CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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AUTO03-A2

Laboratory Automation: Communications With Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard—Second Edition

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 Clinical and Laboratory Standards Institute consensus process.

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Laboratory Automation: Communications With Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard—Second Edition

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Abstract

Clinical and Laboratory Standards Institute document AUTO03-A2—*Laboratory Automation: Communications With Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard—Second Edition* 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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Committee Membership

Area Committee on Automation and Informatics

Contents

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Matrix of CLSI Laboratory Automation Standards

The CLSI laboratory automation standards AUTO01,[1] AUTO02,[2] AUTO03, AUTO04,[3] and AUTO05[4] 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 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 the matrix on the next page.)

The numbers listed on the horizontal (X) and vertical (Y) axes contain multiple-digit numbers [eg, (1)5.4, (5)5.4.1.3].

The 'first digit' (in parentheses) represents one of the five automation documents [eg, (1)5.4 is from AUTO01; (5)5.4.1.3 is from AUTO05].

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 CLSI Laboratory Automation Standards

This matrix cross-links sections from CLSI documents AUTO01,[1] AUTO02,[2] AUTO03, AUTO04,[3] and AUTO05.[4]

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Foreword

Clinical laboratory automation is defined as the integration of laboratory personnel and analytical (examination), preanalytical (preexamination), postanalytical (postexamination), and computer systems to positively benefit the health care 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 System (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 CLSI standards developed by other automation subcommittees and support overall operational goals for future development in laboratory instrumentation and automation: AUTO01,[1] AUTO02,[2] AUTO04,[3] and AUTO05.[4]

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

This document replaces the first approved edition, AUTO03-A, which was published in 2000. Several changes were made in this edition; chief among them is incorporation of Chapter 13 of Health Level 7 (HL7) 2.6 that includes major changes resulting from the introduction of new segments SFT (software segment defined in Chapter 2 of HL7) and SPM (specimen segment defined in Chapter 7 of HL7). Appendix B from the first version was removed.

Because future editions of this AUTO03 standard may not necessarily coincide with the revision of HL7, readers will be referred to the current version 2.x of HL7.

Key Words

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

Laboratory Automation: Communications With Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard—Second Edition

1 Scope

This standard provides a protocol for communications between Laboratory Automation Systems (LASs), Laboratory Information Systems (LISs), automated instruments (analyzers), and pre- and postanalytical (pre- and postexamination) automated devices. The primary audience for this standard is health care providers in the clinical laboratory implementing laboratory automation, vendors of laboratory automation, instrumentation, and LISs. However, in the future, elements of this standard may be applicable to 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 (nonautomated) areas such as small analyzers or point-of-care devices.

This standard fits into the series of interrelated CLSI automation standards (AUTO01,[1] AUTO02,[2] AUTO04,[3] and AUTO05[4]).

1.1 Limitations

This standard focuses 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.

2 Introduction

Clinical laboratory automation is defined as the integration of laboratory personnel and analytical (examination), pre- and postanalytical (pre- and postexamination), and computer systems to positively benefit the health care 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 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.

2.1 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 in the next section.

(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).