this document and the other automation documents, terms such as "system," "automation system," "laboratory automation system," "total laboratory automation," or "clinical laboratory automation" may be used. These terms are used interchangeably. The authors have attempted to

standardize the terminology, but not all instances of such usage may have been corrected and, in most contexts, these variances in terms are not confusing. One of the above terms, however, is used in both a capitalized form and an abbreviated form: Laboratory Automation System (LAS). The LAS, in the context of this document and whether capitalized or abbreviated, refers specifically to the computer and/or software that provides the process control functions for the automation system. However, when laboratory automation system or the other terms are used noncapitalized they are used generically to refer to the entire automation system which may include track or other transport mechanisms, process instruments, analytical instruments, as well as the process control computer.

2 Elements of an Automation System

This section describes the essential requirements for information transfer by all elements in an automation system. This document structures the discussion in three levels as described below.

(1) Define at a macro level the elements of an automation system and their properties.

(2) Define the automation architectures/models (in theory or realized).

(3) Define the relationships and ownership of information in context within each model and by each element.

Automation systems in clinical laboratory systems electronically transfer, analyze, and process information and material related to clinical diagnostic testing of patient specimens, controls, calibrators, standards, and images. While there is no typical automation system today, most can be defined in terms of one to four elements (see Figure 1).

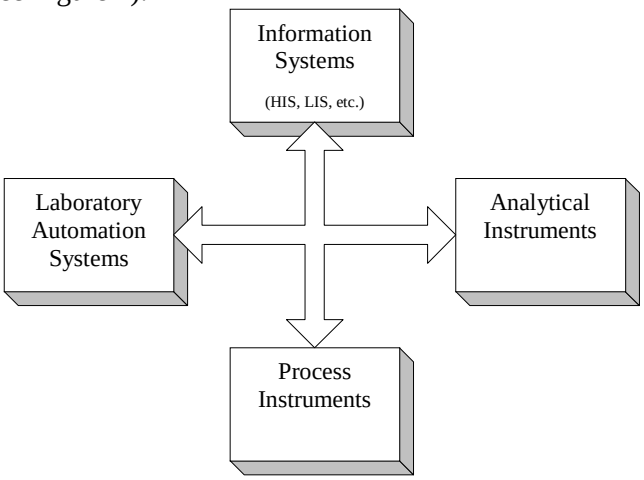


Figure 1. Components of a Clinical Laboratory Automated System

The primary function in an automation system is to perform comprehensive, long-term patient and facility information management. This includes financial functions such as reimbursements and patient tracking (admissions, discharge, transfer, patient procedures, and patient orders), as well as serving as the clinical data repository.

2.1 Information Systems

There are two major categories of information systems utilized in most clinical laboratories. A Laboratory Information System (LIS) manages the data related to the patient, test orders, and specimens. An LIS can be interfaced with analytical and process instruments as the control center or simply serve for data

collection, reporting, and archiving. A Hospital Information System (HIS) is primarily a hospital database for managing accounting, materials, personnel, and patient information including insurance, and does not usually manage test results or diagnostic information. However, the HIS is often interfaced to the LIS to enable orders for laboratory tests that are entered into the HIS by hospital staff to pass directly to the LIS, and conversely, for test results to pass from the LIS back to the HIS. These systems are developed on a general design and frequently customized on a site-by-site basis, with proprietary programming and modules for specific tasks.

2.2 Laboratory Automation Systems

The Laboratory Automation System (LAS) can control, monitor, route data results, and provide process control information between the other automation system elements. The LAS can serve as an electronic interface as a layer on top of an existing system, or as the control center for a ground-up installation. The LAS is frequently a customized design and therefore difficult to describe in general terms. Each existing vendor's system is a unique combination of software and hardware with different degrees of sophistication. In some cases, the laboratory automation product is entirely software.

The Laboratory Automation System (LAS) is defined as an element of a more advanced automation system supported primarily by a hierarchical structure (see Section 4.1 and Appendix A). The LAS hardware, such as specimen transportation conveyance systems, is considered a processing instrument in this architecture. The LAS software can perform complex functions and serve as a complete specimen management system, or perform simple functions such as that of a process controller. An LAS system can combine hardware and software, whereby software in conjunction with appropriate processing instrumentation can act as transporter, controller, and monitoring unit of specimen information and material within a clinical environment. The LAS in a more basic automation system in the market today is supported primarily by the information systems-centric model (see Section 4.1 and Appendix A).

2.3 Analytical Instruments

Analytical instruments are elements that perform clinical diagnostic test(s) on biological material. Analytical instruments obtain or derive information that is commonly called the "test result." The test result is used for diagnostic evaluation purposes. It can be in many forms, such as a qualitative or quantitative value or an image. The analytical instrument performs the action upon the patient specimens, controls, standards, and calibrators that yield the diagnostic test result by measuring or imaging some aspect of the test material. State-of-the-art analytical instruments are designed with various levels of automation modules and interface capability. For some older instruments, the LIS or LAS often can provide these automation functions.

2.4 Process Instruments

The category of process instruments encompasses the automated devices that perform a multitude of pre- and postanalytical tasks. Process instruments are the elements that perform nonanalytical tasks on specimen material, containers, carriers, and similar processes. Process instruments can be modules within specific analytical instruments, or stand-alone units that perform tasks for several analyzers. Examples include aliquotters, centrifuges, conveyers, decappers, label readers, labelers, pipetters, recappers, robotic devices, and sorters.

3 Definitions[b]

Some of the computer-, automation-, or robotics–related terms used in the five interrelated NCCLS automation documents can be found in ANSI X3.172[1], ANSI X3.182-1990[2], ASTM D966[3], ASTM E1013[4], ASTM F149[5], ASTM F1156[6], IEEE 100,[7] IEEE 610,[8] IEEE 1007[9], and HL7 Version 2.4[10, 11]:

ACK, *n* – **1)** A data field name for a general acknowledgment message as specified in the HL7 protocol ***(HL7 V2.4 [10])***; **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.

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.

[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.

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*** [6]***)***; **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*** [8]***)***

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]***)***; **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*** [8]***)***

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*** [8]**)**

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 2.

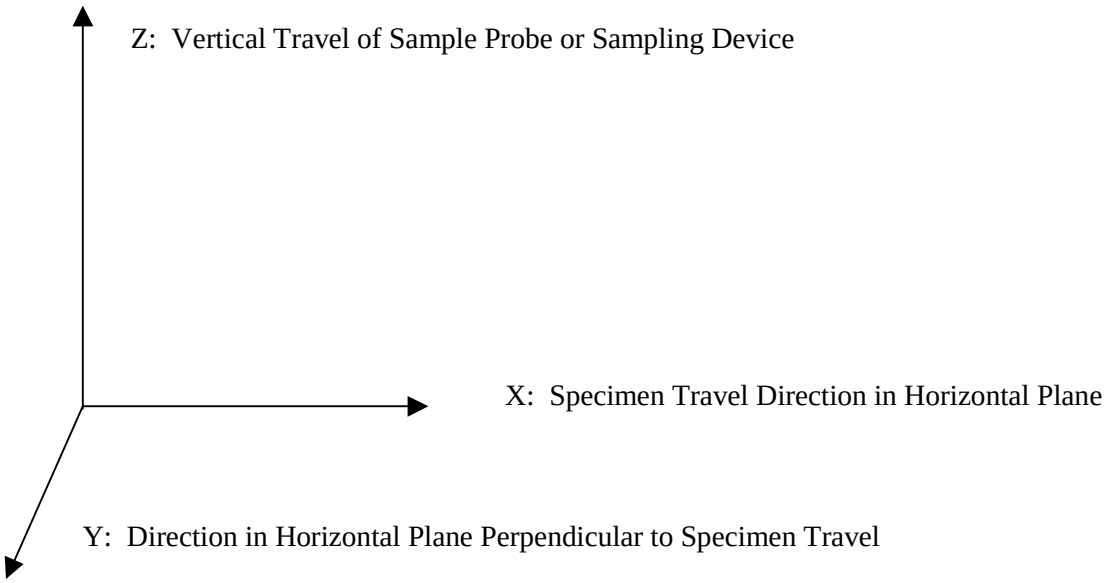


Figure 2. Physical Frame of Reference in a Three-Dimensional Space (X-Y-Z)

- 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 3A).

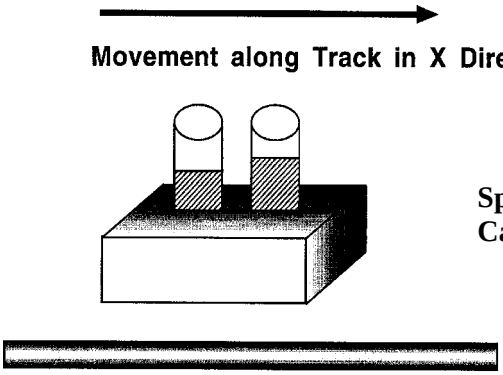


Figure 3A. X Direction

- 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 3B). 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.

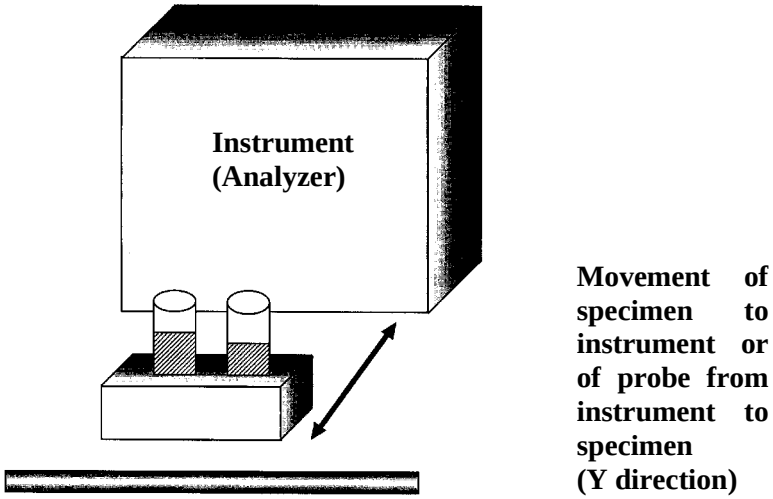


Figure 3B. Y Direction

- 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 3C); 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.

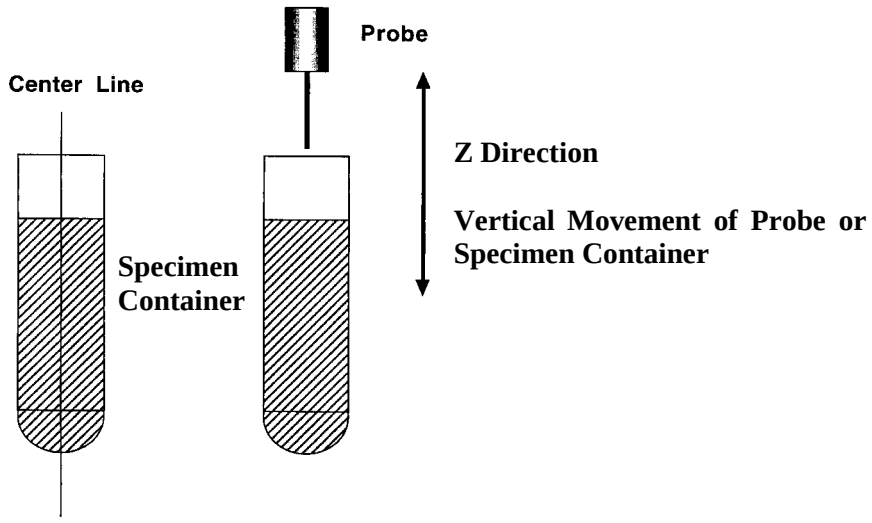


Figure 3C. Z Direction

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 [10]).***

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.

JAHIS, *n* - Abbreviation for Japanese Association of Healthcare Information Systems Industry.

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.

LOINC, *n* – Acronym for Logical Observations Identifiers Names and Codes (refer to website, http://www.regenstrief.org/loinc/loinc.htm).

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*** [10]).

PV2, *n* – An HL7 abbreviation for a patient visit with additional information ***(HL7 V2.4*** [10]).

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*** [10]).

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[15]; 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 social contexts; **4)** Current version, SNOMED Reference Terminology (SNOMED RT), and future version SNOMED Clinical Terms (SNOMED CT), are compatible for use with healthcare standards HL7 and DICOM; **5)** Previous versions (SNOMED II, 1979; SNOMED International, 1993-1999) are encompassed in this new release. http://www.snomed.org.

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 4).

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 4).

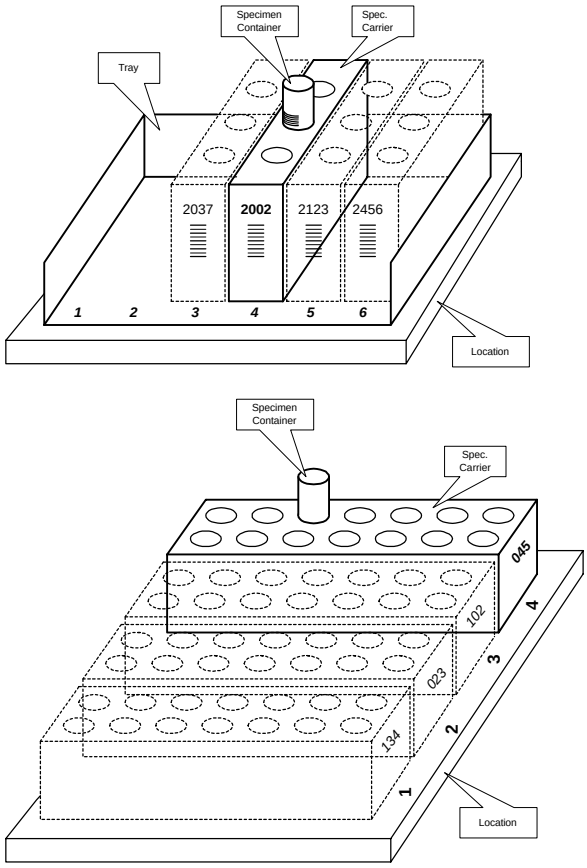


Figure 4. Relationship Among Specimen Container, Specimen Carrier, Tray, and Locations

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, *n* - ***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, *n* – ***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, *n* - Short, understandable contractions for test names.

Top of container//Top of tube, *n* – The open end of the container/test tube, closest to the cap.

Top of tube, *n* - See **Top of container.**

Tray, *n* **–** A holder for one or more carriers (optional). (See Figure 4.)

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

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

X–direction, *n* - See **Directions.**

Y–direction, *n* - See **Directions.**

Z–direction, *n* - See **Directions.**

4 Laboratory Automation Architectures/Models

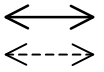
4.1 Overview of Architectures

The total laboratory automation concept can be visualized from both an information-oriented point of view and a material-oriented perspective. The information-oriented view focuses on managing the patient information such as demographics, orders, results, and diagnosis. The material-oriented approach focuses on managing the actual specimen through the automated laboratory. This document is concerned with the information-oriented point of view.

Currently, several architectures are represented in existing laboratory automation systems. Among the most common are LIS-centric, instrument-centric, peer-to-peer, and the hierarchical structure models. The subcommittee believes, however, that none of these architecture models provides the necessary functionality and flexibility to meet the complex needs of total laboratory automation systems. Therefore, a fifth model, the functional control model, described below, was adopted for this standard. For reference, the first four architecture models are described in detail in Appendix A.

4.2 Functional Control Model

The trend in new laboratory element development is away from the traditional functionality described in the previous section towards one of more localized multifunctionality. The relationship between the various elements of the automated laboratory is not always defined with the discrete elemental descriptions presented above.



- Logical information flow (supported by this document)
- Logical information flow (not supported by this document)

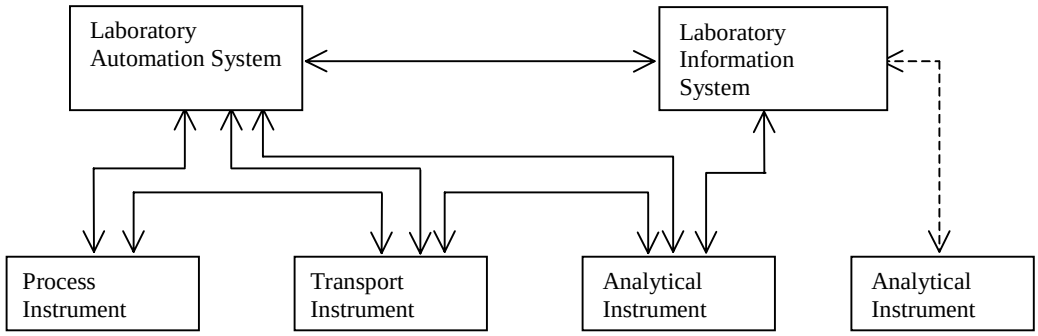


Figure 5. Overview of the Functional Control Model

The elements of a laboratory automation system therefore can be described in terms of functional control and services provided, rather than physical entities alone. For example,

(a) An analytical instrument may include an aliquotter or centrifuge, which is usually the function of process instruments.

(b) An analytical instrument may store patient and quality control data, perform data reduction, and generate reports, which are usually functions of the LIS. The communication between the analytical instrument and an LIS could be data information only, not system control messages. This could be achieved with unidirectional communication, rather than bidirectional signals, for more efficient operation.

(c) A process instrument may have bidirectional signal capability to initiate an analytical run by an analytical instrument, which is usually the function of the LAS. The process instrument could relay status information to the LIS or other LAS components regarding the various states of the instrument, rather than have the instrument communicate with both the process instrument and the LAS.

This standard recommends following the functional control model. The intent of this standard is to allow for connectivity at this efficient level; thereby eliminating the necessity for interface overlays that only serve as "interpreters" of the signals exchanged by the functional elements. The number of system elements and the volume of analytical activity will dictate the level of control, and from which level that control originates. In a broadcast environment, special consideration must be given to ensure that all recipients are guaranteed message delivery. The more centralized this activity, the less noise on the line, and less chance of error in the signals.

Synchronization of activity during various states of the system elements is a primary concern for the automated laboratory. The overall goal of a hierarchical model is to have control at the lowest level achievable in the hierarchy, while maintaining quality and system integrity. The amount of data and number of messages traveling across the cables within a system should be minimized for efficiency and effectiveness. The functional control model achieves this goal better than other hierarchical structure models or the centric models discussed in Appendix A.

4.3 Information Among Elements

This section defines and describes the information shared among elements at a macro level.

Table 1. Information Shared Among Automation Elements

Analytical Instrument Instructions	Information required for instrumentation to perform its function. **Example**: Information includes information systems content such as test orders, specimen information, etc., and optional process control information to integrate specimen handling with other automation system elements.
Analytical Instrument Output	Information pertaining to the specimen or its status, based on the result of an analytical instrument. **Example**: An analytical unit indicates insufficient volume to perform analysis, or cell counter indicates readiness to prepare a slide on the slide preparation station.
Analytical Instrument Results	The determination or end result of the analytical process of the instrument. **Examples**: Quantitative or qualitative values, images, analyses, and any associated processing alarms or errors.

Table 1. (Continued)

Analytical Instrument Status Condition	The status of an analytical instrument or specimen during the preanalytical, analytical, or postanalytical phase. **Example**: An instrument produces a photometer alignment alarm.
Analyzer Instructions	Information required for instrumentation to perform its function. **Example**: Includes information systems content such as test orders, specimen information, etc., as well as optional process control information to integrate specimen handling with other automation system elements.
Clinical Decision	Diagnostic decision determination based on analytical result(s) of the clinical test(s) using artificial intelligent modules or automated decision tree. **Example**: Medical validation based on comparison of patient test patterns with medical profiles and practice guidelines.
Container/Carrier ID	An identification that uniquely distinguishes the container or carrier that retains the specimen. **Example**: Rack number or puck carrier identification; identification of a tube as a 13-mm x 75-mm BD Hemoguard™ tube.
HIS Input	Billing, historical data, results, reorders.
Material ID	An identification of the type of material being presented for processing. **Example**: Decapper/recapper determining height of tube; centrifuge determining if specimen was urine or serum.
Material Type	Specimen, control, or calibration material.
Patient Information	Information pertaining to patient demographics suspected diagnosis (i.e., DRG codes) or treatment information, attending physicians/practice information, insurance/reimbursement information, and historical data including previous test analysis.
Process Control Information	Status or location of the specimen material in process. **Example 1**: Location within the transportation and routing system. **Example 2**: Courier arrival at the laboratory with a specific set of specimens.
Process Control Information (Internal Laboratory or External Laboratory Transportation)	Status of the specimen material within the transportation and routing system. **Example**: Courier arrival at the laboratory with a specific set of specimens or status that a gate properly closed to redirect a specimen to alternate path of track.
Process Control Information (Analytical/Process Instrumentation)	Instructions or adjustments to analytical/process instrumentation to optimize or maintain system targets. **Example**: Direct chemistry analyzer to perform a bath exchange, perform a calibration routine, etc.
Process Control Information (Internal Laboratory or External Laboratory Transportation)	Instructions or redistribution of information to the specimen material transportation and routing system. **Example**: Instruct a gate to close to redirect a specimen to alternate path of track or coordinate courier pick-up schedules of specimen orders.

Table 1. (Continued)

Process Instrument Instructions	Information required for process instrumentation to perform its function. **Example**: Direct an aliquotter to aliquot certain volumes per test; send decapping information to decapper (twist, pull, pinch, 75-mm tube height, etc.)
Process Instrument Status Condition	The status of a process instrument or specimen during, pre-, and/or postprocess phase. **Example**: Bar-code labeler jam or out of paper; recapper is out of replacement caps.
Processing Instrument Feedback (same or other in the system)	Information pertaining to the specimen or its status based on the result of a processing instrument. **Example**: Aliquotter/pipettor notifying the specimen has a fibrin clot, or a decapper not properly removing the cap.
Reports	Information manifested from activity; data gathered from other elements consolidated in specialized formats. **Example**: Quality control reports, exception status reports, workflow analysis, performance evaluation of elements.
Results	The determination or end result of the analytical process of the instrument. **Example**: Quantitative, qualitative, images analysis, and any associated processing alarms/errors.
Specimen ID	An identification that uniquely distinguishes this specimen from other specimens. **NOTE**: It is assumed that the instrument has the appropriate mechanisms to recognize/decode the specimen ID, such as a bar-code reader. (Automation interface may supply this information rather than have a bar-code reader at the interface.)
Specimen Information	Information pertaining to a specimen's material type (i.e., serum, urine, blood), collection date and time, container information, and process and analysis instructions.
Specimen Instructions	Components would include identification of specimen and associated instructions to perform on specimen. **Example**: Dilution, rerun/repeat/reflex test selections, or magnification level.
Specimen Matrix	Sometimes referred to as "specimen type." This defines the type of specimen being presented for processing. **Example**: Urine, serum, biopsy, blood.
Specialized or Other Information System Output	All information listed above may be introduced from other information systems. Specialized information systems may be used in conjunction with the LIS to provide clinical decision making, scheduling or resources (human or nonhuman), etc. Specialized software could be of a support nature to the LIS and provide reflexive specimen, storage/retrieval validation based on physician or institutional rules and guidelines. **Example**: Specimen information is received from physician practice information, historical data from outside clinical data repository.
Status Condition	The status of an analytical/processing instrument or specimen during, pre- and/or postanalytical phase. **Example**: An instrument produces a photometer alignment alarm.

