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AUTO05-A

Laboratory Automation: Electromechanical Interfaces; Approved Standard

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This document provides standards for the development of an electromechanical interface between instruments and specimen processing and handling devices used in automated laboratory testing procedures.

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

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

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Laboratory Automation: Electromechanical Interfaces; Approved Standard

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Abstract

CLSI document AUTO05-A—*Laboratory Automation: Electromechanical Interfaces; Approved Standard* defines a standard connection between instruments and specimen processing and handling devices (including automated centrifuges, automated aliquoters, specimen integrity devices, and automated storage and retrieval systems) and automation systems. The user of the technology can thus create an optimally functioning automated laboratory environment. The issues addressed include:

- optimal configuration of the transport system in relation to the instrument;
- relationship of the instruments and/or specimen processing and handling devices to different types of transportation referenced to a defined point of reference (POR) (e.g., automated guided vehicles or "AGVs," conveyors, and other mechanisms);
- responsibility for positioning of the specimen container in relation to the transport system and instrument;
- communication between the instruments and specimen processing and handling devices and the electromechanical interface transportation mechanism; and
- safety issues related to operation.

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Foreword

In 1996, NCCLS formed the Area Committee on Automation to develop global standards for automated laboratory systems that would result in automated system components that could be integrated into a laboratory, independent of manufacturer. Additionally, the area committee would foster communication of related issues and developments worldwide. These standards are developed to be flexible, such that they accommodate the needs of current systems as much as possible, but are targeted primarily toward future generations of laboratory automation equipment. Five interrelated standards were developed simultaneously to ensure that all aspects of automation were addressed as well as to ensure interconnectivity of the resulting designs.

AUTO05-A, *Laboratory Automation: Electromechanical Interfaces* was developed because the electromechanical interface between the instruments and specimen processing and handling devices and transportation systems is a critical part of the cost-effective manufacture, implementation, and operation of laboratory automation technology. The development of a standard**,** compatible connection between the instruments and specimen processing and handling devices and the automation systems should enable the user of the technology to create an automated laboratory environment that will function optimally for the user's individual laboratory.

In order to develop a standard that is truly global, input from all involved partiesXincluding instrument and specimen processing and handling device manufacturers, automation systems manufacturers and designers, government agencies, and laboratoriansXis necessary and has been sought. Representatives from all these arenas have participated in and contributed to the development and review of this standard. These individuals constitute the audience for this document, and we are grateful for their input. This has been an open process, and all viewpoints were considered valid and important.

These specifications are also intended to complement the 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;*
AUTO3—*Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems;* and
AUTO4—*Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements.*

Key Words

Clearance zones, instrument or specimen processing and handling device, laboratory automation system (LAS), point of reference (POR)

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Laboratory Automation: Electromechanical Interfaces; Approved Standard

1 Introduction

Because the electromechanical interface between laboratory instruments and specimen processing and handling devices and transportation systems is a critical part of the cost-effective manufacture, implementation, and operation of laboratory automation technology, the NCCLS Area Committee on Automation and the Subcommittee on Electromechanical Interfaces developed this standard. The area committee and subcommittee believe that a standard**,** compatible connection between the instruments and specimen processing and handling devices and the automation systems will enable the user of the technology to create an optimally functioning automated laboratory environment.

2 Scope

Issues to be addressed in this standard include the optimal orientation of the transportation system in relation to the instrument and specimen processing and handling devices; relationship of the electromechanical interface to different types of transportation (e.g., automated guided vehicles, conveyors, and other transportation mechanisms) referenced to a defined point of reference; responsibility for positioning of the specimen container/specimen carrier in relation to the transportation system and instrument and specimen processing and handling devices; communication between the instruments and specimen processing and handling devices and the electromechanical interface/transportation mechanism; and safety and ergonomic issues related to operation.

Several issues were considered important to the proper functioning of the electromechanical interface, but were better addressed by one of the other interrelated standards. These issues include the placement of the bar-code label on the specimen container (AUTO2); specimen containers which would be supported (AUTO1); and communication between the laboratory automation system and the instrument and specimen processing and handling devices (AUTO3).

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*; AUTO3—*Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems*; and AUTO4—*Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements*.

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.

[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.

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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/Initialism for American National Standards Institute; **NOTE:** ***In Automation,*** the Microsoft Windows ANSI character set is composed of ISO 8859/x plus additional characters.

ASTM, *n* – The official name of the organization formerly known as the American Society for Testing and Materials; **NOTE:** ASTM has developed various high- and low-level communications protocols.

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

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

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

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

Bar code, *n* – **1)** An array of parallel rectangular bars and spaces that creates a symbology representing a number or alphanumeric identifier; **2)** An array of rectangular lines and spaces that are arranged in a predetermined pattern following unambiguous rules and representing data that are referred to as characters ***(ASTM F1156*** [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.**

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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

AUTO3 **Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems.** This document provides standards to facilitate accurate and timely electronic exchange of data and information between the automated laboratory elements.

AUTO4 **Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements.** This document provides standards of interest to operators for display of system status information such as specimen location, reagent supply, and warnings and alerts to support laboratory automation operations.

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.

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* Proposed- and tentative-level documents are being advanced through the NCCLS consensus process; therefore, readers should refer to the most recent editions.

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Related NCCLS Publications (Continued)

H18-A2 **Procedures for the Handling and Processing of Blood Specimens; Approved GuidelineXSecond 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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