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March 2001

AUTO04-A

Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements; Approved Standard

This document describes operational requirements, characteristics, and required information elements of clinical laboratory automation systems. This information is used to determine the status of a clinical specimen within the clinical laboratory automation system, as well as the status of the actual components of the clinical laboratory automation system.

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

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Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements; Approved Standard

Volume 21 Number 4

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Abstract

CLSI document AUTO04-A—*Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements; Approved Standard* defines operational requirements, characteristics, and required information elements of clinical laboratory automation systems to support continuous, uninterrupted operation with appropriate human intervention. The standard is divided into two parts. The first part of this document was developed to serve as a standard describing elements which will facilitate the rapid determination of the status of a clinical specimen within a clinical laboratory automation system. The second part of this document was developed to serve as a standard describing elements which will facilitate the rapid determination of the status of the components of a clinical laboratory automation system.

CLSI. *Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements; Approved Standard*. CLSI document AUTO04-A (ISBN 1-56238-431-7). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2001.

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Matrix of NCCLS Laboratory Automation Standards

The laboratory automation standards documents, AUTO1, AUTO2, AUTO3, AUTO04, 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.

SAMPLE

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 containers 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.
- 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 (\bar{x}_B) method.
- M29-A** **Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue; Approved Guideline (1997).** A consolidation of M29-T2 and I17-P, this document provides guidance on the risk of transmission of hepatitis viruses and human immunodeficiency viruses in any laboratory setting; specific precautions for preventing the laboratory transmission of blood-borne infection from laboratory instruments and materials; and recommendations for the management of blood-borne exposure.
- NRSCL8-A** **Terminology and Definitions for Use in NCCLS Documents; Approved Standard (1998).** This document provides standard definitions for use in NCCLS standards and guidelines, and for submitting candidate reference methods and materials to the National Reference Systems for the Clinical Laboratory (NRSCL).

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