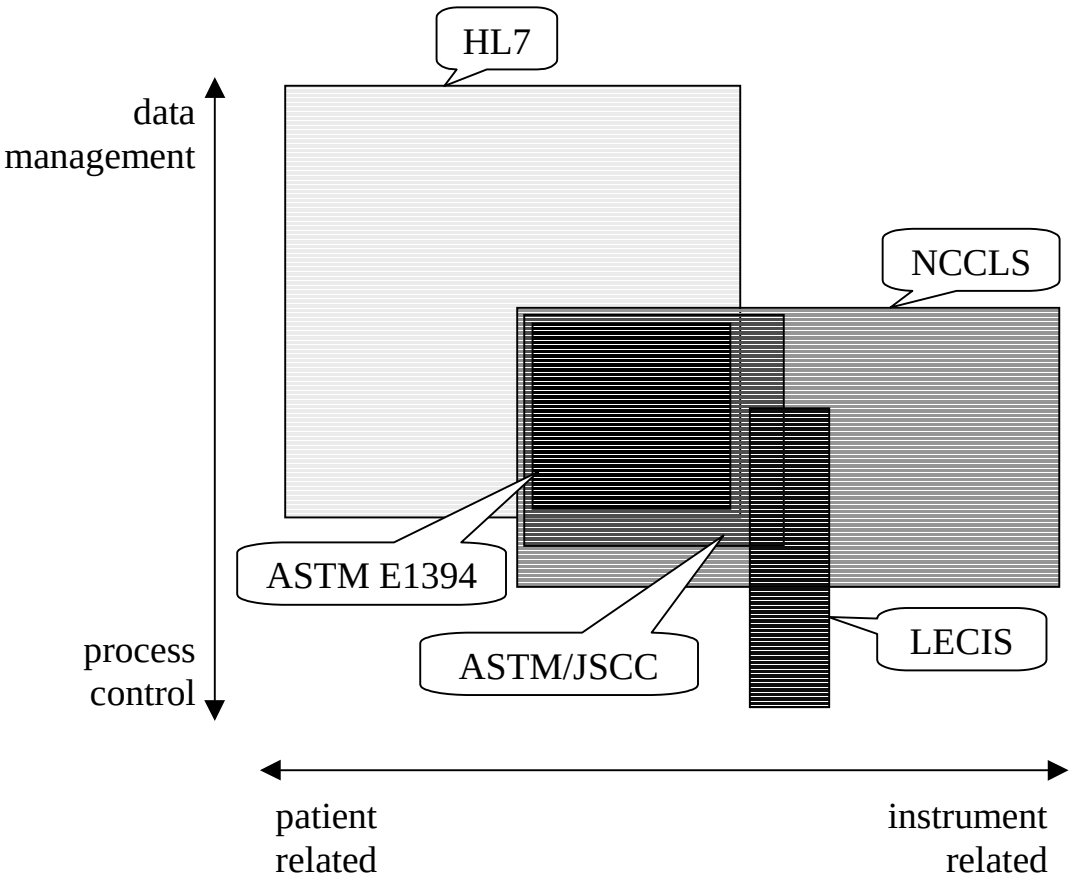
5 Communication Standard

5.1 Introduction and Overview

This section defines the information that is required to be communicated within the laboratory automation environment. The NCCLS communications standard and other relevant communications and their relationship are described in the following section.

5.2 Relationship Among Existing Communications Standards and the NCCLS Standard

Figure 6 shows how the standards within the healthcare industry relate to one another. The NCCLS standard extends HL7 by adding messages that provide instrument-related and process control information so that laboratory automation can be supported.



HL7[10]	transfer of data related to patient and medical institution
ASTM E1394[13]	transfer of laboratory-relevant data related to orders and results
ASTM/JSCC	ASTM E1394 with extensions for transfer of additional data related to specimen transport synchronization (process control and instrument status)
LECIS[14]	transfer of data for process control and synchronization of automated laboratory devices
NCCLS	transfer of laboratory-relevant data related to orders and results; transfer of data for process control, synchronization and workflow optimization of total laboratory automation (extended instrument status and data related to instrument processing, e.g., amount and status of reagents)

Figure 6. Relationships Among the Existing Standards

5.2.1 Commonalties and Differences Between NCCLS Standard and LECIS

5.2.1.1 LECIS Reference

This NCCLS standard references the "Laboratory Equipment Control Interface Specification – Version 3.0 Preview."[14] The LECIS standard was developed by Subcommittee E49.52 of ASTM.

5.2.1.2 Control Model

The control model proposed in this standard is an extension of the model described in LECIS (Chapter 5). The difference is that the NCCLS model includes provisions for communication between modules and not only between controller and module. The LECIS definition of “equipment” includes the NCCLS definitions of both "process instruments" and "analytical instruments."

5.2.1.3 Interactions

LECIS describes a set of standard equipment behaviors that must be accessible under remote control in order to set up and operate laboratory equipment in an automated laboratory. The remote control of the standard behaviors consists of standard interactions that define the dialog between the equipment and the control system that is necessary to coordinate operation. The interactions are described with state models in which individual states are defined for specific, discrete equipment behaviors.

The interactions described in Chapter 5.3 of LECIS are used in the NCCLS standard as the basis for all communications related to control (status, command, … messages). The NCCLS standard provides standard syntax and semantics of the messages defined by LECIS that are used to synchronize the behavior of the equipment and controller under remote control.

The LECIS standard defines the remote control of standard behaviors of laboratory equipment that meets the NIST CAALS requirements for standard laboratory modules (SLMs). (These requirements are described in detail in references 3 and 4 of LECIS). Equipment meeting the SLM requirements must have a single point of external control and be autonomous and asynchronous in operation with the controller.

The NCCLS standard extends the LECIS capabilities by including provisions for multiple points of control and introducing the use of the "requested completion time" command argument as a mechanism for time synchronization of the equipment and controller.

5.2.1.4 Messages

The NCCLS standard specifies command messages used for remote control of processing instruments and analytical instruments. These command messages are provided in the context of the LECIS interactions. The event report messages defined by LECIS to report when the equipment changes state are defined in the NCCLS standard as the ESU/ACK Automated Equipment Status Update (see Section 6.2.1) or the Command Response (see Section 6.3.6).

5.2.1.5 Local/Remote Control

The local/remote control interaction specified in LECIS (Chapter 7.2) should be used for state transitions, even if the remote mode is the routine operation mode. When the device or equipment is in the LOCAL state, the equipment must not accept commands from the controller or any other equipment entities.

5.2.1.6 Operation Management

The control flow interaction model described in the operation management chapter (8.2) of LECIS is used for all equipment control flow transitions relevant for the communication of equipment within its laboratory automation environment. If the internal control flow of the laboratory automation device is different from the LECIS model, then the device must map them to the LECIS model in order to be used in the laboratory automation environment.

5.2.1.7 Status Interaction

The status interaction described in Chapter 9.4 of LECIS is the general message exchange model for status query by the controller and reply by the equipment. In addition, the LECIS provides message syntax for status information related to interactions, inventory, ports, and alarms. The NCCLS standard specifies the message syntax for reports of equipment status, inventory status, and specimen status, and defines the corresponding specific messages, which substitute for the general LECIS message.

5.2.1.8 Command Response

The NCCLS standard generalizes the command response (OK, TI, ER, UN). The OK response corresponds in LECIS to the event report generated by the equipment upon successful exit of the state entered by the command message. The TI, ER, UN responses correspond to the event report defined in many of the LECIS interactions that allow the equipment to enter the "Terminated" state from the initial entry via the "Operation denied" branch.

5.2.1.9 NCCLS-Specific Control Commands

The NCCLS standard defines some NCCLS-specific interactions. These interactions are special cases of the LECIS processing interaction. They are defined by replacing the general LECIS "RUN_OP" command. The NCCLS processing commands are: Load, Unload, Sampling, Transport to, and Clear Notification.

5.2.1.10 Lock/Unlock and Specimen Hand-off

In order to clarify the use of lock/unlock interaction of LECIS (Chapter 9.2), see Table 2. The table presents a command message and state change sequence occurring in a scenario of point-in-space pipetting of a specimen (S) delivered by track to the point P and after the operation moved to point X. To simplify the example, the LECIS states "Lock Requested"→"Locking"→ "Locked" will be described as one state "Locked"; the event report messages from the equipment are not described; and other equipment operation states are not considered here.

Table 2. Command Message and State Change Sequence

Analyzer Command	State	Track Command	State
Lock			
	Locked		
		TransportTo (P,S)	
		Lock	
			Locked
Unlock			
	UNLOCKED		
Sampling (S)			
Lock			
	LOCKED		
		Unlock	
			UNLOCKED
		TransportTo (X,S)	

6 HL7 Communication Standard for Laboratory Automation [10,11]

Section 6 is adapted and incorporated from the standard, Health Level Seven (HL7) – *An Application Protocol for Electronic Exchange in Healthcare Environments, Version 2.4*,[c] Chapter 13, with permission. A complete description of HL7 triggers, messages, and segments is required to understand and implement the interface for laboratory automation. The reader is referred to the entire HL7 standard, Version 2.4, particularly Chapters 2, 4, 7, 8, and 13.

- The content in Section 6 of NCCLS document AUTO3-A is identical to that found in Chapter 13 of HL7 Version 2.4.

- The following box shows the header for Chapter 13 as printed in the document HL7 Version 2.4.

13.

Clinical Laboratory Automation

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6.1 Background and Introduction

6.1.1 Background

Clinical laboratory automation involves the integration or interfacing of automated or robotic transport systems, analytical instruments, and pre- or postanalytical process equipment such as automated centrifuges and aliquotters, decappers, recappers, sorters, and specimen storage and retrieval systems. In addition to the electrical and mechanical interfaces of these various components, the computers that control these devices or instruments must also be interfaced to each other and/or the Laboratory Information System (LIS).

[c] Permission to use portions of the standard, Health Level Seven – *An Application Protocol for Electronic Exchange in Healthcare Environments, Version 2.4* has been granted by Health Level Seven, Inc. The current standard may be obtained from Health Level Seven, Inc., 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104-4261 or via www.HL7.org.

The types of information communicated between these systems include process control and status information for each device or analyzer, each specimen, specimen container, and container carrier; information and detailed data related to patients, orders, and results; and information related to specimen flow algorithms and automated decision making. This wide array of communicated information is essential for a Laboratory Automation System (LAS) to control the various processes and to ensure that each specimen or aliquot has the correct tests performed in the proper sequence.

As of 1999 there are already more than 200 clinical laboratories in the world with "total laboratory automation" systems and hundreds more with a lesser level of automation – generally workcells or modular automation systems. The development of prospective standards for these aspects of clinical laboratory automation will facilitate the interoperability of the systems being developed by the various players in lab automation – the vendors of analytical instruments, LIS systems, automation systems and components, and their laboratory customers.

In the early 1990s an ad hoc task force, Clinical Testing Automation Standards Steering Committee (CTASSC), began to meet at the annual meetings of the International Conference on Automation and Robotics (ICAR) and the American Association for Clinical Chemistry (AACC). In 1996, CTASSC approached NCCLS,[d] a globally recognized, consensus standards organization that has developed more than 125 clinical laboratory standards and related products since it was founded in 1968, about taking on a project for clinical laboratory automation. NCCLS agreed to sponsor this project which was separately funded via a direct solicitation of the vendors in lab automation, instruments, LIS systems, and automation customers. It was organized as a "fast track" project to develop prospective standards to guide future developments in laboratory automation. With the oversight of an Area Committee on Automation, five separate subcommittees have worked since 1997 to develop a series of prospective standards for:

- Specimen containers and carriers;
- Bar codes for specimen container identification;
- Communications;
- System operational requirements and characteristics; and
- Electromechanical interfaces.

Approved-level standards for all five of these areas are expected to be published by NCCLS in calendar year 2000.

6.1.2 Introduction

This chapter specifies HL7 triggers, messages, and segments required for implementation of clinical laboratory automation communication interfaces. It was developed jointly by the HL7 Laboratory Automation Special Interest Group and the NCCLS Subcommittee on Communications with Automated Systems. This chapter, by agreement between HL7 and NCCLS, is also published in its entirety as part of the NCCLS approved-level standard:

- AUTO3, "Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems," © NCCLS.

This document contains other chapters to enable a vendor to successfully implement all of the elements essential to meet the standard.

[d] NCCLS, 940 West Valley Road, Suite 1400, Wayne, PA 19087; www.nccls.org

The other related NCCLS clinical laboratory automation standards are:

- AUTO1: "Laboratory Automation: Specimen Container/Specimen Carrier," © NCCLS.
- AUTO2: "Laboratory Automation: Bar Codes for Specimen Container Identification", © NCCLS.
- AUTO4: "Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements," © NCCLS.
- AUTO5: "Laboratory Automation: Electromechanical Interfaces," © NCCLS.

The reader is referred to any or all of these NCCLS standards, particularly AUTO3 and AUTO4, for detailed information on the communications requirements in clinical laboratory automation applications.

The control model proposed in this standard is an extension of the model described in LECIS:

- ASTM E1989-98. Laboratory Equipment Control Interface Specification (LECIS). American Society for Testing and Materials; 1998

6.1.3 Glossary

The terminology found in ANSI X3.182-1990[2] shall be used where applicable. Other computer-related technical terms used in this document can be found in ASTM Terminology E1013,[4] IEEE 100,[7] IEEE 610,[8] and ANSI X3.172.[1]

6.1.3.1 Accession Identifier (also accession number)

A numeric (or alphanumeric) identifier assigned by the LIS for a test order. Depending on the particular LIS a patient's test orders for a single encounter may use one or more accession identifiers, and each accession identifier may encompass one or more tests and one or more specimens and/or specimen containers. However, accession identifiers are unique within each patient encounter. The Accession identifier may not be equal to the Placer or Filler Order Numbers, because of uniqueness requirement.

6.1.3.2 Additive

As used here, refers to a substance (generally a chemical) that has been added to a specimen collection tube or container to prevent degradation of one or more constituents of the specimen.

6.1.3.3 Aliquot

1) ***In Quantitative Analysis,*** a sample comprising a known fraction or measured portion of the whole***;*** 2**)** ***In NCCLS LAB AUTOMATION Standard documents,*** 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, 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.

6.1.3.4 Analyzer

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.

6.1.3.5 Automated

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**.**

6.1.3.6 Automated instrument

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.

6.1.3.7 Automation system

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.

6.1.3.8 Bar code

An array of parallel rectangular bars and spaces that creates a symbology representing a number or alphanumeric identifier.

6.1.3.9 Bar length

The length of the bars in the bar code.

6.1.3.10 Barrier

See **Separator.**

6.1.3.11 Barrier Delta

Identifies the distance from the Point of Reference to the separator material (barrier) within the container. This distance may be provided by the LAS to the instrument and/or specimen processing/handling device to facilitate the insertion of a sampling probe into the specimen without touching the separator. See the "point of reference" definition or NCCLS standard AUTO5—*Laboratory Automation: Electromechanical Interfaces*.

6.1.3.12 Bottom of cap

The farthest point from the top of the container/test tube that the cap reaches.

Note: This point may be inside the tube.

6.1.3.13 Bottom of container//Bottom of tube

The portion of the container/test tube farthest from the cap (see **Point of reference**).

6.1.3.14 Bottom of tube

See **Bottom of container**.

6.1.3.15 Carrier

See **Specimen carrier**.

6.1.3.16 Character

1) The smallest abstract element of a writing system or script.

Note: A character refers to an abstract idea rather than to a specific shape.

2) A code element.

6.1.3.17 Clinical laboratory automation

The integration of laboratory personnel and preanalytical, analytical, and postanalytical processes and information systems.

6.1.3.18 Clinical laboratory automation systems

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.

6.1.3.19 Closed-container sampling//Closed-tube sampling

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.

6.1.3.20 Closed-tube sampling

See **Closed-container sampling**.

6.1.3.21 Container//Tube//Test Tube

See **Specimen container**.

6.1.3.22 Container identifier

A numeric (or alphanumeric) identifier provided by the LIS or LAS to uniquely identify each specimen container or aliquot container. The *NCCLS LAB AUTOMATION Standard* requires a unique identifier for each container introduced into the LAS or leaving the LAS.

6.1.3.23 Cycle time components

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.

6.1.3.24 Decapping

The removal of a closure from a specimen container.

6.1.3.25 Delimiter

A symbol used to separate items in a list.

6.1.3.26 Directions of the specimen, Transportation system, Instrument or Specimen processing and handling device interfaces

The orthogonal axes.

Note: a) These axes are demonstrated in Figure 7.

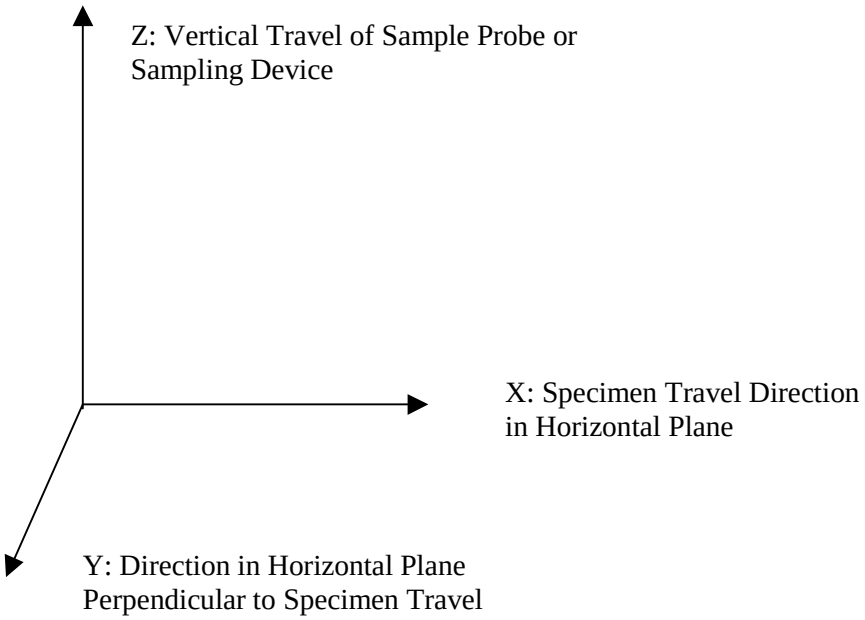


Figure 7. Physical Frame of Reference in a Three-Dimensional Space (X-Y-Z)

- 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 8A.)

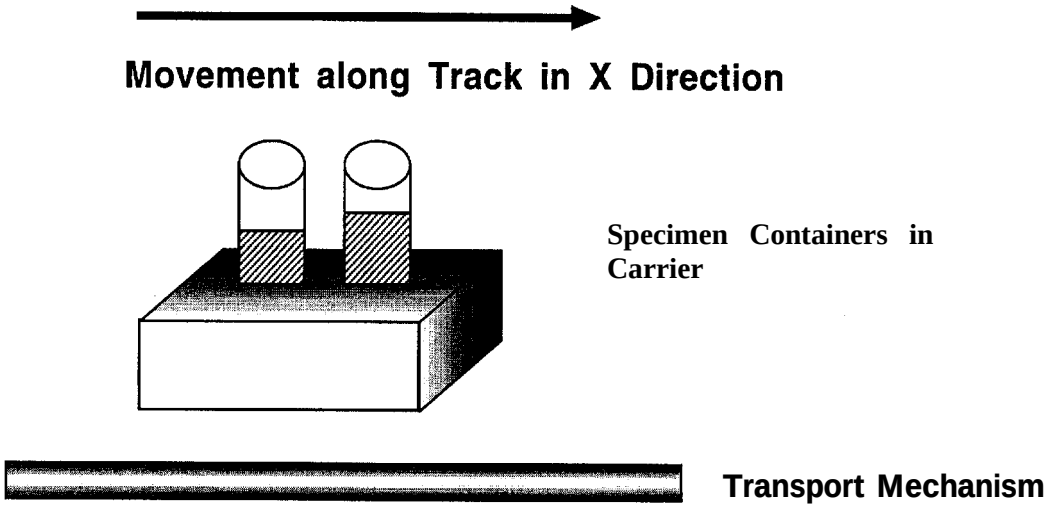


Figure 8A. X Direction

- 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 8B). 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.

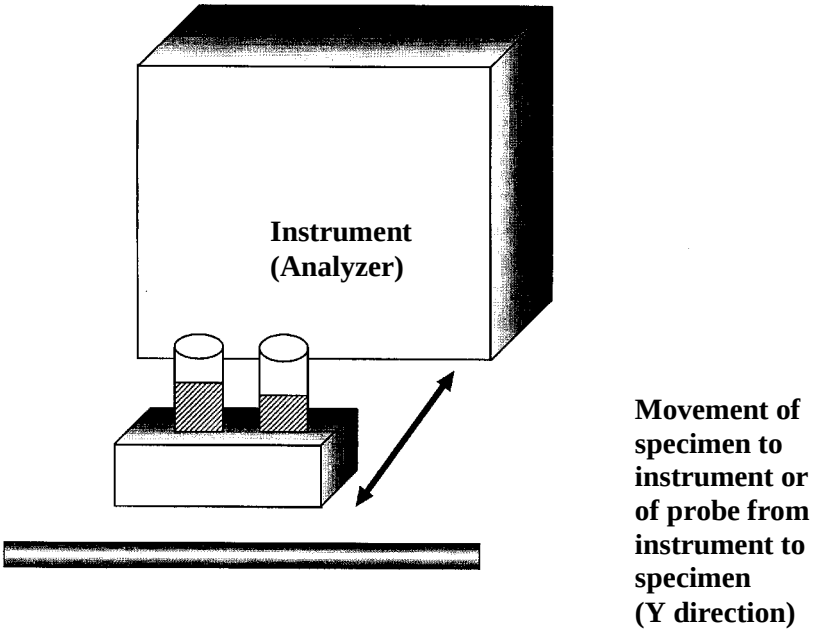


Figure 8B. Y Direction

- 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 8C);

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.

