CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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LIS01-A2

Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems; Approved Standard—Second Edition

This document describes the electronic transmission of digital information between clinical laboratory instruments and computer systems.

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

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Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems; Approved Standard—Second Edition

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Abstract

CLSI document LIS01-A2—*Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems; Approved Standard—Second Edition* describes the electronic transmission of digital information between clinical laboratory instruments (those that measure one or more parameters from one or multiple samples) and computer systems (those that are configured to accept instrument results for further processing, storage, reporting, or manipulation).

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Foreword

In 2001, ASTM Committee E31 decided to restructure its operations, with the intent of focusing on standards-development issues such as security, privacy, and the electronic health record. Part of the reorganization plan was to transfer responsibility for E31.13 standards to CLSI, then known as NCCLS.

Following this transfer, nine standards (formerly ASTM E792; E1029; E1238; E1246; E1381; E1394; E1466; E1639; and E2118) were redesignated as CLSI/NCCLS standards LIS1 through LIS9.[1-8] This collection of standards provides a wide variety of information relating to clinical laboratory computer systems. Some included documents are of general interest as reference sources; others represent specifications of primary importance to instrument manufacturers. LIS2 is a revision of the former ASTM E1381-02.

The Area Committee on Automation and Informatics has assumed responsibility for maintaining the documents and will revise or update each document in accord with the CLSI Administrative Procedures. The area committee prioritized LIS1-A as the second standard from this collection to be updated, incorporated into the CLSI document template, and advanced through the CLSI consensus process. The area committee will revise other documents in the series in a similar manner.

With the transfer of the former ASTM standards, the Area Committee on Automation and Informatics has expanded its mission statement to include laboratory information systems. In the future, the area committee will develop additional standards addressing informatics issues, as well as issues related to the integration of patient clinical data.

This document replaces the first edition of the approved guideline, LIS1-A, which was published in 2003. Several changes were made in this edition; among them, TCP/IP communication is now included (Sections 4.4 and 4.5) and the state diagram was replaced (see Appendix A) so it is consistent with the text of the document.

The revisions in this edition of the LIS01 standard are also intended to delineate this document from its former ASTM edition. The title and text have been revised throughout to indicate that this standard applies to clinical laboratory instruments. The term *computer* has been replaced with the term *information* to better reflect the current terminology (ie, LIS) and the headings of Sections 6 and 8 have been changed to make them more specific.

Key Words

data link layer, physical layer, serial binary data exchange, TCP/IP data exchange

Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems; Approved Standard—Second Edition

1 Scope

This specification describes the electronic transmission of digital information between clinical laboratory instruments and computer systems.

This specification addresses the low-level protocol used for both serial binary data exchange and TCP/IP data exchange. For message content in the interface between clinical instruments and computer systems, reference CLSI/NCCLS document LIS2.[1]

2 Introduction

The clinical laboratory instruments under consideration are those that measure one or more parameters from one or more patient samples. Often they will be automated instruments that measure many parameters from many patient samples. The computer systems considered here are those that are configured to accept instrument results for further processing, storage, reporting, or manipulation. This instrument output may include patient results, quality control results, and other related information. Typically, the computer system will be a clinical laboratory information management system (CLIMS).

The terminology of the International Organization for Standardization (ISO) Reference Model for Open Systems Interconnection (OSI) is generally followed in describing the communications protocol and services.[9] The electrical and mechanical connection between instrument and computer is described in the Physical Layer sections (see Sections 5 and 7). The methods for establishing communication, error detection, error recovery, and sending and receiving of messages are described in the Data Link Layer sections (see Sections 6 and 8). The data link layer interacts with higher layers in terms of sending and receiving "messages," handles data link connection and release requests, and reports the data link status.

3 Terminology

3.1 **receiver** – the device that responds to the sender and accepts the message.

3.2 **sender** – the device that has a message to send and initiates the transmission process.

3.3 The parts of a communication between instrument and computer are identified by the following terms. The parts are hierarchical and are listed in order of most encompassing first.

3.3.1 **session** – a total unit of communication activity, used in this standard to indicate the events starting with the establishment phase and ending with the termination phase, as described in subsequent sections.

3.3.2 **message** – a collection of related information on a single topic, used here to mean all the identity, tests, and comments sent at one time; **NOTE:** When used with CLSI/NCCLS document LIS2,[1] this term means a record as defined by CLSI/NCCLS document LIS2.[1]

3.3.3 **frame** – a subdivision of a message, used to allow periodic communication housekeeping, such as error checks and acknowledgments.

Related CLSI Reference Materials*

AUTO3-A **Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard (2000).** This document provides standards to facilitate accurate and timely electronic exchange of data and information between the automated laboratory elements.

LIS2-A2 **Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems; Approved Standard—Second Edition (2004).** This document covers the two-way digital transmission of remote requests and results between clinical laboratory instruments and information systems.

* Proposed-level documents are being advanced through the Clinical and Laboratory Standards Institute consensus process; therefore, readers should refer to the most current editions.

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