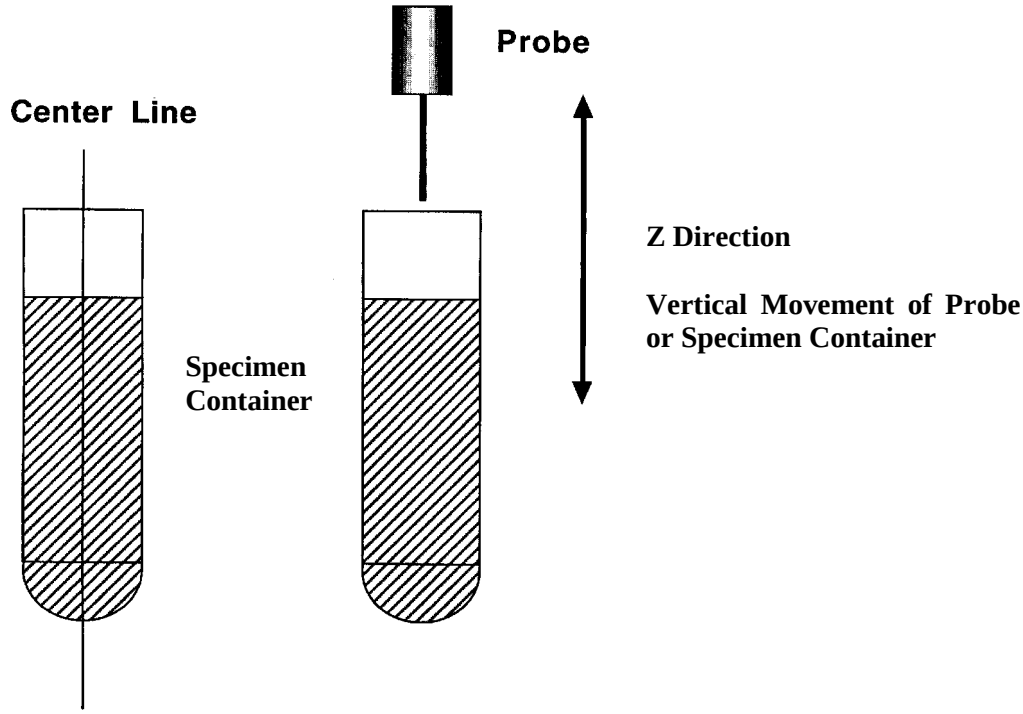


Figure 8C. Z Direction

6.1.3.27 Directions of the sample, Transportation system, Instrument or Specimen processing handling device and interfaces

See **Directions of the specimen**, etc.

6.1.3.28 Direct track sampling

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: This process requires 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.

6.1.3.29 Docking site

1) The location of the physical interface between two components of a system; **2)** ***In NCCLS LAB AUTOMATION Standard documents,*** 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.

6.1.3.30 Flection

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

6.1.3.31 Interaction

A standard exchange of messages between two instances of equipment that synchronizes the execution of one or more commands. State models are used describe the standard interactions.

6.1.3.32 Label

1) The display of written, printed, or graphic matter upon the immediate container of any article; **2)** ***In NCCLS LAB AUTOMATION Standard documents***, the paper and attached adhesive coating on which the bar code and other human readable information is printed.

6.1.3.33 Laboratory automation system (LAS)

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.

6.1.3.34 Laboratory equipment control interface specification (LECIS)

A high-level protocol that defines message content for standard behaviors or interactions for remote control of analytical instruments and devices (ASTM E 1989-98[10]).

6.1.3.35 Laboratory information system (LIS)

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.

6.1.3.36 LECIS

Acronym for Laboratory Equipment Control Interface Specification (ASTM E 1989-98[10]).

6.1.3.37 Location

A physical place within the laboratory, with a unique identifier (e.g., refrigerator shelf number, instrument buffer ID, track identifier).

6.1.3.38 Open-container sampling//Open-tube sampling

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.

6.1.3.39 Open-tube sampling

See **Open-container sampling**.

6.1.3.40 Pitch

The center distance between two specimen containers in a carrier or between two sequential specimen container carriers.

6.1.3.41 Point of reference//Point in space, (POR)

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 are measured.

6.1.3.42 Process instruments

In NCCLS LAB AUTOMATION Standard documents, 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.

6.1.3.43 Quiet zone

In NCCLS LAB AUTOMATION documents, the white {blank} space on a bar code immediately preceding the first bar and immediately following the last bar.

6.1.3.44 Recap

To replace the closure on a specimen container; either with the original closure or with a new replacement closure.

6.1.3.45 Robotic arm

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.

6.1.3.46 Sample//(Specimen)

1) A small part of anything ... intended to show the quality, style, or nature of the whole***;*** **2)** ***In NCCLS LAB AUTOMATION Standard documents,*** a portion or aliquot withdrawn from a container for the actual test.

> **Notes:** ***In NCCLS LAB AUTOMATION Standard documents,***
> 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 ID of the specimen is typically assured by computer linkage of the pipetting or aspiration step to the 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.

6.1.3.47 Sample carrier

See **Specimen carrier**.

6.1.3.48 Sample container

See **Specimen collection container**.

6.1.3.49 Sample-positioning system

See **Specimen-positioning system**.

6.1.3.50 Sample probe

See **Specimen probe**.

6.1.3.51 Separator

A material such as a gel which is contained in blood collection tubes to facilitate separation of blood cells from blood serum by creating a physical “barrier” between them.

6.1.3.52 Serum/Plasma Separator

See **Separator** in Section 6.1.3.51.

6.1.3.53 Service envelope

In NCCLS LAB AUTOMATION Standard documents, 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.

6.1.3.54 Specimen

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.

6.1.3.55 Specimen carrier//Sample carrier//Carrier

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 9).

6.1.3.56 Specimen collection container//Specimen container//Sample container//Container

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 9)

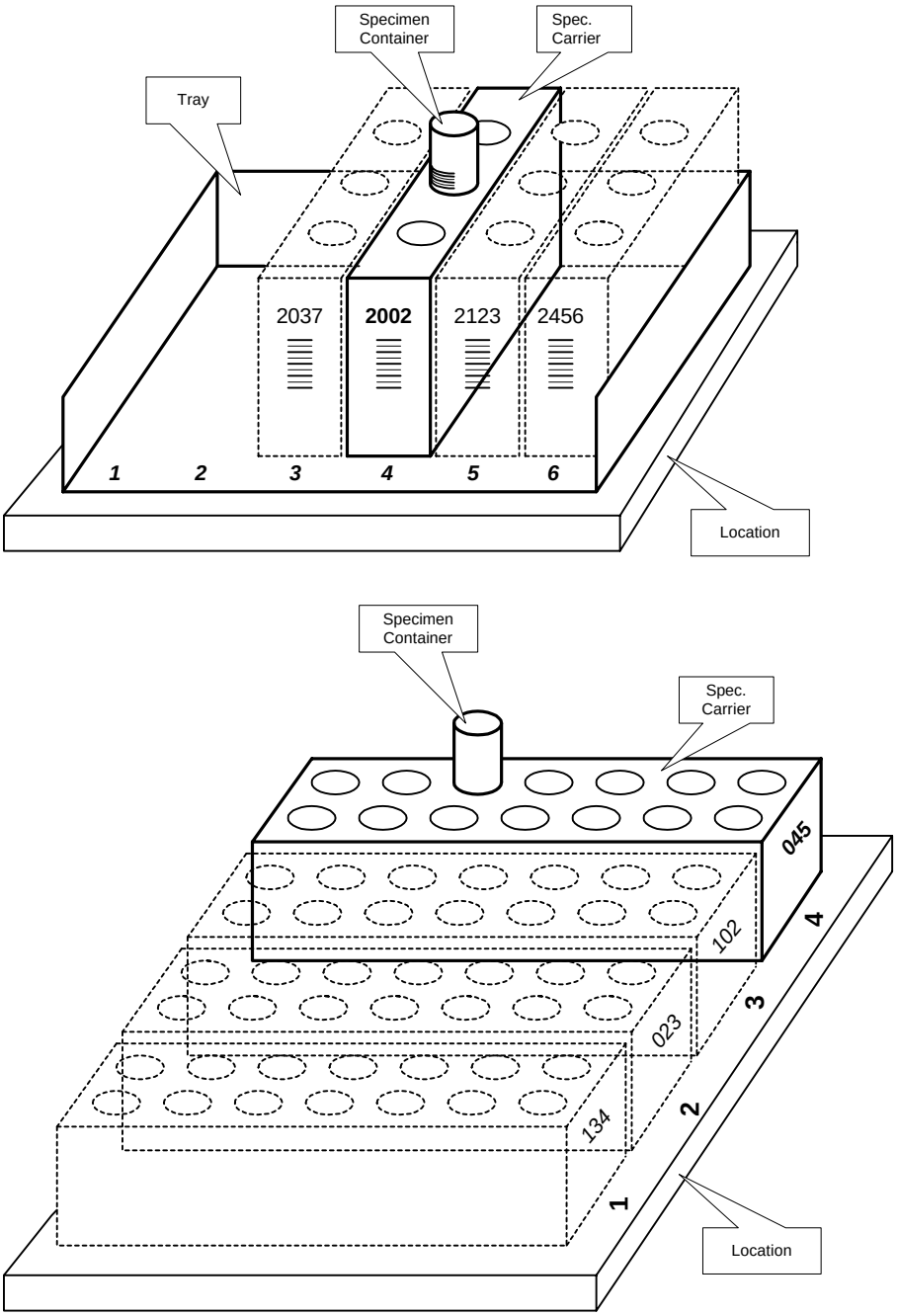


Figure 9. Relationship Among Specimen Container, Specimen Carrier, Tray, and Locations

6.1.3.57 Specimen-positioning system//Sample-positioning system (SPS)

A device to position a specimen container within acceptable tolerances of a POR.

6.1.3.58 Specimen probe//Sample probe

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.

6.1.3.59 Stay-clear zone

In NCCLS LAB AUTOMATION Standard documents, 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.

6.1.3.60 Symbol

In NCCLS LAB AUTOMATION Standard documents, a combination of bar-code characters, including start/stop characters, quiet zones, data elements, and check characters which form a complete scanning entity.

6.1.3.61 Test mnemonics

Short, understandable contractions for test names.

6.1.3.62 Top of container//Top of tube

The open end of the container/test tube, closest to the cap.

6.1.3.63 Top of tube

See **Top of container**.

6.1.3.64 Tray

A holder for one or more carriers (optional). (See Figure 9).

6.1.3.65 X–direction

See **Directions**.

6.1.3.66 Y–direction

See **Directions**.

6.1.3.67 Z–direction

See **Directions**.

6.2 Trigger Events and Message Definitions

Each trigger event is listed below, along with the application form of the message exchange.

The notation used to describe the sequence, the optionality, and the repetition of segments is described in HL7, Chapter 2, under “Format for Defining Abstract Message.”

All the ACK messages are varieties of the 'general acknowledgement' message defined in HL7, Chapter 2. The only difference is the event code.

The “Equipment Notification” message (EAN/ACK event U09) is used to send information about the occurrence of an event. An event does not necessarily cause a state transition. The “Status Update” message (EAU/ACK event U01) is used to transfer information about the current status. This status can

be the result of one or more events that led to the state transition. Example: The event of a "warning level of a consumable being reached" (e.g., 10% left) does not cause a state transition, because the system can remain "In operation." This results in an EAN/ACK message. An event "container transport jammed" causes the state transition to "Emergency stop." This results in both EAN/ACK and EAU/ACK messages.

For the transfer of laboratory automation orders and results refer to *4.4.6 OML - laboratory order message (event O21)* instead of ORM, and *7.3.2 OUL – unsolicited laboratory observation message (event O20)* instead of ORU.

6.2.1 ESU/ACK - automated equipment status update (event U01)

This message is used to send information about the status of a device or equipment from one application to another (e.g., automated device to a Laboratory Automation System). The status update can be sent unsolicited or as a response to the trigger "Automated Equipment Status Request."

ESU^U01^ESU U01	**Equipment Status Message**	**Chapter**
MSH	Message Header	2
EQU	Equipment Detail	13
[{ ISD }]	Interaction Status Detail	13
[ROL]	Role Detail	12

ACK^U01^ACK	**General Acknowledgement**	**Chapter**
MSH	Message Header	2
MSA	Message Acknowledgment	2
[ERR]	Error[e]	2

6.2.2 ESR/ACK - automated equipment status request (event U02)

This message is used to request information about a device's or piece of equipment's status from one application to another (e.g., Laboratory Automation System to automated equipment). The equipment identified in the EQU segment should respond with its status using the "Automated Equipment Status Update."

ESR^U02^ESR U02	**Equipment Status Message**	**Chapter**
MSH	Message Header	2
EQU	Equipment Detail	13
[ROL]	Role Detail	12

ACK^U02^ACK	**General Acknowledgment**	**Chapter**
MSH	Message Header	2
MSA	Message Acknowledgment	2
[ERR]	Error	2

6.2.3 SSU/ACK - specimen status update (event U03)

This message is used to send information concerning the location and status of specimens from one application to another (e.g., automated equipment to a Laboratory Automation System).

The OBX segments attached to the SAC should be used for transfer of information not included in the SAC segment.

[e] This error segment indicates the fields that caused a transaction to be rejected.

SSU^U03^SSU U03	Specimen Status Message	Chapter
MSH	Message Header	2
EQU	Equipment Detail	13
{ SAC	Specimen and Container Detail	13
[OBX]	Observation Result	7
}		
[ROL]	Role Detail	12

ACK^U03^ACK	General Acknowledgment	Chapter
MSH	Message Header	2
MSA	Message Acknowledgment	2
[ERR]	Error	2

6.2.4 SSR/ACK - specimen status request (event U04)

This message is used to request information concerning the location and status of specimens from one application to another (e.g., Laboratory Automation System to automated equipment). The request can be addressed for a specific container, a specific carrier, a specific tray, or a specific location, depending on the arguments set in the SAC segment. The equipment specified in the EQU segment should respond with the "Specimen Status Update."

SSR^U04^SSR U04	Specimen Status Message	Chapter
MSH	Message Header	2
EQU	Equipment Detail	13
{ SAC }	Specimen and Container Detail	13
[ROL]	Role Detail	12

ACK^U04^ACK	General Acknowledgment	Chapter
MSH	Message Header	2
MSA	Message Acknowledgment	2
[ERR]	Error	2

6.2.5 INU/ACK – automated equipment inventory update (event U05)

This message is used to send information about inventory items from one application to another (e.g., automated equipment to a Laboratory Automation System).

INU^U05^INU U05	Inventory Update Message	Chapter
MSH	Message Header	2
EQU	Equipment Detail	13
{ INV }	Inventory Detail	13
[ROL]	Role Detail	12

ACK^U05^ACK	General Acknowledgment	Chapter
MSH	Message Header	2
MSA	Message Acknowledgment	2
[ERR]	Error	2

6.2.6 INR/ACK – automated equipment inventory request (event U06)

This message is used to request information about inventory items from one application to another (e.g., Laboratory Automation System to automated equipment). The equipment specified in the EQU segment should respond with the information about inventory item requested in the INV segment (or all items).

INR^U06^INR U06	**Inventory Request Message**	**Chapter**
MSH	Message Header	2
EQU	Equipment Detail	13
{ INV }	Inventory Detail	13
[ROL]	Role Detail	12

ACK^U06^ACK	**General Acknowledgment**	**Chapter**
MSH	Message Header	2
MSA	Message Acknowledgment	2
[ERR]	Error	2

6.2.7 EAC/ACK – automated equipment command (event U07)

This message is used to send equipment commands from one application to another (e.g., a Laboratory Automation System to automated equipment).

EAC^U07^EAC U07	**Equipment Command Message**	**Chapter**
MSH	Message Header	2
EQU	Equipment Detail	13
{ ECD }	Equipment Command Detail	13
[SAC]	Specimen and Container Detail	13
[CNS]	Clear Notification	13
[ROL]	Role Detail	12

ACK^U07^ACK	**General Acknowledgment**	**Chapter**
MSH	Message Header	2
MSA	Message Acknowledgment	2
[ERR]	Error	2

6.2.8 EAR/ACK – automated equipment response (event U08)

This message is used to send equipment responses to previously issued commands from one application to another (e.g., automated equipment to a Laboratory Automation System).

EAR^U08^EAR U08	**Equipment Command Message**	**Chapter**
MSH	Message Header	2
EQU	Equipment Detail	13
{ ECD	Equipment Command Detail	13
[SAC]	Specimen and Container Detail	13
ECR }	Equipment Command Response	13
[ROL]	Role Detail	12

ACK^U08^ACK	**General Acknowledgment**	**Chapter**
MSH	Message Header	2
MSA	Message Acknowledgment	2
[ERR]	Error	2

6.2.9 EAN/ACK - automated equipment notification (event U09)

This message is used to send equipment notifications from one application to another (e.g., alerts sent by automated equipment to a Laboratory Automation System).

EAN^U09^EAB U09	**Equipment Status Message**	**Chapter**
MSH	Message Header	2
EQU	Equipment Detail	13
{ NDS	Notification Detail	13
[NTE]	Notification Note	2
}		
[ROL]	Role Detail	12

ACK^U09^ACK	**General Acknowledgment**	**Chapter**
MSH	Message Header	2
MSA	Message Acknowledgment	2
[ERR]	Error	2

6.2.10 TCU/ACK - automated equipment test code settings update (event U10)

This message is used to send information concerning test codes and parameters from one application to another (e.g., automated equipment to a Laboratory Automation System). This message transfers the current snapshot of the test parameters of the sending system. The sent parameter sets are supposed to replace the parameter sets existing at the receiver of this message before the trigger (there is no selective "Add" or "Delete").

TCU^U10^TCU U10	**Test Code Settings Update**	**Chapter**
MSH	Message Header	2
EQU	Equipment Detail	13
{ TCC }	Test Code Configuration	13
[ROL]	Role Detail	12

ACK^U10^ACK	**General Acknowledgment**	**Chapter**
MSH	Message Header	2
MSA	Message Acknowledgment	2
[ERR]	Error	2

6.2.11 TCR/ACK - automated equipment test code settings request (event U11)

This message is used to request information concerning test codes from one application to another (e.g., Laboratory Automation System to automated equipment).

TCR^U11^TCU_U10	**Test Code Settings Request**	**Chapter**
MSH	Message Header	2
EQU	Equipment Detail	13
{ TCC }	Test Code Configuration	13
[ROL]	Role Detail	12

ACK^U11^ACK	**General Acknowledgment**	**Chapter**
MSH	Message Header	2
MSA	Message Acknowledgment	2
[ERR]	Error	2

6.2.12 LSU/ACK - automated equipment log/service update (event U12)

This message is used to send log and/or service events from one application to another (e.g., automated equipment to Laboratory Automation System).

LSU^U12^LSU U12	Equipment Log/Service Message	Chapter
MSH	Message Header	2
EQU	Equipment Detail	13
{ EQP }	Equipment Log/Service	13
[ROL]	Role Detail	12

ACK^U12^ACK	General Acknowledgment	Chapter
MSH	Message Header	2
MSA	Message Acknowledgment	2
[ERR]	Error	2

6.2.13 LSR/ACK - automated equipment log/service request (event U13)

This message is used to request log and/or service events from one application to another (e.g., Laboratory Automation System to automated equipment).

LSR^U13^LSU U12	Equipment Log/Service Message	Chapter
MSH	Message Header	2
EQU	Equipment Detail	13
{ EQP }	Equipment Log/Service	13
[ROL]	Role Detail	12

ACK^U13^ACK	General Acknowledgment	Chapter
MSH	Message Header	2
MSA	Message Acknowledgment	2
[ERR]	Error	2

6.3 Message Segments

The following section identifies the message segments proposed for incorporation in this standard, and will be submitted for incorporation or reference in other HL7 and NCCLS standard documents. Valid entries are presented in an attribute table for each segment.

6.3.1 EQU - equipment detail segment

The equipment detail segment contains the data necessary to identify and maintain the equipment that is being used throughout the Laboratory Automation System.

HL7 Attribute Table – EQU – Equipment Detail

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM #	ELEMENT NAME
1	22	EI	R			01479	Equipment Instance Identifier
2	26	TS	R			01322	Event Date/Time
3	250	CE	C		0365	01323	Equipment State
4	250	CE	O		0366	01324	Local/Remote Control State
5	250	CE	O		0367	01325	Alert Level

6.3.1.1 EQU-1 Equipment instance identifier (EI) 01479

Components: <entity identifier (ST)> ^ <namespace ID (IS)> ^ <universal ID (ST)> ^ <universal ID type (ID)>

Definition: This field identifies the equipment. This is the identifier from an institution's master list of equipment. The <namespace ID> identifies the institution.

6.3.1.2 EQU-2 Event date/time (TS) 01322

Definition: This field is the date/time that the event (e.g., state transition, issuing of command, finishing of command execution) occurred.

6.3.1.3 EQU-3 Equipment state (CE) 01323

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field identifies the status that the equipment was in at the time that the transaction was initiated. Refer to *HL7 Table 0365 – Equipment state* for valid values. The Equipment State is required in the ESU message and is optional otherwise.

HL7 Table 0365 - Equipment state

Value	Description
PU	Powered Up
IN	Initializing
ID	Idle
CO	Configuring
OP	Normal Operation
CL	Clearing
PA	Pausing
PD	Paused
ES	E-stopped
	(null) No state change

This table is based on LECIS (see sub-chapter "Introduction and Overview")

6.3.1.4 EQU-4 Local/remote control state (CE) 01324

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field identifies the current state of control associated with the equipment. Equipment can either work autonomously ('Local' control state) or it can be controlled by another system, e.g., LAS computer ('Remote' control state). Refer to *HL7 Table 0366 – Local/remote control state* for valid values.

HL7 Table 0366 - Local/remote control state

Value	Description
L	Local
R	Remote
	(null) No state change

This table is based on LECIS (see sub-chapter “Introduction and Overview”)

6.3.1.5 EQU-5 Alert level (CE) 01325

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field identifies the highest level of the alert state (e.g., highest alert severity) that is associated with the indicated equipment (e.g., processing event, inventory event, QC event). Refer *to HL7 Table 0367 – Alert level* for valid values.

HL7 Table 0367 - Alert level

Value	Description	Note
N	Normal	No Corrective Action Needed
W	Warning	Corrective Action Anticipated
S	Serious	Corrective Action Required
C	Critical	Shut Down, Fix Problem and Re-init
	(null) No level change	

6.3.2 ISD – interaction status detail segment

The interaction detail segment contains information about the status of specific interaction (e.g., processing — see section Glossary) on the specific equipment.

HL7 Attribute Table – ISD – Interaction Status Detail

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM #	ELEMENT NAME
1	20	NM	R			01326	Reference Interaction Number (unique identifier)
2	250	CE	O		0368	01327	Interaction Type Identifier
3	250	CE	R		0387	01328	Interaction Active State

6.3.2.1 ISD-1 Reference interaction number (NM) 01326

Definition: This number uniquely identifies the interaction. If the interaction is performed as the result of a previous command, then the Reference Command Number should be used. (See Section 6.3.5.1 ECD-1 Reference command number (NM) 01390)

6.3.2.2 ISD-2 Interaction type identifier (CE) 01327

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field specifies the type of interaction. If the interaction is performed as the result of a previous command, then the interaction type as specified *in User-defined Table 0368 - Remote control command* should be used.

6.3.2.3 ISD-3 Interaction active state (CE) 01328

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field transfers the state of the interaction. If the interaction is performed as the result of a previous command, then the interaction state should be one of the Command Responses (Refer to *User-defined Table 0387 – Command response*). If the interaction is not performed as a result of a command (e.g., periodically time-triggered automatic maintenance) then this state is interaction specific, and should refer to either the LECIS state transitions for interactions or a user- or equipment-specific table.

6.3.3 SAC– specimen and container detail segment

The container detail segment is the data necessary to maintain the containers that are being used throughout the Laboratory Automation System.

HL7 Attribute Table – SAC – Specimen and container detail

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM #	ELEMENT NAME
1	80	EI	O			01329	External Accession Identifier
2	80	EI	O			01330	Accession Identifier
3	80	EI	C			01331	Container Identifier
4	80	EI	C			01332	Primary (parent) Container Identifier
5	80	EI	O			01333	Equipment Container Identifier
6	300	CM	O		0070/0369	00249	Specimen Source
7	26	TS	O			01334	Registration Date/Time
8	250	CE	O		0370	01335	Container Status
9	250	CE	O		0378	01336	Carrier Type
10	80	EI	O			01337	Carrier Identifier
11	80	NA	O			01338	Position in Carrier
12	250	CE	O		0379	01339	Tray Type - SAC
13	80	EI	O			01340	Tray Identifier
14	80	NA	O			01341	Position in Tray
15	250	CE	O	Y		01342	Location
16	20	NM	O			01343	Container Height
17	20	NM	O			01344	Container Diameter
18	20	NM	O			01345	Barrier Delta
19	20	NM	O			01346	Bottom Delta
20	250	CE	O			01347	Container Height/Diameter/Delta Units
21	20	NM	O			00644	Container Volume
22	20	NM	O			01349	Available Volume
23	20	NM	O			01350	Initial Specimen Volume
24	250	CE	O			01351	Volume Units
25	250	CE	O		0380	01352	Separator Type
26	250	CE	O		0381	01353	Cap Type
27	250	CE	O	Y	0371	00647	Additive
28	250	CE	O			01355	Specimen Component
29	20	SN	O			01356	Dilution Factor
30	250	CE	O		0373	01357	Treatment
31	20	SN	O			01358	Temperature
32	20	NM	O			01359	Hemolysis Index
33	250	CE	O			01360	Hemolysis Index Units
34	20	NM	O			01361	Lipemia Index
35	250	CE	O			01362	Lipemia Index Units
36	20	NM	O			01363	Icterus Index
37	250	CE	O			01364	Icterus Index Units
38	20	NM	O			01365	Fibrin Index
39	250	CE	O			01366	Fibrin Index Units
40	250	CE	O	Y	0374	01367	System Induced Contaminants
41	250	CE	O	Y	0382	01368	Drug Interference
42	250	CE	O		0375	01369	Artificial Blood
43	250	CE	O	Y	0376	01370	Special Handling Considerations
44	250	CE	O	Y	0377	01371	Other Environmental Factors

6.3.3.1 SAC-1 External accession identifier (EI) 01329

Components: <entity identifier (ST)> ^ <namespace ID (IS)> ^ <universal ID (ST)> ^ <universal ID type (ID)>

Definition: This field identifies the laboratory accession (see section *Glossary*). This identifier is assigned by the external laboratory information system.

Example: If laboratory A sends a specimen to laboratory B, then within laboratory B this field contains accession identifier of lab A.

6.3.3.2 SAC-2 Accession identifier (EI) 01330

Components: <entity identifier (ST)> ^ <namespace ID (IS)> ^ <universal ID (ST)> ^ <universal ID type (ID)>

Definition: This field identifies the laboratory accession (see section *Glossary*). This identifier is assigned by the information system of the laboratory performing the tests.

An accession identifier can refer to more than one container. A Container Identifier (see below) is a Unique Identifier for that container.

6.3.3.3 SAC-3 Container identifier (EI) 01331

Components: <entity identifier (ST)> ^ <namespace ID (IS)> ^ <universal ID (ST)> ^ <universal ID type (ID)>

Definition: This field identifies the container. This field is the container's unique identifier assigned by the corresponding equipment. A container may contain the primary (original) specimen or an aliquot (secondary sample) of that specimen. For primary sample this field contains Primary Container ID; for bar-coded aliquot samples this field contains Aliquot Container ID; for non-bar-coded aliquot samples (e.g., microtiter plate) this field is empty.[f]

The NCCLS standard requires a unique identifier for each container introduced into the Laboratory Automation System. The combination of the fields: Primary Container ID, Container ID, Carrier ID / Position, Tray ID / Position must identify the container uniquely within the LAS. The naturally best solution is unique machine-readable ID attached to the container (which of course is sufficient to ensure the uniqueness of the fields' combination). A bar code that symbolizes this ID should meet the standard NCCLS AUTO2 (*Laboratory Automation: Bar Codes for Specimen Container Identification).*

[f] Example of use of container id fields for various sample types:

SAC field	Primary container	Aliquot container with Bar-code	Aliquot container without Bar-code, e.g., microtiter well
"Container ID" (SAC-3)	Primary container ID	Aliquot container ID	—
"Primary (parent) Container ID" (SAC-4)	—	Primary container ID	Primary container ID

6.3.3.4 SAC-4 Primary (parent) container identifier (EI) 01332

Components: <entity identifier (ST)> ^ <namespace ID (IS)> ^ <universal ID (ST)> ^ <universal ID type (ID)>

Definition: If this field is filled in, it identifies the primary container from which this specimen came. For primary samples this field is empty; for aliquot samples this field should contain the identifier of primary container.

6.3.3.5 SAC-5 Equipment container identifier (EI) 01333

Components: <entity identifier (ST)> ^ <namespace ID (IS)> ^ <universal ID (ST)> ^ <universal ID type (ID)>

Definition: This field identifies the container in a particular device (e.g., one container in a carousel or rack of containers within an analyzer, analyzer-specific bar-code mapping, etc.).

6.3.3.6 SAC-6 Specimen source (CM) 00249

Components: <specimen source name or code (CE)> ^ <additives (TX)> ^ <free text (TX)> ^ <body site (CE)> ^ <site modifier (CE)> ^ <collection method modifier code (CE)> ^ <specimen role (CE)>

Sub-components of specimen source name or code: <identifier (ST)> & <test (ST)> & <name of coding system (IS)> & <alternate identifier (ST)> & <alternate text (ST)> & <name of alternate coding system (ST)>

Sub-components of body site: <identifier (ST)> & <test (ST)> & <name of coding system (IS)> & <alternate identifier (ST)> & <alternate text (ST)> & <name of alternate coding system (ST)>

Sub-components of site modifier: <identifier (ST)> & <test (ST)> & <name of coding system (IS)> & <alternate identifier (ST)> & <alternate text (ST)> & <name of alternate coding system (ST)>

Sub-components of collection method modifier code: <identifier (ST)> & <test (ST)> & <name of coding system (IS)> & <alternate identifier (ST)> & <alternate text (ST)> & <name of alternate coding system (ST)>

Sub-components of specimen role: <identifier (ST)> & <test (ST)> & <name of coding system (IS)> & <alternate identifier (ST)> & <alternate text (ST)> & <name of alternate coding system (ST)>

Definition: This field is the site where the specimen should be obtained or where the service should be performed.

The first component contains the specimen source name or code (as a CE data type component). (Even in the case of observations whose name implies the source, a source may be required, e.g., blood culture: heart blood.) Refer to *HL7 Table 0070 – Specimen source codes* for valid entries.

The second component should include free text additives to the specimen such as heparin, EDTA, or oxalate, when applicable.

The third is a free text component describing the method of collection when that information is a part of the order. When the method of collection is logically an observation result, it should be included as a result segment.

The fourth component specifies the body site from which the specimen was obtained, and the fifth is the site modifier. For example, the site could be antecubital fossa, and the site modifier "right." The components of the CE fields become sub-components. Refer to *HL7 Table 0163 - Administrative site* for valid entries.

The sixth component indicates whether the specimen is frozen as part of the collection method. Suggested values are F (Frozen); R (Refrigerated). If the component is blank, the specimen is assumed to be at room temperature.

The seventh component indicates the role of the sample. Refer to *User-defined Table 0369 – Specimen role* for suggested values. Each of these values is normally identifiable by the systems and its components and can influence processing and data management related to the specimen.

User-defined Table 0369 - Specimen role

Value	Description
P	Patient (default if blank component value)
Q	Control specimen
C	Calibrator
B	Blind sample
R	Replicate (of patient sample as a control)

6.3.3.7 SAC-7 Registration date/time (TS) 01334

Definition: This field is the date/time that the container was last registered with the "automated system," e.g., reading of a container bar code by a device.

6.3.3.8 SAC-8 Container status (CE) 01335

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field identifies the status of the unique container in which the specimen resides at the time that the transaction was initiated. Refer to *HL7 Table 0370 - Container status* for valid values. The equipment-specific container status should be sent as *<alternate identifier>* as needed.

HL7 Table 0370 - Container status

Value	Description
I	Identified
P	In Position
O	In Process
R	Process Completed
L	Left Equipment
M	Missing
X	Container Unavailable
U	Unknown

The container states are relevant for the exchange of information among devices (within the LAS). Not all of them are relevant for information transfer between the LAS and the LIS.

In the explanations below the system means the LAS or any equipment interfaced to it or to another equipment.

Identified status is used by one system to inform another that it has received a container. In the exchange between the LAS and LIS the *Identified* status can be used for reporting of the "In Lab" (Specimen Received) status. In some cases this may not be equal to the first event of sample recognition.

In Position status is used by one system to inform another that the container is in position for specimen transfer (e.g., container removal from track, pipetting, etc.).

In Process status is used by one system to inform another that the specific container is being processed by the equipment. It is useful as a response to a query about Container Status, when the specific step of the process is not relevant.

Process Completed status is used by one system to inform another that the processing has been completed, but the container has not been released from that system.

Left Equipment status is used by one system to inform another that the container has been released from that system.

Missing status is used by one system to inform another that the container did not arrive at its next expected location.

Cancelled status is used by one system to inform another that the container is no longer available within the scope of the system (e.g., tube broken or discarded).

Unknown status is used by one system to inform another that the container has not been identified.

6.3.3.9 SAC-9 Carrier type (CE) 01336

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field identifies the type of the carrier (see section Glossary). Refer *to User-defined Table 0378 – Carrier type* for suggested values. Because the geometry can be different, the carrier type should, if possible, express the number of positions in the carrier.

The definition assumes hierarchical nesting using the following phrases: container is located in a carrier, carrier is located in a tray.

User-defined Table 0378 – Carrier type

Value	Description
	No suggested values defined

Examples of values: R01 (one-position carrier), R05 (five-position carrier)

6.3.3.10 SAC-10 Carrier identifier (EI) 01337

Components: <entity identifier (ST)> ^ <namespace ID (IS)> ^ <universal ID (ST)> ^ <universal ID type (ID)>

Definition: This field identifies the carrier. It is the ID (e.g., number or bar code) of the carrier where the container (e.g., tube) is located.

Example: A carrier could be a rack with single- or multiple-specimen containers. A carrier is usually used for automated specimen transport. Multiple carriers can be stacked in a tray, which is then used for manual or automatic transport.

6.3.3.11 SAC-11 Position in carrier (NA) 01338

Components: <value1 (NM)> ^ <value2 (NM)> ^ <value3 (NM)> ^ <value4 (NM)> ^ …

Definition: This field identifies the position of the container in the carrier (e.g., 1…3…). The sub-components allow, if necessary, to transfer multiple-axis information, e.g., 2-dimensional carrier (X^Y).

6.3.3.12 SAC-12 Tray type – SAC (CE) 01339

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field identifies the type of the tray (see section Glossary). Refer to *User-defined Table 0379 – Tray type* for suggested values. Because the geometry can be different, the tray type should if possible express the number of positions in the tray.

The definition assumes hierarchical nesting using the following phrases: container is located in a carrier, carrier is located in a tray.

User-defined Table 0379 – Tray type

Value	Description
	No suggested values defined

6.3.3.13 SAC-13 Tray identifier (EI) 01340

Components: <entity identifier (ST)> ^ <namespace ID (IS)> ^ <universal ID (ST)> ^ <universal ID type (ID)>

Definition: This field identifies the tray identifier (e.g., a number of a tray or a bar code on the tray) where the container carrier is located.

6.3.3.14 SAC-14 Position in tray (NA) 01341

Components: <value1 (NM)> ^ <value2 (NM)> ^ <value3 (NM)> ^ <value4 (NM)> ^ …

Definition: This field identifies the position of the carrier in the tray. The sub-components allow, if necessary, to transfer multiple-axis information, e.g., 2-dimensional tray (X^Y).

6.3.3.15 SAC-15 Location (CE) 01342

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field is the physical location that the specimen was at the time that the transaction was initiated. The location description can vary with the LAS. For example, it can be an X,Y,Z coordinate in a storage system; a refrigerator number and drawer number where the container-carrier-tray is located; or it can be the name of the institution and the laboratory which owns the container currently. The repeating of this field allows for hierarchical representation of location (lowest level first), e.g., shelf number, refrigerator storage ID, lab name, institution name, etc.

6.3.3.16 SAC-16 Container height (NM) 01343

Definition: This field identifies the height of the container in units specified below.

6.3.3.17 SAC-17 Container diameter (NM) 01344

Definition: This field identifies the outside diameter of the container in units specified below.

6.3.3.18 SAC-18 Barrier delta (NM) 01345

Definition: This field identifies the distance from the Point of Reference to the separator material (barrier) within the container in units specified below. This distance may be provided by the LAS to the instrument and/or specimen processing/handling device to facilitate the insertion of a sampling probe into the specimen without touching the separator. Refer to Point Of Reference definition in section *Glossary* or in NCCLS standard AUTO5—*Laboratory Automation: Electromechanical Interfaces*.

6.3.3.19 SAC-19 Bottom delta (NM) 01346

Definition: This field identifies the distance from the Point of Reference to the outside bottom of the container in units specified below. Refer to Point Of Reference definition in section *Glossary* or in NCCLS standard AUTO5—*Laboratory Automation: Electromechanical Interfaces*.

6.3.3.20 SAC-20 Container diameter/height/delta units (CE) 01347

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field is the unit identifier that is being used to describe the diameter, height, and deltas of the container. If the units are ISO+ units, they should be recorded as single-case abbreviations. If the units are ANS+ or L (local), the units and the source code table must be recorded, except that in this case, component delimiters should be replaced by sub-component delimiters. The default unit is millimeters (mm), which should be assumed if no units are reported.

6.3.3.21 SAC-21 Container volume (NM) 00644

Definition: This field indicates the capacity of the container in the units specified below.

6.3.3.22 SAC-22 Available volume (NM) 01349

Definition: This field identifies the current volume available for use in the container in the units specified below.

6.3.3.23 SAC-23 Initial specimen volume (NM) 01350

Definition: This field identifies the draw volume of the container in the units specified below.

6.3.3.24 SAC-24 Volume units (CE) 01351

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field is the unit identifier that is being used to describe the volume of the container. If the units are ISO+ units, they should be recorded as single-case abbreviations. The default unit is milliliters (ml), which should be assumed if no units are reported.

6.3.3.25 SAC-25 Separator type (CE) 01352

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field identifies the type of the separator that is being used (e.g., gel separator in the container – not to be confused with the communication separators). Refer *to User-defined Table 0380 – Separator type* for suggested values. It is recommended that the first table entry be "NO" meaning "No Separator."

User-defined Table 0380 – Separator type

Value	Description
	No suggested values defined

Examples of values: NO (no separator), GEL (gel separator), M01 (manufacturer specific)

6.3.3.26 SAC-26 Cap type (CE) 01353

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field indicates the type of cap that is to be used with this container for decapping, piercing, or other mechanisms. Refer to *User-defined Table 0381 – Cap type* for suggested values.

User-defined Table 0381 – Cap type

Value	Description
	No suggested values defined

Examples of values: SCR (screw cap), PSH (push cap), FOIL (foil)

6.3.3.27 SAC-27 Additive (CE) 00647

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field identifies any additives introduced to the specimen before or at the time of collection. It is a repetitive field. Refer to *HL7 Table 0371 – Additive* for valid values. The table's values are taken from *NCCLS AUTO4*. The value set can be extended with user- specific values.

HL7 Table 0371 – Additive

Value	Description
EDTK	Potassium/K EDTA
EDTN	Sodium/Na EDTA
HEPL	Lithium/Li Heparin
HEPN	Sodium/Na Heparin
C32	3.2% Citrate
C38	3.8% Citrate
BOR	Borate
HCL6	6N HCL

6.3.3.28 SAC-28 Specimen component (CE) 01355

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field identifies the specimen component, e.g., supernatant, sediment, etc. Refer to *User-defined Table 0372 – Specimen component* for valid values. This table's values are taken from *NCCLS AUTO4*. The value set can be extended with user-specific values.

User-defined Table 0372 - Specimen component

Value	Description
SUP	Supernatant
SED	Sediment
BLD	Whole blood, homogeneous
BSEP	Whole blood, separated
PRP	Platelet-rich plasma
PPP	Platelet-poor plasma
SER	Serum, NOS (not otherwise specified)
PLAS	Plasma, NOS (not otherwise specified)

6.3.3.29 SAC-29 Dilution factor (SN) 01356

Components: <comparator (ST)> ^ <num1 (NM)> ^ <separator/suffix (ST)> ^ <num2 (NM)>

Definition: This field identifies the factor of dilution already performed on the specimen. The equipment entity that changes the dilution is responsible for sending this information to other equipment. If the endogenous content of the test (analyte) in the diluent is required for the calculation of the test (analyte) concentration, then the test (analyte)-specific values should be exchanged between the systems via Master Files or other means.

Examples of use:

|^1^:^5| - means dilution 1 to 5, i.e., 1 part sample, 4 parts diluent

|^1^+| - sample is diluted, but the factor is unknown

|^1^:^1| - not diluted sample

|| - dilution not changed

6.3.3.30 SAC-30 Treatment (CE) 01357

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field identifies the specimen collection treatment. Refer to *User-defined Table 0373 – Treatment* for valid values. This table's values are taken from *NCCLS AUTO4.* The value set can be extended with user-specific values.

User-defined Table 0373 – Treatment

Value	Description
LDLP	LDL Precipitation
RECA	Recalification
DEFB	Defibrination
ACID	Acidification
NEUT	Neutralization
ALK	Alkalization
FILT	Filtration
UFIL	Ultrafiltration

6.3.3.31 SAC-31 Temperature (SN) 01358

Components: <comparator (ST)> ^ <num1 (NM)> ^ <separator/suffix (ST)> ^ <num2 (NM)>

Definition: This field identifies the specimen temperature in degrees Celsius [°C] at the time of the transaction specified in the EQU segment.

6.3.3.32 SAC-32 Hemolysis index (NM) 01359

Components: <comparator (ST)> ^ <num1 (NM)> ^ <separator/suffix (ST)> ^ <num2 (NM)>

Definition: This field is the index identifier that is being used to describe the Hemolysis Index of the specimen.

6.3.3.33 SAC-33 Hemolysis index units (CE) 01360

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field is the unit's identifier that is being used to describe the Hemolysis Index of the specimen. It is recommended to use g/L. (The transmission of the index values is added here instead of the original use of the OBX segments, because the frequency of the transfer of the specimen details justifies use of more efficient mechanism.)

If this field is null, the recommended value is assumed.

6.3.3.34 SAC-34 Lipemia index (NM) 01361

Definition: This field is the index identifier that is being used to describe the Lipemia Index of the specimen. It is recommended to use the optical turbidity at 600 nm (in absorbance units).

6.3.3.35 SAC-35 Lipemia index units (CE) 01362

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field is the unit's identifier that is being used to describe the Lipemia Index of the specimen.

If this field is null, the recommended value is assumed.

6.3.3.36 SAC-36 Icterus index (NM) 01363

Definition: This field is the index identifier that is being used to describe the Icterus Index of the specimen.

6.3.3.37 SAC-37 Icterus index units (CE) 01364

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field is the unit's identifier that is being used to describe the Icterus Index of the specimen. It is recommended to use mMol/L of bilirubin.

If this field is null, the recommended value is assumed.

6.3.3.38 SAC-38 Fibrin index (NM) 01365

Definition: This field is the index identifier that is being used to describe the Fibrin Index of the specimen. In the case of only differentiating between Absent and Present, we recommend using 0 and 1, respectively, and send the field Fibrin Index Units null.

6.3.3.39 SAC-39 Fibrin index units (CE) 01366

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field is the unit's identifier that is being used to describe the Fibrin Index of the specimen.

6.3.3.40 SAC-40 System-induced contaminants (CE) 01367

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field describes the specimen contaminant identifier that is associated with the specimen. Refer to *User-defined Table 0374 – System-induced contaminants* for valid values. This table's values are taken from *NCCLS AUTO4*. The value set can be extended with user-specific values.

User-defined Table 0374 – System-induced contaminants

Value	Description
CNTM	Present, type of contamination unspecified

6.3.3.41 SAC-41 Drug interference (CE) 01368

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field describes the drug interference identifier that is associated with the specimen. Refer to *User-defined Table 0382 – Drug interference* for suggested values.

User-defined Table 0382 – Drug interference

Value	Description
	No suggested values defined

6.3.3.42 SAC-42 Artificial blood (CE) 01369

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field describes the artificial blood identifier that is associated with the specimen. Refer to *User-defined Table 0375 – Artificial blood* for valid values. This table's values are taken from *NCCLS AUTO4*. The value set can be extended with user-specific values.

User-defined Table 0375 - Artificial blood

Value	Description
SFHB	Stromal-free hemoglobin preparations
FLUR	Fluorocarbons

6.3.3.43 SAC-43 Special handling considerations (CE) 01370

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field describes any special handling considerations that are associated with the specimen (e.g., centrifugation). Refer to *User-defined Table 0376 – Special handling considerations* for valid values. This table's values are taken from *NCCLS AUTO4*. The value set can be extended with user-specific values.

User-defined Table 0376 - Special handling considerations

Value	Description
PRTL	Protect from light
CFRZ	Critical frozen
CATM	Critical do not expose to atmosphere – Do not uncap
CREF	Critical refrigerated
CAMB	Critical ambient temperature
C37	Critical maintain at 37C (e.g., cryoglobulin specimen)

6.3.3.44 SAC-44 Other environmental factors (CE) 01371

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field describes other environmental factors that are associated with the specimen, e.g., atmospheric exposure. Refer to *User-defined Table 0377 – Other environmental factors* for valid values. This table's values are taken from *NCCLS AUTO4*. The value set can be extended with user-specific values.

User-defined Table 0377 - Other environmental factors

Value	Description
ATM	Opened container, atmosphere/duration unspecified
A60	Opened container, indoor atmosphere, 60 minutes duration

6.3.4 INV – inventory detail segment

The inventory detail segment is the data necessary to track the inventory of substances (e.g., reagent, tips, waste) on equipment.

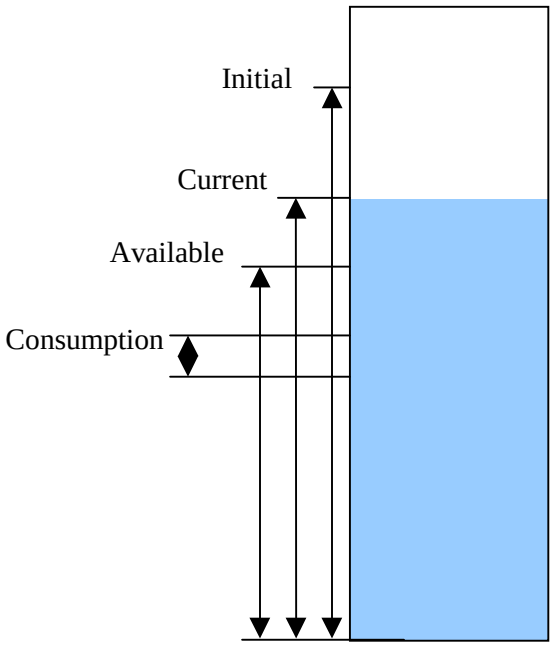


Figure 10. Information on the Types of Measures on a Container

HL7 Attribute Table –INV – Inventory Detail

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM #	ELEMENT NAME
1	250	CE	R		0451	01372	Substance Identifier
2	250	CE	R	Y	0383	01373	Substance Status
3	250	CE	O		0384	01374	Substance Type
4	250	CE	O			01532	Inventory Container Identifier
5	250	CE	O			01376	Container Carrier Identifier
6	250	CE	O			01377	Position on Carrier
7	20	NM	O			01378	Initial Quantity
8	20	NM	O			01379	Current Quantity
9	20	NM	O			01380	Available Quantity
10	20	NM	O			01381	Consumption Quantity
11	250	CE	O			01382	Quantity Units
12	26	TS	O			01383	Expiration Date/Time
13	26	TS	O			01384	First Used Date/Time
14	200	TQ	O			01385	On Board Stability Duration
15	250	CE	O	Y		01386	Test/Fluid Identifier(s)
16	200	ST	O			01387	Manufacturer Lot Number
17	250	CE	O		0385	00286	Manufacturer Identifier
18	250	CE	O		0386	01389	Supplier Identifier

6.3.4.1 INV-1 Substance identifier (CE) 01372

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: Unique identifier for the substance that is in inventory. This is a manufacturer-specific identifier.

User-defined Table 0451 – Substance identifier

Value	Description
ALL	Used for query of all inventory items

6.3.4.2 INV-2 Substance status (CE) 01373

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: The status of the inventoried item. The status indicates the current status of the substance. Refer *to HL7 Table 0383 – Substance status* for suggested values.

HL7 Table 0383 - Substance status

Value	Description
EW	Expired Warning
EE	Expired Error
CW	Calibration Warning
CE	Calibration Error
QW	QC Warning
QE	QC Error
NW	Not Available Warning
NE	Not Available Error
OW	Other Warning
OE	Other Error
OK	OK Status

6.3.4.3 INV-3 Substance type (CE) 01374

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: The type of substance. Refer to *HL7 Table 0384 – Substance type* for suggested values.

HL7 Table 0384 - Substance type

Value	Description
SR	Single-Test Reagent
MR	Multiple-Test Reagent (consumption cannot be tied to orders for single test)
DI	Diluent
PT	Pretreatment
RC	Reagent Calibrator
CO	Control
PW	Purified Water
LW	Liquid Waste
SW	Solid Waste
SC	Countable Solid Item (e.g., Tip, etc.)
LI	Measurable Liquid Item
OT	Other

6.3.4.4 INV-4 Inventory container identifier (CE) 01532

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: Identifies the inventory container, e.g., unique identifier of a specific package instance of a specific substance. This is a manufacturer-specific identifier.

6.3.4.5 INV-5 Container carrier identifier (CE) 01376

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This is the carrier used to transport the substance containers, (e.g., a removable rotor with reagent bottles).

6.3.4.6 INV-6 Position on carrier (CE) 01377

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: Identifies the position (e.g., index) on the carrier.

6.3.4.7 INV-7 Initial quantity (NM) 01378

Definition: This field identifies the initial quantity of the substance in inventory.

6.3.4.8 INV-8 Current quantity (NM) 01379

Definition: This field is the current quantity, i.e., initial quantity minus what has been actually used.

6.3.4.9 INV-9 Available quantity (NM) 01380

Definition: This field is the available quantity of substance. This is the current quantity minus any planned consumption (e.g., tests that are planned).

6.3.4.10 INV-10 Consumption quantity (NM) 01381

Definition: This field is the consumption that is used each time the equipment uses this substance.

6.3.4.11 INV-11 Quantity units (CE) 01382

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field is the units of measure of the available quantity. If the units are ISO+ units, they should be recorded as single-case abbreviations. If the units are ANS+ or L (local), the units and the source code table must be recorded, except that in this case, component delimiters should be replaced by sub-component delimiters. For example, “l” indicates liters, whereas pt&&ANS+ indicates pints (ANSI units). The default unit is milliliters (ml), which should be assumed if no units are reported.

6.3.4.12 INV-12 Expiration date/time (TS) 01383

Definition: This field is the expiration date/time of the substance.

6.3.4.13 INV-13 First used date/time (TS) 01384

Definition: This field is the time and date when the substance was first used. This date and time can be necessary to determine the stability of the substance.

6.3.4.14 INV-14 On-board stability duration (TQ) 01385

Components: <quantity (CQ)> ^ <interval (CM)> ^ <duration (ST)> ^ <start date/time (TS)> ^ <end date/time (TS)> ^ <priority (ST)> ^ <condition (ST)> ^ <text (TX)> ^ <conjunction (ID)> ^ <order sequencing (CM)>

Definition: This field is the time duration that the substance is stable.

6.3.4.15 INV-15 Test/fluid identifier(s) (CE) 01386

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field is the list of tests and body fluid that apply to this substance. This is a repeating field. An empty field means that this substance is not test-specific, i.e., it applies to all tests.

6.3.4.16 INV-16 Manufacturer lot number (ST) 01387

Definition: This field specifies the lot number assigned by the manufacturer during production of the substance.

6.3.4.17 INV-17 Manufacturer Identifier (CE) 00286

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field identifies the manufacturer of this substance. Refer to *User-defined Table 0385 – Manufacturer identifier* for suggested values.

User-defined Table 0385 – Manufacturer identifier

Value	Description
	No suggested value defined

6.3.4.18 INV-18 Supplier identifier (CE) 01389

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field identifies the supplier of this substance. Refer to *User-defined Table 0386 – Supplier identifier* for suggested values.

User-defined Table 0386 – Supplier identifier

Value	Description
	No suggested value defined

6.3.5 ECD - equipment command segment

The equipment command segment contains the information required to notify the receiving component what is to happen.

HL7 Attribute Table – ECD – Equipment Command

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM #	ELEMENT NAME
1	20	NM	R			01390	Reference Command Number
2	250	CE	R		0368	01391	Remote Control Command
3	80	ID	O		0136	01392	Response Required
4	200	TQ	O			01393	Requested Completion Time
5	65536	ST	O	Y		01394	Parameters

6.3.5.1 ECD-1 Reference command number (NM) 01390

Definition: This field contains the unique identifier for this particular command that should be used by the various components for future referral to this command. It is similar to the concept of MSH-10 “Message control ID,” but at the equipment command/response level. This number is generated by the originator of this command.

6.3.5.2 ECD-2 Remote control command (CE) 01391

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field identifies the command that the component is to initiate. Refer to *User-defined Table 0368 – Remote control command* for valid values. Refer to LECIS standard for details.

User-defined Table 0368 - Remote control command

Value	Description
SA	Sampling
LO	Load
UN	Unload
LK	Lock
UC	Unlock
TT	Transport To
CN	Clear Notification
IN	Initialize/Initiate
SU	Setup
CL	Clear
PA	Pause
RE	Resume
ES	Emergency –stop
LC	Local Control Request
RC	Remote Control Request
AB	Abort
EN	Enable Sending Events
DI	Disable Sending Events
EX	Execute (command specified in field Parameters (ST) 01394)

6.3.5.3 ECD-3 Response required (ID) 01392

Definition: This field identifies the mode of synchronization that is to be used in relation to the execution of the command. "Y" (Yes) means that the response is required immediately after execution, "N" (No) response is not required at all. Refer to *HL7 Table 0136 – Yes/no indicator* for valid values.

6.3.5.4 ECD-4 Requested completion time (TQ) 01393

Components: <quantity (CQ)> ^ <interval (CM)> ^ <duration (ST)> ^ <start date/time (TS)> ^ <end date/time (TS)> ^ <priority (ST)> ^ <condition (ST)> ^ <text (TX)> ^ <conjunction (ID)> ^ <order sequencing (CM)>

Definition: This field identifies when the remote control action must be completed. The devices managed in the LAS should have synchronized time (use original HL7 message NMQ, NMD with "System Clock Segment" NCK). If relative time quantity is used, then the referenced time is the time transferred in the EQU segment.

6.3.5.5 ECD-5 Parameters (ST) 01394

Definition: This field identifies the parameters of the command (if they are not included in separate segment[s]).

Note: Elements of this segment (or other elements not defined here) may be required for certain vendor-specific equipment such as centrifuges, aliquoters, sorters, uncappers, recappers, automated storage units, etc.

6.3.6 ECR - equipment command response segment

The equipment command response segment contains the receiving component's response to the previously received command.

HL7 Attribute Table - ECR - Equipment Command Response

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM #	ELEMENT NAME
1	250	CE	R		0387	01395	Command Response
2	26	TS	R			01396	Date/Time Completed
3	65536	ST	O	Y		01397	Command Response Parameters

6.3.6.1 ECR-1 Command response (CE) 01395

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field identifies the response of the previously issued command. Refer *to User-defined Table 0387 – Command response* for valid values.

User-defined Table 0387 - Command response

Value	Description
OK	Command completed successfully
TI	Command cannot be completed within requested completion time
ER	Command cannot be completed because of error condition (see response parameters)
ST	Command cannot be completed because of the status of the requested equipment
UN	Command cannot be completed for unknown reasons

6.3.6.2 ECR-2 Date/time completed (TS) 01396

Definition: This field contains the date and time that the receiving component completed the requested command.

6.3.6.3 ECR-3 Command response parameters (ST) 01397

Definition: This field identifies any associated parameters that relate to the returned response command message.

6.3.7 NDS - notification detail segment

The equipment notification detail segment is the data necessary to maintain an adequate audit trail as well as notifications of events (e.g., alarms that have occurred on a particular piece of equipment).

HL7 Attribute Table - NDS - Notification Detail

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM #	ELEMENT NAME
1	20	NM	R			01398	Notification Reference Number
2	26	TS	R			01399	Notification Date/Time
3	250	CE	R		0367	01400	Notification Alert Severity
4	250	CE	R			01401	Notification Code

6.3.7.1 NDS-1 Notification reference number (NM) 01398

Definition: This field contains a unique, sequential reference number that may be used by various components to refer to this transaction. This number is generated by the originator of this notification.

6.3.7.2 NDS-2 Notification date/time (TS) 01399

Definition: This field is the date/time of the notifications.

6.3.7.3 NDS-3 Notification alert severity (CE) 01400

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: The severity of the specific notification. Refer to *HL7 Table 0367 – Alert level* for valid entries.

6.3.7.4 NDS-4 Notification code (CE) 01401

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field contains information about the type of notification being sent. These are manufacturer- and equipment-specific error or status codes, e.g., AQN0123 – aliquotting error – clot detected.

6.3.8 CNS – clear notification segment

The clear equipment notification segment contains the data necessary to allow the receiving equipment to clear any associated notifications.

HL7 Attribute Table – CNS – Clear Notification

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM #	ELEMENT NAME
1	20	NM	O			01402	Starting Notification Reference Number
2	20	NM	O			01403	Ending Notification Reference Number
3	26	TS	O			01404	Starting Notification Date/Time
4	26	TS	O			01405	Ending Notification Date/Time
5	250	CE	O			01406	Starting Notification Code
6	250	CE	O			01407	Ending Notification Code

6.3.8.1 CNS-1 Starting notification reference number (NM) 01402

Definition: This field contains the starting notification reference number that is to be cleared.

6.3.8.2 CNS-2 Ending notification reference number (NM) 01403

Definition: This field contains the ending notification reference number that is to be cleared. If empty, then only notification with Starting Notification Reference Number will be cleared.

6.3.8.3 CNS-3 Starting notification date/time (TS) 01404

Definition: This field is the starting date/time of the notifications to be cleared. If this field is empty but Ending Notification Date/Time is filled, then all notifications before Ending Notification Date/Time will be cleared.

6.3.8.4 CNS-4 Ending notification date/time (TS) 01405

Definition: This field is the ending date/time of the notifications to be cleared. If this field is empty but Starting Notification Date/Time is filled, then all notifications after Starting Notification Date/Time will be cleared.

6.3.8.5 CNS-5 Starting notification code (CE) 01406

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field contains the starting notification code that is to be cleared (see Section 6.3.7.4, NDS-4 Notification Code (CE) 01401).

6.3.8.6 CNS-6 Ending notification code (CE) 01407

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field contains the ending notification code that is to be cleared (see Section 6.3.7.4, NDS-4 Notification Code (CE) 01401). If empty, then only notification with Starting Notification Code will be cleared.

6.3.9 TCC - test code configuration segment

The test (e.g., analyte) code configuration segment is the data necessary to maintain and transmit information concerning the test entity codes that are being used throughout the "automated system."

HL7 Attribute Table - TCC - Test Code Configuration

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM #	ELEMENT NAME
1	250	CE	R			00238	Universal Service Identifier
2	80	EI	R			01408	Test Application Identifier
3	300	CM	O		0070/0163/0369	00249	Specimen Source
4	20	SN	O			01410	Auto-Dilution Factor Default
5	20	SN	O			01411	Rerun Dilution Factor Default
6	20	SN	O			01412	Pre-Dilution Factor Default
7	20	SN	O			01413	Endogenous Content of Pre-Dilution Diluent
8	10	NM	O			01414	Inventory Limits Warning Level
9	1	ID	O		0136	01415	Automatic Rerun Allowed
10	1	ID	O		0136	01416	Automatic Repeat Allowed
11	1	ID	O		0136	01417	Automatic Reflex Allowed
12	20	SN	O			01418	Equipment Dynamic Range
13	250	CE	O			00574	Units
14	250	CE	O		0388	01419	Processing Type

6.3.9.1 TCC-1 Universal service Identifier (CE) 00238

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field identifies the test code about which information is being transmitted. The alternate elements represent the test code identifier that has been assigned by the manufacturer to this particular test code.

6.3.9.2 TCC-2 Equipment test application identifier (EI) 01408

Components: <entity identifier (ST)> ^ <namespace ID (IS)> ^ <universal ID (ST)> ^ <universal ID type (ID)>

Definition: This field identifies the test application code assigned by the manufacturer of the equipment or reagents and associated with performing of the particular test specified by the Universal Test Identifier.

6.3.9.3 TCC-3 Specimen source (CM) 00249

Components: <specimen source name or code (CE)> ^ <additives (TX)> ^ <freetext (TX)> ^ <body site (CE)> ^ <site modifier (CE)> ^ <collection method modifier code (CE)> ^ <specimen role (CE)>

Subcomponents of specimen source name or code: <identifier (ST)> & <test (ST)> & <name of coding system (IS)> & <alternate identifier (ST)> & <alternate text (ST)> & <name of alternate coding system (ST)>

Subcomponents of body site: <identifier (ST)> & <test (ST)> & <name of coding system (IS)> & <alternate identifier (ST)> & <alternate text (ST)> & <name of alternate coding system (ST)>

Subcomponents of site modifier: <identifier (ST)> & <test (ST)> & <name of coding system (IS)> & <alternate identifier (ST)> & <alternate text (ST)> & <name of alternate coding system (ST)>

Subcomponents of collection method modifier code: <identifier (ST)> & <test (ST)> & <name of coding system (IS)> & <alternate identifier (ST)> & <alternate text (ST)> & <name of alternate coding system (ST)>

Subcomponents of specimen role: <identifier (ST)> & <test (ST)> & <name of coding system (IS)> & <alternate identifier (ST)> & <alternate text (ST)> & <name of alternate coding system (ST)>

Definition: This field is the site where the specimen should be obtained or where the service should be performed.

The first component contains the specimen source name or code (as a CE data-type component). (Even in the case of observations whose name implies the source, a source may be required (e.g., blood culture: heart blood.) Refer to *HL7 Table 0070 - Source of specimen* for valid entries.

The second component should include free text additives to the specimen such as heparin, EDTA, or oxalate, when applicable.

The third is a free text component describing the method of collection when that information is a part of the order. When the method of collection is logically an observation result, it should be included as a result segment.

The fourth component specifies the body site from which the specimen was obtained, and the fifth is the site modifier. For example, the site could be antecubital fossa, and the site modifier "right." The components of the CE fields become sub-components. Refer to *HL7 Table 0163 - Administrative site* for valid entries.

The sixth component indicates whether the specimen is frozen as part of the collection method. Suggested values are F (Frozen); R (Refrigerated). If the component is blank, the specimen is assumed to be at room temperature.

The seventh component indicates the role of the sample. Refer to *User-defined Table 0369 – Specimen role.*

6.3.9.4 TCC-4 Auto-dilution factor default (SN) 01410

Components: <comparator (ST)> ^ <num1 (NM)> ^ <separator/suffix (ST)> ^ <num2 (NM)>

Definition: This field is the value that is to be used as the default factor for automatically diluting a specimen by an instrument for this particular test code. (See examples in definition of "Dilution factor" in the "Specimen and Container Detail Segment.")

6.3.9.5 TCC-5 Rerun dilution factor default (SN) 01411

Components: <comparator (ST)> ^ <num1 (NM)> ^ <separator/suffix (ST)> ^ <num2 (NM)>

Definition: This field is the value that is to be used as the default factor for automatically diluting a specimen in case of rerun for this particular test code.

6.3.9.6 TCC-6 Pre-dilution factor default (SN) 01412

Components: <comparator (ST)> ^ <num1 (NM)> ^ <separator/suffix (ST)> ^ <num2 (NM)>

Definition: This field is the value that is to be used as the default factor for a specimen that is delivered to the laboratory automation system as pre-diluted for this particular test code.

6.3.9.7 TCC-7 Endogenous content of pre-dilution diluent (SN) 01413

Definition: This field represents a baseline value for the measured test that is inherently contained in the diluent. In the calculation of the actual result for the measured test, this baseline value is normally considered.

6.3.9.8 TCC-8 Inventory limits warning level (NM) 01414

Definition: This field is the value that is to be used as the threshold for initiating inventory warning-level messages.

6.3.9.9 TCC-9 Automatic rerun allowed (ID) 01415

Definition: This field identifies whether or not automatic reruns are to be initiated on specimens for this particular test code. Refer to *HL7 Table 0136 -Yes/no indicator* for valid values.

6.3.9.10 TCC-10 Automatic repeat allowed (ID) 01416

Definition: This field identifies whether or not automatic repeat testing is to be initiated on specimens for this particular test code. Refer to *HL7 Table 0136 -Yes/no indicator* for valid values.

6.3.9.11 TCC-11 Automatic reflex allowed (ID) 01417

Definition: This field identifies whether or not automatic or manual reflex testing is to be initiated on specimens for this particular test code. Refer to *HL7 Table 0136 -Yes/no indicator* for valid values.

6.3.9.12 TCC-12 Equipment dynamic range (SN) 01418

Components: <comparator (ST)> ^ <num1 (NM)> ^ <separator/suffix (ST)> ^ <num2 (NM)>

Definition: This is the range over which the equipment can produce results.

6.3.9.13 TCC-13 Units (CE) 00574

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field is the units that have a data type of CE. The default coding system for the units codes consists of the ISO+ abbreviation for a single case unit (ISO 2955-83) plus extensions, that do not collide with ISO abbreviations. We designate this coding system as ISO+. Both the ISO unit's abbreviations and the extensions are defined in Section TBD," and listed in Figure 7-13. The ISO+ abbreviations are the codes for the default coding system. Consequently, when ISO+ units are being used, only ISO+ abbreviations need be sent, and the contents of the units field will be backward compatible to HL7 Version 2.1. For more information on this field see reference HL7, Chapter 7, Section 7.4.2.6.

These units apply to fields "Endogenous content of pre-dilution diluent" and "Equipment dynamic range."

6.3.9.14 TCC-14 Processing type (CE) 01419

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field identifies the processing type that applies to this test code. If this attribute is omitted, then regular production is the default. Refer to *HL7 Table 0388 – Processing type* for valid values.

HL7 Table 0388 - Processing type

Value	Description
P	Regular Production
E	Evaluation

6.3.10 TCD - test code detail segment

The test code detail segment contains the data necessary to perform operations or calculations, or execute decisions by the laboratory automation system, and which are not supported by the original HL7 segments related to orders (ORC, OBR). For detail of use see messages of laboratory orders and observations in Chapters 4 and 7.

HL7 Attribute Table – TCD – Test Code Detail

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM #	ELEMENT NAME
1	250	CE	R			00238	Universal Service Identifier
2	20	SN	O			01420	Auto-Dilution Factor
3	20	SN	O			01421	Rerun Dilution Factor
4	20	SN	O			01422	Pre-Dilution Factor
5	20	SN	O			01413	Endogenous Content of Pre-Dilution Diluent
6	1	ID	O		0136	01416	Automatic Repeat Allowed
7	1	ID	O		0136	01424	Reflex Allowed
8	250	CE	O		0389	01425	Analyte Repeat Status

6.3.10.1 TCD-1 Universal service Identifier (CE) 00238

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field identifies the test code that information is being transmitted about.

6.3.10.2 TCD-2 Auto-dilution factor (SN) 01420

Components: <comparator (ST)> ^ <num1 (NM)> ^ <separator/suffix (ST)> ^ <num2 (NM)>

Definition: This field is the value that is to be used as the factor for automatically diluting a particular specimen by an instrument for this particular test code. (See examples in definition of "Dilution factor" in the "Specimen and Container Detail Segment.")

6.3.10.3 TCD-3 Rerun dilution factor (SN) 01421

Components: <comparator (ST)> ^ <num1 (NM)> ^ <separator/suffix (ST)> ^ <num2 (NM)>

Definition: This field is the value that is to be used as the factor for automatically diluting a particular specimen in case of rerun for this particular test code.

6.3.10.4 TCD-4 Pre-dilution factor (SN) 01422

Components: <comparator (ST)> ^ <num1 (NM)> ^ <separator/suffix (ST)> ^ <num2 (NM)>

Definition: This field is the value that is to be used as the factor for a particular specimen that is delivered to the automated system as pre-diluted for this particular test code.

6.3.10.5 TCD-5 Endogenous content of pre-dilution diluent (SN) 01413

Components: <comparator (ST)> ^ <num1 (NM)> ^ <separator/suffix (ST)> ^ <num2 (NM)>

Definition: This field represents the rest concentration of the measured test in the diluent. It is the value that is to be used for calculation of the concentration of pre-diluted specimens for this particular test code.

6.3.10.6 TCD-6 Automatic repeat allowed (ID) 01416

Definition: This field identifies whether or not automatic repeats are to be initiated for this particular specimen for this particular test code. Refer to *HL7 Table 0136 -Yes/no indicator* for valid values.

6.3.10.7 TCD-7 Reflex allowed (ID) 01424

Definition: This field identifies whether or not automatic or manual reflex testing is to be initiated for this particular specimen. Refer *to HL7 Table 0136 -Yes/no indicator* for valid values.

6.3.10.8 TCD-8 Analyte repeat status (CE) 01425

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field identifies the repeat status for the analyte/result (e.g., original, rerun, repeat, reflex). Refer to *HL7 Table 0389 – Analyte repeat status* for valid values.

For purpose of this chapter we assume the following:

Repeated test without dilution — performed usually to confirm correctness of results (e.g., in case of results flagged as “Panic” or mechanical failures).

Repeated test with dilution — performed usually in case the original result exceeded the measurement range (technical limits).

Reflex test — this test is performed as the consequence of rules triggered based on other test result(s).

HL7 Table 0389 - Analyte repeat status

Value	Description
O	Original, first run
R	Repeated without dilution
D	Repeated with dilution
F	Reflex test

6.3.11 SID – substance identifier segment

The Substance Identifier segment contains data necessary to identify the substance (e.g., reagents) used in the production of analytical test results. The combination of these fields must uniquely identify the substance, i.e., depending on the manufacturer all or some fields are required (this is the reason the optionality is ‘C’ (conditional)). If the analysis requires multiple substances, this segment is repeated for each substance. The segment(s) should be attached to the TCD segment.

Another purpose of this segment is to transfer the control manufacturer, lot, etc. information for control specimens. In this case the SID segment should be attached to the SAC segment describing the container with the control specimen.

HL7 Attribute Table – SID – Substance Identifier

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM #	ELEMENT NAME
1	250	CE	C			01426	Application / Method Identifier
2	20	ST	C			01129	Substance Lot Number
3	200	ST	C			01428	Substance Container Identifier
4	250	CE	C		0385	01429	Substance Manufacturer Identifier

6.3.11.1 SID-1 Application / method identifier (CE) 01426

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field identifies the application / method used for the analysis.

Example: GLUCOSE is an orderable test. GLUCOSE can be analyzed using various applications /methods, which have manufacturer-specific identifiers.

6.3.11.2 SID-2 Substance lot number (ST) 01129

Definition: This field specifies the lot number assigned by the manufacturer during production of the substance.

6.3.11.3 SID-3 Substance container identifier (ST) 01428

Definition: This field specifies the container assigned by the manufacturer during production of the substance. This identifier should be unique within specific lot of specific application / method.

6.3.11.4 SID-4 Substance manufacturer identifier (CE) 01429

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field identifies the manufacturer of this substance. Refer to *User-defined Table 0451 - Manufacturer identifier* for suggested values.

6.3.12 EQP - equipment log/service segment

The equipment log/service segment is the data necessary to maintain an adequate audit trail of events that have occurred on a particular piece of equipment.

HL7 Attribute Table – EQP – Equipment/log Service

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM #	ELEMENT NAME
1	250	CE	R		0450	01430	Event type
2	20	ST	O			01431	File Name
3	26	TS	R			01202	Start Date/Time
4	26	TS	O			01432	End Date/Time
5	65536	FT	R			01433	Transaction Data

6.3.12.1 EQP-1 Event type (CE) 01430

Components: <identifier (ST)> ^ <text (ST)> ^ <name of coding system (IS)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (IS)>

Definition: This field identifies the type of event of the message. Refer to *HL7 Table 0450 – Event type* for valid values.

HL7 Table 0450-Event type

Value	Description
LOG	Log Event
SER	Service Event

6.3.12.2 EQP-2 File name (ST) 01431

Definition: This field is the physical file name that is being used to store information about the transmitted log and/or service event.

6.3.12.3 EQP-3 Start date/time (TS) 01202

Definition: This field is the date/time that the event started.

6.3.12.4 EQP-4 End date/time (TS) 01432

Definition: This field is the date/time that the event was completed.

6.3.12.5 EQP-5 Transaction data (FT) 01433

Definition: This field is the data that the log and/or service event was about and is to be logged.

6.4 Notes Regarding Usage

6.4.1 Other required original HL7 messages

The transaction for synchronization of system clocks must be supported by all equipment as receiver. The master (sender) of the time is either the LAS computer or the LIS.

6.4.2 Transfer of laboratory test orders and results

For the transfer of laboratory automation orders and results refer to *4.2.6 OML - laboratory order message (event O21)* instead of ORM, and *7.2.2 ORL – unsolicited laboratory observation message (event O20)* instead of ORU.

6.4.3 Transfer of QC results

Use the seventh component of *OBR-15-specimen source* or *SAC-6 -specimen source* to indicate that this is a control specimen. Use *SAC-3-container identifier* for the identification of a control specimen container. The SID segment appended to this SAC segment specifies the manufacturer, lot identifiers, etc. for the control specimen.

The identification of the instrument performing the QC measurement should be transferred with the *OBX-18-equipment instance identifier*, and the measurement data/time with *the OBX-19 date/time of the analysis*.

6.4.4 Query for order information – triggers for download of test orders

There is no specific query for laboratory order information. Instead, the order information should be downloaded to the LAS either unsolicited (based on LIS internal triggers such as Sample Collected or Order Entered) or after an implicit trigger such as Sample Status Update – sample identified by the LAS.

6.4.5 Transfer of additional information for automated processing

Instruments requiring additional information for performing automated processing based on automatic validation, such as Expected Date of Birth (Delivery Date), Menstrual Status, History of Medication Use, should consider using OBX segments and LOINC codes. For example, the LOINC code for Delivery Date is 11778-8, Menstrual status is 8678-5, History of Medication Use is 10160-0.Example Messages

6.4.6 Laboratory order message

Laboratory order with multiple containers and multiple test orders related to each container.

MSH|^~\&|INSTPROG|AUTINST|LASPROG|LASSYS|19980630080040|SECURITY
|OML^O21|MSG00001|P|2.4|<cr>
PID|1||28514753||Joan^Howard^J||196303241225|F<CR>
SAC|991912376^EXTLAB|01039421^THISLAB|092321A^LAS|092321^LAS||SER
|19980620080037|U^UNKNOWN<cr>
ORC|NW|5212400021A||||^^^^^R<CR>
OBR|1|5212400021A||2951-2^SODIUM^LN|||199808101444||||A||||SER<CR>
ORC|NW|5212400021A||||^^^^^R<CR>
OBR|1|5212400021A||2000-8^CALCIUM.TOTAL^LN|||199808101444||||A||||XXX<CR>
SAC|991912376^EXTLAB|01039421^THISLAB|092321B^LAS|092321^LAS||SER
|19980620080037|U^UNKNOWN<cr>
ORC|NW|5212400021A||||^^^^^R<CR>
OBR|1|5212400021A||4064-2^TRAZODONE^LN|||199808101444||||A||||SER<CR>
ORC|NW|5212400021A||||^^^^^R<CR>
OBR|1|5212400021A||3042-9^TRICHLOROETHANOL^LN|||199808101444||||A||||SER<CR>

Laboratory order with test order requiring multiple containers (1st with special treatment, 2nd without).

MSH|^~\&|INSTPROG|AUTINST|LASPROG|LASSYS|19980630080040|SECURITY
|OML^O21|MSG00001|P|2.4|<cr>
PID|1||28514753||Joan^Howard^J||196303241225|F<CR>
ORC|NW|5212400021A||||^^^^^R<CR>
OBR|1|5212400021A||11054-4^CHOLESTEROL.LDL/CHOLESTEROL.HDL^LN||
|199808101444||||A||||XXX<CR>
SAC|991912376^EXTLAB|01039421^THISLAB|092321T^LAS|092321^LAS||ORH
|19980620080037|I^IDENTIFIED|R5^5_HOLE_RACK|120|1||||BUF1^IN BUFFER 1
||||||||||||||^1^:^1|LDLP<cr>
SAC|991912376^EXTLAB|01039421^THISLAB|092321A^LAS|092321^LAS||SER
|19980620080037|I^IDENTIFIED|R5^5_HOLE_RACK|732|3||||BUF1^IN BUFFER 1
||||||||||||||^1^:^1<cr>

Laboratory order with test order with previous result, where patient data did not change.

MSH|^~\&|INSTPROG|AUTINST|LASPROG|LASSYS|19980630080040|SECURITY
|OML^O21|MSG00001|P|2.4|<cr>
PID|1||28514753||Joan^Howard^J||196303241225|F<CR>
SAC|991912376^EXTLAB|01039421^THISLAB|092321A^LAS|092321^LAS||BLDV
|19980620080037|U^UNKNOWN<cr>
ORC|NW|5212400021A||||^^^^^R<CR>
OBR|1|5212400021A||2951-2^SODIUM^LN|||199808101444||||A||||SER<CR>
ORC|RE|5212498721A||||^^^^^R<CR>
OBR|1|5212498721A||2951-2^SODIUM^LN|||199807240826|||||||SER<CR>
OBX|1|NM|2951-2^SODIUM^LN||24.3|ug/g||N<CR>

6.4.7 Unsolicited laboratory observation message

Analysis results related to a particular container with patient sample.

MSH|^~\&|INSTPROG|AUTINST|LASPROG|LASSYS|19980630080040|SECURITY
|OUL^R21|MSG00001|P|2.4|<cr>
PID|1||28514753||Joan^Howard^J||196303241225|F<CR>
SAC|991912376^EXTLAB|01039421^THISLAB|092321A^LAS|092321^LAS||SER
|19980620080037|R^PROCESS COMPLETED<cr>
ORC|RE|5212498721A||||^^^^^R<CR>
OBR|1|5212498721A||2951-2^SODIUM^LN|||199807240826|||||||SER<CR>
OBX|1|NM|2951-2^SODIUM^LN||24.3|ug/g||N<CR>

Analysis results related to a particular container with QC sample and the lot and manufacturer information about this sample (see use of SAC-SID segments).

MSH|^~\&|INSTPROG|AUTINST|LASPROG|LASSYS|19980630080040|SECURITY
|OUL^R21|MSG00001|P|2.4|<cr>
SAC|||Q092321^LAS|||SER^^^^^^Q |19980620080037|R^PROCESS COMPLETED<cr>
SID|01230^Na|ABCDE-01234567890||04^RD<cr>
ORC|RE|5212498721A||||^^^^^R<CR>
OBR|1|5212498721A||2951-2^SODIUM^LN|||199807240826|||||||SER^^^^^^Q<CR>
OBX|1|NM|2951-2^SODIUM^LN||24.3|ug/g||N<CR>

Analysis results of a reflex test for a patient sample with basic identification data (lot, manufacturer, etc.) of the reagent involved in the results generation (see TCD-SID segments).

MSH|^~\&|INSTPROG|AUTINST|LASPROG|LASSYS|19980630080040|SECURITY
|OUL^R21|MSG00001|P|2.4|<cr>
PID|1||28514753||Joan^Howard^J||196303241225|F<CR>
SAC|991912376^EXTLAB|01039421^THISLAB|092321A^LAS|092321^LAS||SER
|19980620080037|R^PROCESS COMPLETED<cr>
ORC|RE|5212498721A||||^^^^^R<CR>
OBR|1|5212498721A||2951-2^SODIUM^LN|||199807240826|||||||SER<CR>
OBX|1|NM|2951-2^SODIUM^LN||24.3|ug/g||N<CR>
TCD|2951-2^SODIUM^LN||||||F
SID|01230^Na|PQRST-01234567890||04^RD<cr>

6.4.8 Automated equipment status update

The chemistry analyzer 0001 was powered up directly by the operator (local control) and correctly performed the initialization process. This information is sent by the analyzer to the LAS.

```
MSH|^~\&|INSTPROG|AUTINST|LASPROG|LASSYS|19980630080040|SECURITY
    |ESU^U01|MSG00001|P|2.4|<cr>
EQU|0001^CHEMISTRYANALYZER|19980630080038|PU^POWERED_UP|L^LOCAL|N^NO
    RMAL<cr>
ISD|123456789|IN^INIT|OK<cr>
```

6.4.9 Automated equipment status request

The LAS queries the chemistry analyzer 0001 for status information.

```
MSH|^~\&|LASPROG|LASSYS|INSTPROG|AUTINST|19980630080040|SECURITY
    |ESR^U02|MSG00001|P|2.4|<cr>
EQU|0001^CHEMISTRYANALYZER|19980630080038<cr>
```

6.4.10 Specimen status update

The chemistry analyzer 0001 recognized an aliquot container (id=092321A) with blood. This container is in a position 1 of carrier type R5 (id=120) and is located in the input buffer 1.

```
MSH|^~\&|INSTPROG|AUTINST|LASPROG|LASSYS|19980630080040|SECURITY
    |SSU^U03|MSG00001|P|2.4|<cr>
EQU|0001^CHEMISTRYANALYZER|19980630080038<cr>
SAC|991912376^EXTLAB|01039421^THISLAB|092321A^LAS|092321^LAS||BLD^BLOOD
    |19980620080037|I^IDENTIFIED|R5^5_HOLE_RACK|120|1||||BUF1^INPUT BUFFER
    1<cr>
```

A preanalytical instrument 0001 performed aliquotting and sorting operation. (See Figure 9 for visualization of positions and locations.)

The carrier (id=2002) with primary/parent container (id=12345) at position 2 was transported in the location: output buffer 1, into position 4 of the output tray (id=A1203).

The aliquot container (id=12345A) was sorted into the manual transportable carrier (id=045), in row 3, column 2. This carrier is located in the sorter bed at location 4.

```
MSH|^~\&|PREANPROG|AUTPREAN|LASPROG|LASSYS|19980630080040|SECURITY
    |SSU^U03|MSG00002|P|2.4|<cr>
EQU|0001^AQS|19980630080043<cr>
SAC|991912376^EXTLAB|01039421^THISLAB|12345^LAS||||19980620080039|R^COMPLETED
    |R3^3_HOLE_RACK|2002|1|OT^OUTPUTTRAY|A1203^AQSTRAY|4|OB1^OUTPUTBUF
    FER<cr>
SAC|991912376^EXTLAB|01039421^THISLAB|12345A^LAS|12345^LAS|||19980620080039
    |R^COMPLETED|R14^14_HOLE_RACK|045|3^2||||AQSBED||||||2|0.5||ml<cr>
```

6.4.11 Specimen status request

The chemistry analyzer 0001 queries the LAS for status of specimen/container (id=092321A).

MSH|^~\&|LASPROG|LASSYS|INSTPROG|AUTINST|19980630080040|SECURITY
|SSR^U04|MSG00001|P|2.4|<cr>
EQU|0001^CHEMISTRYANALYZER|19980630080038<cr>
SAC|991912376^EXTLAB|01039421^THISLAB|092321A^LAS||||199806200823<cr>

6.4.12 Automated equipment inventory update

The chemistry analyzer 0001 sends to the LAS the status of a TSH reagent (id=MF01239) in bottle (id=12345).

MSH|^~\&|INSTPROG|AUTINST|LASPROG|LASSYS|19980630080040|SECURITY
|INU^U05|MSG00001|P|2.4|<cr>
EQU|0001^CHEMISTRYANALYZER|19980630080038<cr>
INV|MF01239^REAGENT1|OK^OK_STATUS|SR^SINGLE_TEST_REAGENT
|12345^BOTTLE_NUM|||||190||ML|20000101||^^D60|TSH|A12345678|PROD1<cr>

6.4.13 Automated equipment inventory request

The LAS queries the chemistry analyzer 0001 for status of all packages of the substance (id=MF01239).

MSH|^~\&|LASPROG|LASSYS|INSTPROG|AUTINST|19980630080040|SECURITY
|INR^U06|MSG00001|P|2.4|<cr>
EQU|0001^CHEMISTRYANALYZER|19980630080038<cr>
INV|MF01239^REAGENT1|OK^OK_STATUS<cr>

6.4.14 Automated equipment command

The LAS sends command of “Clearing Notification” to the chemistry analyzer 0001.

MSH|^~\&|LASPROG|LASSYS|INSTPROG|AUTINST|19980630080040|SECURITY
|EAC^U07|MSG00001|P|2.4|<cr>
EQU|0001^CHEMISTRYANALYZER|19980630080038<cr>
ECD|89421|CN^CLEAR NOTIFICATION|Y^YES<cr>
CNS|1209|1500|199806010800|199806300800<cr>

6.4.15 Automated equipment response

The chemistry analyzer confirms completion of the execution of the initialization command.

MSH|^~\&|INSTPROG|AUTINST|LASPROG|LASSYS|19980630080040|SECURITY
|EAR^U08|MSG00001|P|2.4|<cr>
EQU|0001^CHEMISTRYANALYZER|19980630080038<cr>
ECD|89421|IN^INIT|Y^YES<cr>
ECR|OK^COMMAND_COMPLETE|19980630080035<cr>

6.4.16 Automated equipment notification

The chemistry analyzer sends a notification (warning) about drift in the detection unit.

MSH|^~\&|INSTPROG|AUTINST|LASPROG|LASSYS|19980630080040|SECURITY
|EAN^U09|MSG00001|P|2.4|<cr>
EQU|0001^CHEMISTRYANALYZER|19980630080038<cr>
NDS|8923|199806300800|W^WARNING^|DU001^DETECTIO UNIT DRIFT<cr>

6.4.17 Automated equipment test code settings update

The LAS sends an update of configuration parameters for the Glucose test.

MSH|^~\&|LASPROG|LASSYS|INSTPROG|AUTINST|19980630080040|SECURITY
|TCU^U10|MSG00001|P|2.4|<cr>
EQU|0001^CHEMISTRYANALYZER|19980630080038<cr>
TCC|15074-8^GLUCOSE|GLU-HK^CHEMISTRYANALYZER|SER^SERUM|10|10|0|0|500|
Y^YES|Y^YES|N^NO |^2^-^400|mg/dL|P<cr>

6.4.18 Automated equipment test code settings request

The chemistry analyzer 0001 queries the LAS for configuration parameters of the Glucose test.

MSH|^~\&|INSTPROG|AUTINST|LASPROG|LASSYS|19980630080040|SECURITY
|TCR^U11|MSG00001|P|2.4|<cr>
EQU|0001^CHEMISTRYANALYZER|19980630080038<cr>
TCC|15074-8^GLUCOSE|GLU-HK^CHEMISTRYANALYZER<cr>

6.4.19 Automated equipment log/service update

The chemistry analyzer 0001 sends 1 record from the event log to the LAS.

MSH|^~\&|INSTPROG|AUTINST|LASPROG|LASSYS|19980630080040|SECURITY
|LSU^U12|MSG00001|P|2.4|<cr>
EQU|0001^CHEMISTRYANALYZER|19980630080038<cr>
EQP|LOG^LOG_EVENT||199806300755|199806300800|I976 Instrument Initialization<cr>

6.4.20 Automated equipment log/service request

The LAS queries chemistry analyzer for log file of events occurring between 7am and 8am on 30th June 1998.

MSH|^~\&|LASPROG|LASSYS|INSTPROG|AUTINST|19980630080040|SECURITY
|LSR^U13|MSG00001|P|2.4|<cr>
EQU|0001^CHEMISTRYANALYZER|19980630080038<cr>
EQP|LOG^LOG_EVENT||199806300700|199806300800<cr>

6.5 Outstanding Issues

None.

7 Low-Level Protocol Considerations

This section summarizes the NCCLS recommendations for lower layers of the communication protocol for Laboratory Automation Systems (LAS). Some implementation issues are also provided.

7.1 Requirements to Low-Level Protocol

7.1.1 Limitations for LAS Architecture

The low-level communication protocol (LLP) should not limit the architecture of LAS. For example, the system management software may need to have information on inventory to allow optimization of

routing, redirection, and requesting user interactions. On the other hand, some elements of the automation system may need to exchange data and events without involving the system manager (e.g., the synchronization between preanalytical processes and the analytical instrument when the sample reaches the pipetting position).

7.1.2 Automated System Transactions Routing

Routing of information allows the simultaneous communication of various tasks of the analytical instrument, transport mechanism, and system management software to either the LIS or the LAS. For example, the analyzer can simultaneously exchange information with the system management software about the reagent and consumable status, synchronize with the transport, upload measurement results to the LIS (perhaps, but not necessarily, through the system manager), and upload maintenance information to the manufacturer service organization connected via modem through the system management software.

7.1.3 Bandwidth and Time Characteristics

In the case of network/bus topology where all peers share the connection, the minimum bandwidth should be 1M bit/second. For larger and more complex systems, the bandwidth should be extensible to a minimum of 5M bit/second. For reasonable information transfer for all sessions managed by one peer, 100K bit/second is the minimum recommended bandwidth.

The deterministic and repeatable performance of the protocol is one of the most important requirements of the low-level protocol. The unidirectional transaction time should not exceed 0.1 second. Some existing systems require a peer to react within 1.5 second, which limits all protocol overhead delay for bi-directional communication to 0.5 second (assuming 1 second for reaction of the peer). This leaves approximately 0.1 second to establish the communication link per direction.

In cases where a poorly designed application “swamps” the network by sending big amounts of data and does not react to the “Disable Sending Events” command, the receiving node should close the connection and post an alert requiring user intervention.

7.1.4 Transaction Types

The asynchronous and synchronous transactions should be supported by the LLP.

7.1.5 Error Recovery and Startup

The LLP should support error recovery and startup procedures, e.g., in the case of interruption of a transmission, all participating nodes should know which portion of the data needs to be re-transmitted.

7.2 Recommendations for the Low-Level Protocol

7.2.1 Physical Layer

The main task of the physical layer is to transmit raw bits of information. NCCLS recommends use of the network interfaces: 10BaseT (twisted pair), 10Base2 (coax). Use of the RS-232C interface is not recommended, because it does not provide sufficient bandwidth. Legacy systems can use protocol converters to allow them to communicate on a network. These protocol converters are readily available on the market.

7.2.2 Data Link/Medium Access Layer

The main task for the data link/medium access layer is to ensure error-free transmission over the wire. NCCLS recommends use of 802.3 standard (Ethernet).

Time characteristics and bandwidth problems of "simplex stop & wait" protocols over a serial interface is limited to applications with low throughput. This class of protocol is not recommended by NCCLS.

Even though Ethernet is not deterministic, it can, with its higher bandwidth capability, meet an acceptable response time in most cases, i.e., the time characteristics of Ethernet are sufficient for laboratory automation. Ethernet's popularity facilitates support and acceptance of the standard.

7.2.3 Network Layer

The main task of the network layer is routing from source to destination devices. NCCLS recommends the IP (Internet protocol).

The popularity of the TCP/IP communications protocol facilitates support of this protocol. If the RS-232C interface is used, i.e., it uses a point-to-point type connection, this layer is not needed.

7.2.4 Transport Layer

The main task of the transport layer is reliable, network-independent, end-to-end transport. NCCLS recommends TCP (transmission control protocol). Additionally, a special header for process-to-process routing as well as for synchronization and recovery (session layer) is added.

If TCP/IP is used, it is recommend that the minimal low-level protocol (MLLP – see "Health Level Seven Implementation Support Guide for HL7 Standard Version 2.4, APPENDIX C - LOWER LAYER PROTOCOLS) be used. The MLLP is used to break up, and make identifiable, messages in the stream-oriented TCP/IP protocol. Alternatively, a unique transaction terminator can be introduced or a message chaining information can be added in the header.

7.2.5 Session Layer

The main task of the session layer is to establish sessions and deliver mechanisms for synchronization and recovery. NCCLS recommends utilizing the mechanisms proposed in the HL7 Message Header Segment (MSH).

The fields "Sending Application" and "Sending Facility" should be filled in with values definable for each equipment application (three subcomponents per field). In some cases it means configurability of these fields for each message type for outgoing messages.

The "Receiving Application" and "Receiving Facility" fields in the incoming message should be compared with values defined in the equipment application configuration. Only messages with matching text will be processed.

For outgoing messages, the "Receiving Application" and "Receiving Facility" fields should be filled with information extracted from the "Sending …" fields of the incoming message. It means these fields should be stored on "receive" and used on "send," respectively. For example, the response to a request from application Z will be sent to application Z, or for orders downloaded by the facility X, results should be returned to the facility X.

The “Message Control ID” should be used for acknowledgments and error recovery as defined in the HL7 standard.

8 Implementation Considerations

Numerous issues will arise in the implementation of Laboratory Automation Systems (LAS). These issues will require extensive discussion between the laboratory, the laboratory instrument vendor(s), the Laboratory Information System (LIS) vendor, and the LAS vendor. This section presents several statements on issues that should be addressed by the laboratory staff early in the installation process. This is not an all-inclusive list, but hopefully, by addressing and evaluating these statements early in the process, it will trigger other questions, thereby preventing problems from occurring in the future.

The coherent exchange of information between the LIS, the LAS, the transportation system, and all attached instruments and devices is required to ensure the entire system performs its required functions. The statements below are grouped according to interface function. Refer to the appropriate HL7 chapter for detailed descriptions of each message segment and the automation systems usage of each sequence.

The discussion which follows relates to issues that deal with the following interface functions:

- LIS to LAS ADT and episode-of-care functions;
- LIS to LAS order entry inbound and LAS order outbound function;
- LAS to LIS and LIS to LAS result reporting function;
- LAS to LIS query function; and
- LAS network management function, LAS-to-instrument and instrument-to-LAS function.

8.1 ADT, Patient, Episode-of-Care Functions

The LAS probably does not provide for a census function; however, accurate and current patient data is required to perform many of its functions. Also, the LAS probably does not require that the patient data associated with ADT functions be provided via standard HL7 ADT message formats. An acceptable alternative would be for fully valued PID, PV1, PV2, DG1, AL1, and IN1 messages to be provided with "order entry," "status change," "results," and "query" functions. The LAS would not send HL7 ADT messages to the LIS or HIS. The following ADT statements apply to either alternative.

8.1.1 Patient Location

The LAS may be concerned about a patient’s current location (room/bed, clinic, facility, etc.) and the current patient type (inpatient, outpatient, preadmit, etc.). It would be less concerned about an institution’s rules for moving from one location to another or their rules for changing from one type to another. The HIS and/or LIS vendors should ensure that patient movement and type changes follow the institution’s rules.

8.1.2 Patient Identifying Numbers

The LIS should send a medical record or patient identifying number for the LAS patient number that is unique for that patient at the enterprise level.

The alternate patient or episode-of-care identifier could be provided so that episodic or visit and on-line inquiries could be supported within the LAS.

The LAS should support both enterprise and facility identification. Because of the LAS rules processing capability, the laboratory would be able to provide different levels of service at the enterprise/facility level; e.g., give higher priority to hospitals versus clinics.

8.1.3 Dates/Times

The LAS should follow the date/time format as suggested by the HL7 TS standard. The LIS should send all dates and times in the same format (i.e., YYYYMMDDHHMMSS+-ZZZZ).

8.1.4 Physician Identifier Codes

The LAS should be able to accept physician numbers from the LIS that are not in the LAS database (e.g., outside physicians). In fact, if the LIS would fully value the physician fields, the LAS should be able to build its physician master table from that information and not have to synchronize the table with the LIS unless physician demographic information is required by the LAS.

8.1.5 Diagnosis Identifier Codes

If the LAS maintains a diagnosis code file (ICD9-CM is one example of such a coding system), the LAS would only require that the LIS send the diagnosis code and not the associated, free, text diagnosis description.

8.1.6 Outside Patients

If the laboratory performs laboratory testing on outside patients, those patients must have obtained unique patient IDs from the LIS before the orders are sent to the LAS. If specimens are received in the laboratory without LIS identification, the orders for those specimens must be entered into the LIS, the containers must be labeled, and the orders must be sent to the LAS.

8.2 Order Entry Function

8.2.1 Order Entry

Orders can be created by the HIS, the LIS, or the LAS. The LAS may require that orders for specimens that have been received by the laboratory be sent to the LAS immediately upon receipt. The LIS should send all orders to the LAS upon specimen receipt in the laboratory. The "specimen receipt" function can occur either on the LIS or the LAS. If it occurs on the LAS, the LAS should notify the LIS, via a status update message and then follow with a query request message, so the LIS could send the orders assigned to that specimen container. The LAS will send all orders created on the LAS to the LIS.

8.2.2 Test Grouping

The LAS may require that the LIS send all individual component tests of a profile, battery, or group as ORC/OBR pairs.

8.2.3 Specimen Container Identification

The LAS depends upon unique specimen identification (bar-code label). If multiple containers have the same identifier, they must be relabeled or linked to uniquely identified carriers.

8.2.4 Batch Transactions

These are real-time systems; batch transactions should not be supported. The LIS must send individual HL7 messages.

8.2.5 Priorities

Routing of containers on an LAS may consider the priority of the tests associated with the container. The LIS and the LAS can use any valid priority defined in the HL7 Table 27.

8.2.6 Ordering Locations

If ordering location codes rather than terminal IDs are used, the LAS could possibly prioritize routing to instruments by this code.

8.2.7 Laboratory Automation System (LAS)-Generated Orders

The LIS must support LAS-generated orders. LAS-generated orders will be for additional tests to existing identified specimens when there is enough specimen remaining to perform the test.

8.2.8 Test Codes

The LAS requires a one-to-one match of test codes between the LAS and the LIS.

8.2.9 Order Cancels

Orders may be canceled from the LIS or within the LAS. Cancels may be performed automatically as a result of a duplicate order or by LAS rule-based logic. Definitions of a duplicate order are based on both the interface logic and the user parameter settings. The disposition of containers that are on the transportation system when a "cancel" has been received by the LAS should be negotiated with the client.

8.2.10 Order Comments

The LIS and the LAS should support an NTE segment for sending order comments to the LAS. NTE segments can also be used for sending messages from some instruments.

8.2.11 Multiple Orders per Message

The LAS should support multiple orders per ORM (this assumes they would all be associated with the same patient, episode, and specimen container identifier). The LIS must be able to send and receive multiple orders.

8.3 Results Function

8.3.1 Order and Result Identifiers

The LAS should send all results it receives from instruments attached to the LAS in an ORC/OBR/OBX HL7 message. These results could have a status of "preliminary" if results are “accepted” by the LIS, or they could have a status of "final" if the LAS has an acceptance or auto-acceptance function.

If the LIS accepts results and sets the status as "final," some LASs may require that the LIS then forward those finalized results to the LAS.

The LIS should support F (final) and S (partial) as result status flags in the OBR segment. These flags should not be at the battery, profile, or group level, but at the test-level status.

8.3.2 Error, Warning, and Abnormal Flags

The LIS and LAS both require various error and warning flags generated by instruments. The usage and designation of these flags should be discussed by all parties.

8.4 Query Function

The LIS and LAS should support deferred queries. Queries can be used when specimen containers are received by the LAS prior to patient and order information being sent from the LIS to the LAS.

Query filter content should be negotiated between the LIS and LAS vendors. Possible query filters that could be supported by the LAS are:

- patient ID (only one per query);
- test or battery code;
- order number;
- container and/or accession number;
- date and time range; and
- all (is interpreted by the LAS to be all orders for a particular container or accession number).

The LIS should respond to queries with the above-identified filters with the patient ADT, orders, status, and results messages in standard HL7 formats in "deferred response" mode.

8.5 Network Management Function

The LIS should support network management queries for time and statistical information.

It is important that various master files be synchronized between the LIS and the LAS. HL7 provides the capability for file synchronization.

8.6 Analyzer/Instrument Functions

Instrumentation can be defined to be analyzers, centrifuges, decappers, aliquotters, recappers, and any other device that can be attached or controlled by the LAS. The specifications for several new segments are described elsewhere in this document. These segments will allow for standardized communication between these devices.

Various methods have been developed by instrument manufacturers and LAS vendors to attach instruments to LASs. Until all of these vendors have adopted the standards defined in this document, negotiation between the parties on the rules, methods, interfaces, etc., will be required.

The capabilities of the equipment using this standard will vary greatly from point-of-care equipment requiring only to report results to large, sophisticated, multifunction, intelligent analyzers requiring demographic information and producing results and inventory information. As a consequence, it is expected that equipment manufacturers will implement more or less of this standard as their equipment

requires. It is expected that as a minimum, the HL7 V2.3 message structure will be followed, but which messages and segments are supported will be equipment dependent.

8.7 Timing and Throughput Considerations

8.7.1 Message Timing

Message timing, which is a function of network traffic, message frequency, message length, and message turnaround time, should be considered when designing the communications between computers within a laboratory automation system. This specification recommends the use of high-speed network communications such as Ethernet and TCP/IP and consequently, message communications are expected to be fast. However, it is known that TCP/IP is nondeterministic and can become a problem if the network is overloaded. Careful planning of the network and network traffic should be done to allow the laboratory automation system to meet its needs.

8.7.2 System Throughput

System throughput is a function of equipment and possibly also network communications cycle times. Even though this standard recommends the use of high-speed network communications such as Ethernet and TCP/IP, communications timing may be a factor in systems requiring high throughput. Because throughput requirements are system dependent, they cannot be standardized. It is up to the designers to specify equipment and communications throughput requirements to meet the needs of the laboratory automation system.

8.8 Recommended Character Set Support

The support sets of character should include ASCII and UNICODE (ISO10646).

8.9 Example Transactions

The examples of laboratory automation system message exchange are described in HL7 Chapter 13.

MSH|^~\&|PCIS|MEDCENTER|REPOSITORY|MEDCENTER|||PGL^PC4| <cr>

Appendix A. Laboratory Automation Architectures/Models

Overview of Architectures

The total laboratory automation concept can be visualized from both an information-oriented point of view and a material-oriented perspective. The information-oriented view focuses on managing the patient information such as demographics, orders, results, and diagnosis. The material-oriented approach focuses on managing the actual sample through the automated laboratory.

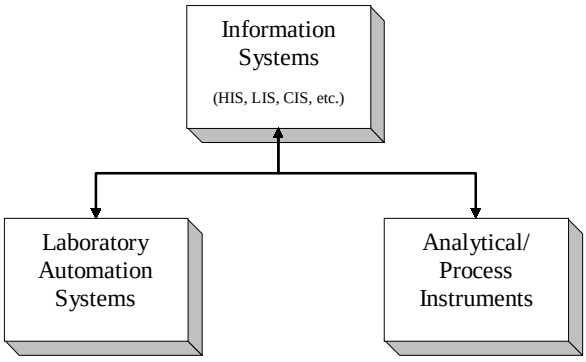
Four typical automation architectures are identified in the following models. The arrows indicate the direction of information and/or information transfer among the elements as well as the electronic interfaces for process control. These models are based on the assumption that each element of the model performs only the unique functions. These four models were considered by the subcommittee, but were not adopted because of limitations inherent in each. The functional control model described in Chapter 4.2 is the preferred model for information flow and control in total laboratory automation.

Laboratory Information System-Centric Model

The Laboratory Information System (LIS)-centric model is most easily understood, since the information-oriented subsystems and material-oriented subsystems are readily recognized. The IS serves as the central processing unit and control center for the LAS and the analytical and processing instruments, as well as the data depository.

The design is apparently simple, although it can be complicated to implement due to interfacing challenges. Since many analytical instruments have one communication port, the IS may be necessary for simultaneous electronic communication of analyzers with multiple elements, such as the IS and process instruments.

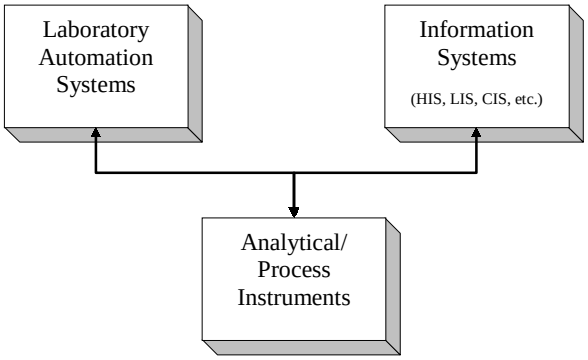
The advantage to the IS-centric model is that when one system or process is off-line, the others can remain functional. Information can be buffered within the IS until functionality is restored. When the system is fully functional, the borders between elements are transparent with respect to information and information transfer.



Appendix A (Continued)

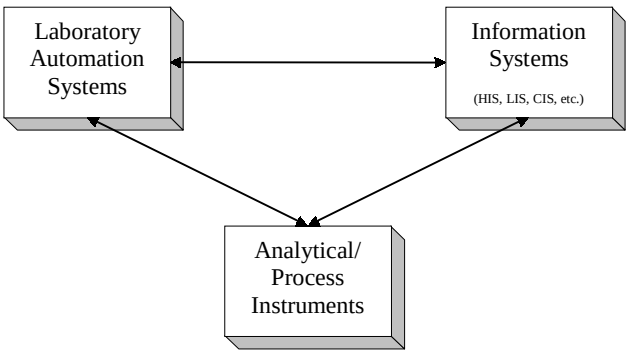
Instrument-Centric Model

The analytical instrument is the driving force in the instrument-centric model, aided by process instruments when utilized. The information-oriented subsystems are difficult to distinguish; therefore, design and implementation can be difficult. Information transfer is transparent among elements. The information-oriented subsystem resides totally within the analytical/processing instrument element. The feedback mechanisms to the laboratory automation systems tend to be redundant when the analytical instrument is the control center, which can lead to inefficiencies in the total system. The information system serves primarily as an information repository with little or no control functionality.



Peer-to-Peer Model

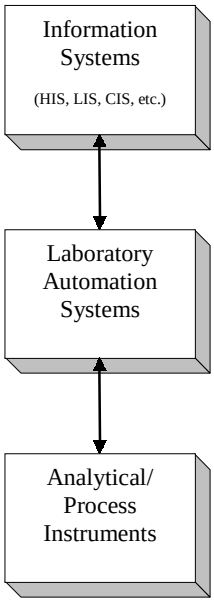
There are two scenarios for the peer-to-peer model. As an information-share model with little or no inter-element control, each element functions independently and provides information on a query basis to the other elements through electronic interfaces. Clear, distinct borders separate information and materials between the elements. As a control and information-share model, constant feedback loops of status and error messages provide synchronized control between the elements. A common database would lend efficiency to the overall system, although this is not essential.



Appendix A (Continued)

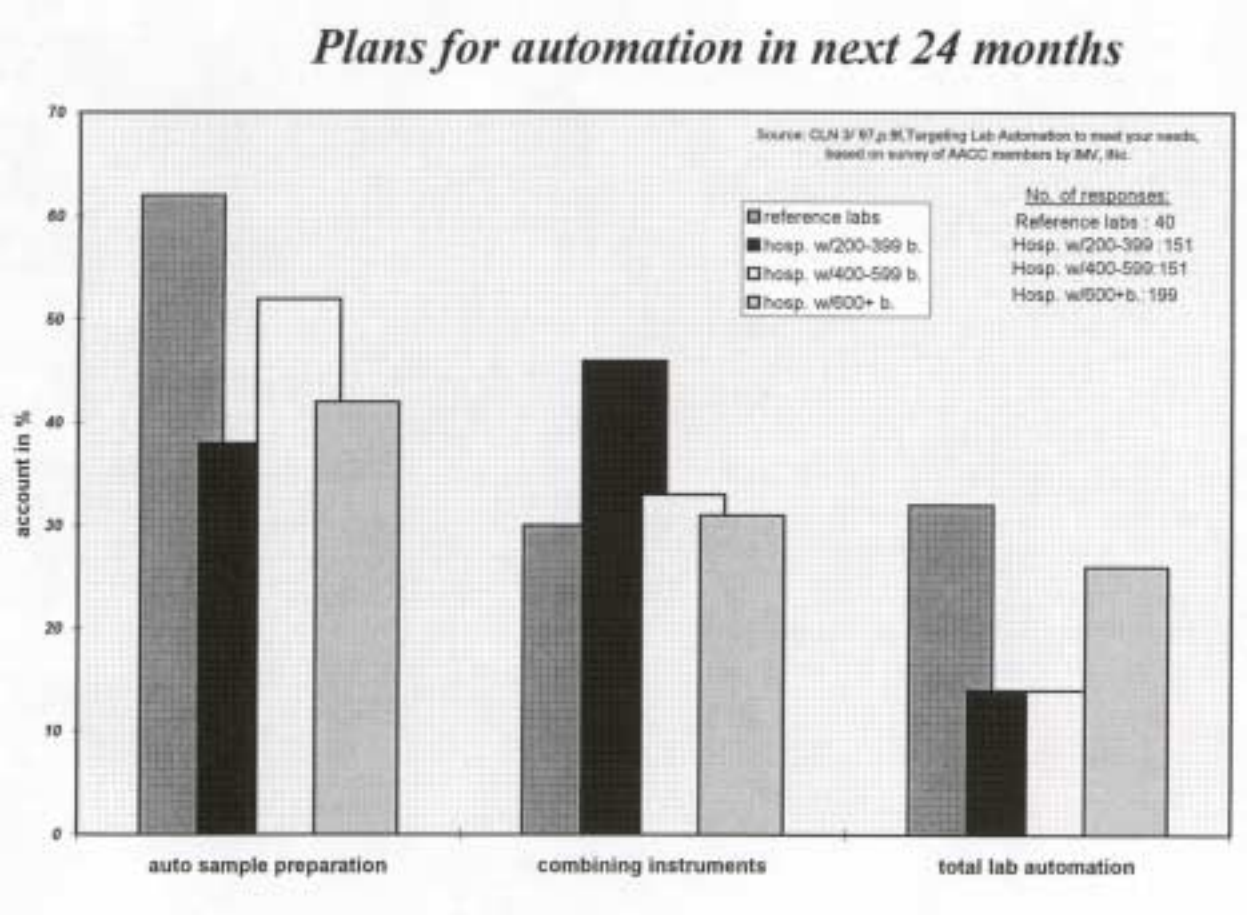
Hierarchical Structure Model

The hierarchical structure model is a useful model to achieve compliance with the standard, although not as useful as the functional control model described in Section 4.2. The hierarchical structure model employs a top-down mechanism for information transfer that is more restrictive than the other models. Likewise, there could be a restrictive top-down control hierarchy as well for both the information- and material-oriented subsystems. Control redundancy within modules is possible if one element is off-line. For example, an analytical instrument could be still used as a stand-alone element. This is a very important fail-safe capability for any automation system.



Appendix B. Survey of Plans for Automation in 1999 – 2000

(From Boyce N. Targeting lab automation to meet your needs. *Clinical Laboratory News.* March 1997;9f. Reprinted with permission from American Association for Clinical Chemistry.)



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[3] ASTM D966. *Specification for Secondary Butyl Acetate (85-88% grade).* West Conshohocken, PA: ASTM; 1975.

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[15] JIS Standard X0208. *7-bit and 8-bit Double Byte Coded KANJI Sets for Information Interchange.* Tokyo, Japan: Japan Standards Association; 1997.

NCCLS consensus procedures include an appeals process that is described in detail in Section 9.0 of the Administrative Procedures. For further information, contact the Executive Offices or visit our website at www.nccls.org.

Summary of Comments and Subcommittee Responses

AUTO3-P: *Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Proposed Standard*

General

1. If this standard will fix certain data element values as shown for several fields, and that field has a data type of CE, what identifier will be used to indicate the coding system? The current HL7 and ASTM standards do not have a code for NCCLS. Will these data element tables be incorporated into HL7 defined tables or will NCCLS have a code assigned by HL7 to reference this data?

- **The NCCLS specifications as related to HL7-defined information have been incorporated into Chapter 13 in the HL7 standard. Some additional non-HL7 tables (e.g., LOINC, LECIS) have been incorporated into AUTO3 and have been appropriately referenced. The subcommittee has revised the HL7-specific tables to include HL7 codes.**

2. In several places in the standard reference is made to the fact that each specimen container must be uniquely identified, even aliquots and, presumably, diluted specimens. This concept will wreak havoc with LISs. The accession/specimen number will be assigned by the LIS and most, if not all LISs, will assign a single accession number to all specimens collected at the same time. Some LISs do have the ability to assign a prefix or suffix to the primary accession number according to a laboratory section. There is too much logic built into the LIS that is based upon this concept. Requiring the LIS vendors to change the method of assigning specimen/accession numbers will require major reprogramming of most systems and would result in a failure of the implementation of this standard. A way of having the LAS handle this concept of accession numbers that would allow the LIS to assign the accession numbers as they currently do and download that information to the LAS needs to be developed. This would require the LAS to assign new internal numbers to each specimen container, have the LAS print new bar-code labels, and have someone affix those labels to each correct specimen container. This entire concept of the unique identifiers really needs to be thought through much more completely. In reviewing the committee membership there seems to be only one representative from an LIS vendor. I would suggest that you must have much more participation of LIS vendors if this effort is to be successful.

- **The standard as written is sufficiently flexible to enable the LIS vendor and LAS vendor to solve this problem without the LIS vendor necessarily being forced to do a major reprogramming of its system. If the LIS vendor is unable to provide a unique identifier per container, then it must be provided by a separate processing system to replace the LIS functionality.**

Section 3

3. Why do all of the Japanese societies and journals have an acronym definition? The acronym could be given in parentheses in the text of the document, i.e., Japanese Association of Healthcare Information Systems Industry (JAHIS).

- **The subcommittee, area committee, and NCCLS editorial staff agreed that this format would be helpful for readers/users of the automation standards.**

4. "Definitions"— add the definition for SNOMED.

- **SNOMED has been added to the Definitions section.**

Comments 5 - 91 are related to the message segments recommended by HL7. The responses were provided by the HL7 Special Interest Group (SIG) on Laboratory Automation in coordination with the NCCLS Subcommittee on Communications with Automated Systems.

Section 5.3.3 (now Section 6.3.3)

5. With reference to the AUTO2-P standard, there should also be a common understanding about specimen type extension in the sample identification. Therefore, I would like to suggest an extension of Table 5-7 *SAC Attributes* in Section 5.3.3 (now Section 6.3.3) with corresponding sequence field.

   For example: sample-ID specimen type
   xxxxxxxx – 01 serum
   xxxxxxxx – 02 citrate
   xxxxxxxx – 03 EDTA
   xxxxxxxx – 04 urine
   xxxxxxxx – yyA archive aliquot etc.

- **The HL7 Specimen Source Table (Table 0070) is used to define specimen type.**

Section 5.3.3.1 (now Section 6.3.3.2)

6. Wouldn't this be a required field? If not, there should be an explanation in the document for QC purposes.

- **The subcommittee has decided that it doesn't need to be required. The caveat is that the user needs to have a unique ID that can be the combination of primary container ID, container ID/position, and the tray ID.**

7. How will QC specimens be sent in this segment?

- **All specimen containers, whether QC or patient, need to be uniquely identified.**

8. Why would this field's data type be EI as opposed to ST? Is it required so you can include the institution's identity?

- **Most instruments do not have the ability to parse out the different components. The standard focuses on what is required for the future and not necessarily what exists today.**

9. The field size is given as 22; however, this would conflict with the bar-code standard. In addition most instruments have an upper limit on the accession number that would not allow 22 characters.

- **The subcommittee believes the practical limit is about 15 characters. The committee has adopted a standard field size of 80 characters for the data type EI. The field size is only used as a maximum size and doesn't indicate a recommendation for the length of the particular**

attribute. In this particular field, we have agreed on 24, as this is the maximum printable bar code for Code 128, as specified in NCCLS document AUTO2—*Laboratory Automation: Bar Codes for Specimen Container Identification*.

Section 5.3.3.2 (now Section 6.3.3.3)

10. The standard needs to provide a much better explanation of the difference of this number from the accession identifier.

- **An accession number can refer to more than one container. A container ID is a unique identifier for that container. If the container ID is an aliquot, the primary container ID identifies where the aliquot originated.**

Section 5.3.3.5 (now Section 6.3.3.6)

11. Should the data type be CE instead of CM? HL7 is not using the CM type any longer. Thus, one must rethink all of the components of this field using the CE data type.

- **Specimen source is an existing HL7 field attribute, so the CM data type is still a valid data type.**

12. This section seems to be cloned directly from HL7. HL7 uses an HL7-defined table for these sources. In my opinion this is not practical; I believe that the source table should be user defined. What is the NCCLS view of this issue? (Note that ASTM E1394 does not have any fixed codes.)

- **HL7 uses many user-defined tables and so does the AUTO3 extension to HL7. This particular table should not be user defined, because specimen containers and specimen information, including specimen source/type can be shared across different entities (e.g., a hospital laboratory that uses a foreign reference laboratory).**

Section 5.3.3.6 (now Section 6.3.3.7)

13. Why would the word “latest” be more appropriate than “last”?

- **The subcommittee has revised the text.**

14. None of the components of this field are listed.

- **The time stamp (TS) data type has a commonly recognizable format, so it wasn’t shown. The same logic applies to the numeric/number (NM) data type.**

Section 5.3.3.7 (now Section 6.3.3.8)

15. Is the proposal to have a fixed set of “container status” codes, or would they be user defined?

- **They have been defined. It is important to have them predefined for intervendor interoperability purposes**.

16. If they are fixed codes will they be a designated HL7 table, or will it be user defined?

- **They are fixed codes of the following table form: CE with a one-character code and a description.**

17. Will NCCLS be assigned a code to identify the coding system?

- **Yes, the committee has defined the codes.**

Section 5.3.3.10 (now Section 6.3.3.11)

18. Should this field be an NM data-type field? If so, then the field length can be much less than 80.

- **It is an NA type. The field identifies the position (e.g., 1…5…) of the tube in the carrier. The subcomponents allow, if necessary, transfer of multiple-axis information (X^Y^Z).**

Section 5.3.3.11 (now Section 6.3.3.12)

19. Why wouldn't this field be an ST data type? All of these CE data-type fields would indicate that some system would need a user-defined definition table in order to support the data element.

- **This field identifies the type of the tray. This is a user-defined table. Because the geometry can be different, the tray type should, if possible, express the number of positions in the tray**.

Section 5.3.3.12 (now Section 6.3.3.13)

20. Why wouldn't this field be an ST data type? All of these CE data-type fields would indicate that some system would need a user-defined definition table in order to support the data element.

- **It is an EI type. This field identifies the tray identifier (e.g., a number of a tray or a bar code on the tray) where the container carrier is located**.

Section 5.3.3.13 (now Section 6.3.3.14)

21. Should this field be an NM data-type field? If so, then the field length can be much less than 80.

- **It's a type NA. This field identifies the position of the carrier in the tray. The subcomponents allow, if necessary, to transfer multiple-axis information (X^Y^Z).**

22. How is this field different than the position in the carrier?

- **Multiple carriers can reside in a tray.**

Section 5.3.3.14 (now Section 6.3.3.15)

23. The subcommittee may wish to change the name of this field to something other than "location" in order not to be confused with patient locations.

- **The patient location is defined in the PV1 segment at Sequence 3. It is a data-type PL and is called the "assigned patient location." The subcommittee believes there is adequate differentiation between the two.**

Section 5.3.3.15

24. What is the difference between this field and the one described in Section 5.3.3.2?

- **The section, Container Type, has been removed. The sequences describing the container are used (e.g., container height, container diameter, etc.) in Sections 6.3.3.16 and 6.3.3.17.**

Section 5.3.3.16 (now Section 6.3.3.16)

25. Why does this field size need 20 characters? It could be a lot less.

- **It is a data-type NM, and we have chosen 20 as the maximum size for all NMs. It does not require that the actual length of data in this position be 20 characters long.**

Section 5.3.3.18 (now Section 6.3.3.17)

26. Why does this field size need 20 characters? It could be a lot less.

- **See response to Comment 25.**

Section 5.3.3.19 (now Section 6.3.3.16)

27. Isn't this field redundant? Wouldn't the height and diameter units always be expressed in the same units?

- **The subcommittee has combined height and diameter units, since they would use the same units.**

Section 5.3.3.20 (now Section 6.3.3.21)

28. Why does this field size need 20 characters? It could be a lot less.

- **See response to Comment 25.**

Section 5.3.3.22 (now Section 6.3.3.24)

29. Why does this field size need 20 characters? It could be a lot less.

- **See response to Comment 25.**

Section 5.3.3.23 (now Section 6.3.3.24)

30. Isn't this field redundant? Wouldn't the container volume, current volume, and draw volume units always be expressed in the same units?

- **Yes, they would. We have combined them.**

Section 5.3.3.24 (now Section 6.3.3.24)

31. Why does this field size need 20 characters? It could be a lot less.

- **See response to Comment 25.**

Section 5.3.3.25 (now Section 6.3.3.24)

32. Isn't this field redundant? Wouldn't the container volume, current volume, and draw volume units always be expressed in the same units?

- **See response to Comment 30.**

Section 5.3.3.26 (now Section 6.3.3.26)

33. Why wouldn't this be an ST data type?

- **The subcommittee believes that coded entries work better than strings.**

Section 5.3.3.27 (now Section 6.3.3.27)

34. Why only "fluid" additives?

- **We now use just "additives."**

35. Why wouldn't this be an ST data type?

- **See response to Comment 33**.

36. The definition should read, "This field identifies any additives to the manufactured specimen container/tube."

- **The text has been revised.**

Section 5.3.3.28 (now Section 6.3.3.28)

37. Why wouldn't this be an ST data type?

- **See response to Comment 33.**

38. Section 5.3.3.28 should be "Specimen Collection Treatment."

- **The section has been renamed "Specimen Component."**

Section 5.3.3.29

39. Many current instruments may detect lipemia, hemolysis, etc.; however, when they transmit this information to another device (LAS or LIS), it would be in the form of an OBX message that would include the identifier and the result. The proposed standard does not fit this model.

- **We weighed the options of using an OBX versus having all information that defines the content of the container in one segment, and after discussions with several HL7 "experts" decided to go this route.**

Section 5.3.3.30 (now Section 6.3.3.29)

40. I don't understand how one would use this data element as a CE data type. Why would it not be an NM data type? If CE data type is correct, a full explanation needs to be added to the standard**.**

- **We have switched to a data type of structured numeric (SN) to address this type of concern.**

Section 5.3.3.31 (now Section 6.3.3.30)

41. Why wouldn't this field be an ST data type?

- **See response to Comment 33.**

42. Section 5.3.3.31 should be Specimen Laboratory Treatment.

- **The text has been revised.**

Section 5.3.3.32 (now Section 6.3.3.31)

43. Temperature measurements are usually sent as an OBX record in HL7. Why is it different here? If this is going to stay as an NM field, then the length of 80 is excessive. Should a temperature units field also be included in this segment?

- **We have canvassed several institutions and so far, it seems that everyone uses metric/Celsius for temperature measurement/units.**

44. How will the SAC segment handle panels-profiles-batteries? Is there a provision for parent/child relationships between records? The ORC/OBR continues to handle panels-profiles-batteries. The SAC is used to define carriers, containers, and the container contents.

    It seems that a lot of the container information fields in the SAC segment are unnecessary. If the system has any decent design, a container identifier should provide all of the other information.

- **The SAC segment has been expanded to 44 sequences. We needed to define not only the characteristics of the container but also the characteristics of the specimen within the container. One of our goals was not to design 'a system' but to provide a standard for instrument and component manufacturers, and for LIS and LAS vendors to use to achieve levels of interoperability between all systems and components.**

Section 5.3.4.2 (now Section 6.3.4.2)

45. User-defined, HL7-defined, or NCCLS-defined?

- **This table has been defined by this subcommittee in HL7.**

Section 5.3.4.3 (now Section 6.3.4.3)

46. User-defined, HL7-defined, or NCCLS-defined?

- **See response to Comment 45.**

Section 5.3.4.6 (now Section 6.3.4.6)

47. Should this be an NM data-type field?

- **It is now a coded element (CE) data type.**

Section 5.3.4.7 (now Section 6.3.4.7)

48. A field length of three characters is too restrictive.

- **This is now a length of 20, following our standard for NM data types.**

Section 5.3.4.8 (now Section 6.3.4.8)

49. A field length of three characters is too restrictive.

- **See response to Comment 48.**

Section 5.3.4.9 (now Section 6.3.4.9)

50. A field length of three characters is too restrictive.

- **See response to Comment 48.**

Section 5.3.4.10 (now Section 6.3.4.10)

51. A field length of three characters is too restrictive.

- **See response to Comment 48.**

Section 5.3.4.12 (now Section 6.3.4.12)

52. The wrong components are shown for a TS data-type field.

- **The component layout has been eliminated, since the TS component is used and there is extensive familiarity of time-stamp layouts.**

Section 5.3.4.13 (now Section 6.3.4.13)

53. The wrong components shown for a TS data-type field.

- **See response to Comment 52.**

Section 5.3.4.16 (now Section 6.3.4.16)

54. Field length of 200 is probably excessive.

- **The committee believes it's only a maximum field size.**

Section 5.3.4.17 (now Section 6.3.4.17)

55. Field length of 200 is probably excessive. Why wouldn't this be a CE data type?

- **The committee agrees—it should have been a CE type. It has been changed to 80.**

Section 5.3.4.18 (now Section 6.3.4.18)

56. Field length of 200 is probably excessive. Why wouldn't this be a CE data type?

- **See response to Comment 55.**

Section 5.3.5.4 (now Section 6.3.5.4)

57. Why isn't this a TS data type?

- **It identifies a future completion time and needs to use a TQ data type.**

Section 5.3.7.3 (now Section 6.3.7.3)

58. If this field and alert level field in EQU-5 are to reference the same table, the terminology of the field names should be consistent (e.g., notification alert level).

- **We now refer to this field as the "notification alert severity."**

59. Why would this be a required field?

- **This field is required for the receiving entity to evaluate different possible actions it could take.**

Section 5.3.9.2 (now Section 6.3.9.2)

60. If this is a code, then a field length of 80 is probably excessive.

- **This has now been combined with the universal service identifier, a CE data type.**

Section 5.3.9.3 (now Section 6.3.9.3)

61. HL7 is not using CM data types any longer.

- **"Specimen source" is an existing HL7 field attribute, so the CM data type is still a valid data type.**

Section 5.3.9.4 (now Section 6.3.9.4)

62. The field size may be too restrictive.

- **The subcommittee agrees; it is now a maximum length of 20.**

Section 5.3.9.5 (now Section 6.3.9.5)

63. The field size may be too restrictive.

- **See response to Comment 62.**

Section 5.3.9.6 (now Section 6.3.9.6)

64. The field size may be too restrictive.

- **See response to Comment 62.**

Section 5.3.9.8

65. This item number has been incorrectly assigned to a definition statement for the previous field. Thus all paragraphs following, 5.3.9.9 to 5.3.9.15 are misnumbered.

- **The text has been corrected.**

Section 5.3.9.12 (now Section 6.3.9.12)

66. Use the term “dynamic” or “linearity” instead of “reference.” Reference ranges are normally thought of as the “normal ranges.”

- **We now use the term "equipment dynamic range."**

67. How will this field handle age/sex/species-specific ranges?

- **This is just the ‘outside limit’ range.**

68. A field size of 10 is much too restrictive.

- **This sequence is now an SN data type and has a maximum length of 20.**

69. Does it allow repeats?

- **Repeats are not necessary, because the subcommittee is only supporting technical ranges.**

Section 5.3.9.14

70. A larger field than three characters is needed.

- **This sequence is no longer used.**

71. What if the local units are SI and the user wants to convert to conventional (US) units? How will the system know how to calculate? An explanation of how a user would set this up is needed.

- **See response to Comment 70.**

Section 5.3.9.15

72. Can this field have repeats?

- **See response to Comment 70.**

Section 5.3.10

73. This segment is no longer part of this standard.

- **The appropriate sequences will be added to OBX, PID, and/or PV1s.**

Section 5.3.10.1

74. This data element would be considered an observation result and would be sent in an OBX record.

- **See response to Comment 73.**

75. Further the data is patient/specimen-specific and would be better sent once in the SAC segment.

- **See response to Comment 73.**

Section 5.3.10.2

76. This data element would be considered an observation result and would be sent in an OBX record.

- **See response to Comment 73.**

77. Further the data is patient/specimen-specific and would be better sent once in the SAC segment.

- **See response to Comment 73.**

78. Would the values shown in table 5-22 be user- or HL7-defined?

- **See response to Comment 73.**

Section 5.3.10.3

79. Wouldn't this field be better as a CE data type and allow repeats?

- **See response to Comment 73.**

Section 5.3.10.4

80. These fields need to be separated into different segments unless HL7 agrees to add them to the exiting patient segments. Species would be associated with PID, expected date of birth would be associated with PID (this assumes that the patient ID is associated with the fetus and not the mother); menstruation cycle should be associated with the order and would be an OBX segment. Active medications present a significant problem. These would probably be best suited to either the existing HL7 RXA-pharmacy/administration segment or make this field a CE data type with repeats. The sending system would then need to filter out those medications that are not current.

- **See response to Comment 73.**

Section 5.3.11.2 (now Section 6.3.10.2)

81. The field size may be too restrictive.

- **This is now a data type of SN (structured numeric) and has a maximum length of 20.**

82. The standard really does not explain adequately or show examples of how the data would be used in these fields.

- **Autodilution is used by some instruments to specify the factor (e.g., x2) as the factor to use if a dilution is requested.**

Section 5.3.11.3 (now Section 6.3.10.3)

83. The field size may be too restrictive.

- **See response to Comment 81.**

Section 5.3.11.4 (now Section 6.3.10.4)

84. The field size may be too restrictive.

- **See response to Comment 81.**

Section 5.3.11.5 (now Section 6.3.10.5)

85. The field size may be too restrictive.

- **See response to Comment 81.**

Section 5.3.12.1 (now Section 6.3.12.1)

86. NCCLS-, HL7- or user-defined table?

- **This is an HL7- defined table, having two entries, 'log event' or 'service event.'**

87. Current marketed products or systems under development do not communicate the information requested or interact per the specified commands. All systems software will have to be reconfigured to meet the specified communication protocols.

- **One of our goals was not to design 'a system' but to provide a standard for instrument and component manufacturers, and LIS and LAS vendors to use to achieve levels of interoperability between all systems and components.**

88. I reviewed the draft of the proposed standard AUTO3-P. I furthermore got the impression that all standardization activities are focused to describe total lab-automation like CLAS-systems. Due to the working group composition, it might be natural with this focus, but I don't think that is the global situation.

- **This standard does also apply to stand-alone equipment/instruments (e.g., aliquotters). The standard should and does allow for all levels of laboratory automation implementation. See Section 1.1, 'Scope.'**

89. Once again, lab automation is not necessarily a conveyor or whatever linked composition of devices; it is also an intelligent workflow scenario with standardized interfaces for specimen distribution and

data management = work area management. Therefore, I would like to suggest putting a few words/sentences about this approach in a chapter of this standard.

Please refer to Appendix B to access a survey from the AACC about *segmentation (total automation, stand-alone devices approach)* for the lab-org focus within the next 24 months.

- **The subcommittee has included text in Section 1 in response to this comment.**

Table 5-12 (now Table 0384 under Section 6.3.4.3)

90. "Substance Type"— Add a code for deionized water (most labs use this instead of distilled water).

- **"Distilled water" with code DW has been changed to "purified water" with code PW. The substance identifier describes the type of purified water.**

91. "Substance Type"— Add a code for purified water (lab specific).

- **See response to Comment 90.**

Section 6.2.1 (now Section 7.2.1)

92. "Physical Layer"— Remove the "10Base2 (coax)" from the section (there are MANY potential problems with 10Base2 in a laboratory environment).

- **The subcommittee currently recommends a minimum bandwidth that is provided with 10BaseT.**

93. "Physical Layer"— Add "100BaseT."

- **See response to Comment 92.**

Section 7.1.2 (now Section 8.1.2)

94. There is a lot of work going on within HL7 regarding various patient ID numbers. HL7 currently does not work with patient ID numbers that are associated with "clients." Many laboratories will accept referral specimens from outside their institutions. That outside institution assigns a patient ID number which is different from the ID number that is assigned to the patient at the performing laboratory system. There is also the issue of the Canadian provincial ID number that may be used in addition to the internal or external patient ID number. Whatever HL7 decides to implement with regard to all of these different patient identifier schemes, this NCCLS standard will need to meet.

- **There has been significant progress made in meeting the needs for "external" patient identification. This NCCLS standard meets these needs, because it uses the existing PID segment to communicate patient information to the LAS. The LAS is responsible for accommodating the various identifiers that it requires to properly identify the patient that belongs to a particular specimen.**

Section 7.2.1 (now Section 8.2.1)

95. If the LAS can create orders (reflex testing?), how would the order be sent to the LIS? What user code would be used to indicate who entered the order? What are the legal/regulatory implications?

- **The LAS will send add-on orders and canceled orders to the LIS. The order will reflect the LAS as the originator of the order. The "rule" that determines if an order or cancellation is to occur, it must be authorized by the institution, the medical staff, and the laboratory. The LAS will only enter reflex orders that are permitted by rules established by the institution and residing in the LIS or a related system.**

96. The standard states that if "specimen receipt" occurs on the LAS, the LAS should notify the LIS via a status update message. Where is that message segment? The SAC-7 field, Container Status, does not appear to support this kind of information. I know of no other HL7 segment that would support this information. Specimen receipt functionality is totally within an LIS.

- **(a) The LAS could send an MSH, PID, PV1, ORC, and OBR sequence that would value the status of the OBR-25 (Result Status) to show I = Specimen Received (refer to HL7 Data Definition Table Number 123) and also value the OBR Sequence OBR-14 (Specimen Received Date/Time). This technique would work if the LAS had previously received the orders. If the LAS were dependent on specimen receipt to cause/trigger orders to be sent from the LIS to the LAS, the user could be faced with a "catch-22" situation. To avoid this, the LAS must send a query to the LIS, requesting the orders which in turn could set the order status as "specimen received."**

  (b) The notification functionality is provided in the SAC as I = Identified in the Container Status Table. The subcommittee has revised Section 6.3.3.8, "Container Status."

Section 7.2.7 (now Section 8.2.7)

97. The standard states that additional tests can be ordered by the LAS when there is "enough specimen remaining" to perform the test. I do not see how either the LIS or LAS will be able to determine that information.

- **LAS vendors, along with other laboratory component manufacturers, have or will have devices that have the capability to "measure" the quantity of specimen in a specimen container. Instrument manufacturers can pass the amount of specimen that was used by the instrument. It would be the LAS's responsibility to keep track of the remaining amount of specimen, only if that LAS had the ability to reroute a specimen container for additional testing.**

Section 7.2.8 (now Section 8.2.8)

98. This states that the LAS requires a one-to-one match of codes between the LAS and LIS. I know there are some current instruments that use the same test code for a single analyte whether testing blood, urine, csf, etc. How will this be considered? These instruments may or may not use a secondary identifier that would indicate the specimen type; however, it is NOT part of the test code in the instrument.

- **Section 7.2.8 has been revised to address LOINC codes. The OBR contains the specimen source in OBR-15 (refer to HL7 Data Definitions Table 0070), and this information is forwarded to the LAS from the LIS. The LAS sends this information to the instrument in the**

SAC segment in SAC-5 specimen source. The instruments in question are outside the scope of this document.

Section 7.3.1 (now Section 8.3.1)

99. The last paragraph refers to the OBR segment and then states that the flag should be at the test level. Wouldn't a test level status have to be in the OBX record?

- **The OBR identifies the test; the OBX identifies the result so flags are at the OBR level. OBR-25 result status uses values defined in HL7 Data Definitions Table 0123. The reason that the status needs to be at the test/component level is that some instruments send results on individual tests as soon as they are completed. Other tests from the same specimen on that instrument may be pending.**

Section 7.5 (now Section 8.5)

100. File synchronization – HL7 provides very limited capability for these functions. Most LISs currently do not have the ability to export this information to another system. Due to the database designs between various LIS vendors and LAS vendor, I believe this would be extremely difficult to accomplish, but it is a desirable goal.

- **The subcommittee agrees with the comment. The development of the standard has focused on the future and has not been constrained by present capabilities.**

Summary of Delegate Voting Comments and Subcommittee Responses

AUTO3-A: *Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard*

1. This standard seems unnecessary as well. These automated systems are so expensive that for most laboratories, it will never be a reality. The manufacturers have standardized with each other and the specimen tubes. For such a small audience, why have a standard?

   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 is well educated on the subject. 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 CTASSC, the NCCLS Area Committee on Laboratory Automation, a broad spectrum of NCCLS's constituency, and other interested groups, including worldwide interests expressed at both World Lab and the Cherry Blossom Symposium (1998 and 2000), have agreed that this standard is necessary and, in fact, all agree that HL7 is the mechanism by which this standardization should occur. The manufacturers have not standardized with each other. This is, of course, the reason that these organizations, as well as hospitals and other supporters, contributed funds to support NCCLS's automation-standards initiative. The audience is not small, and depending upon the evolution of the technology, which we believe is supported by the NCCLS standards, will be significant (estimated, 1,500 to 2,500 operating automation installations of various sizes and shapes) in North America. The price points have also changed dramatically.**

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

- **The interrelated collection of automation documents was written and developed in a slightly 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*

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

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

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.

GP2-A3 **Clinical Laboratory Technical Procedure Manuals – Third Edition; Approved Guideline (1996)**. This document provides guidance for the patient-testing community by addressing the design, preparation, maintenance, and use of paper or electronic technical procedure manuals.

GP18-A **Laboratory Design; Approved Guideline (1998).** This guideline provides a foundation of information about laboratory design elements that can be used to help define the issues being considered when designing a laboratory.

GP19-A **Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline (1995).** This document identifies important factors that designers and laboratory managers should consider when developing new software-driven systems and selecting software user interfaces. Also included are simple rules to help prepare validation protocols for assessing the functionality and dependability of software.

* 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 ($-/+_B$) 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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NCCLS...

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

- the authorization of a project
- 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.

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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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Healthcare professionals in all specialties are urged to volunteer for participation in NCCLS projects. Please contact the NCCLS Executive Offices for additional information on committee participation.

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