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LIS02-A2

Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems; Approved Standard—Second Edition

This document covers the two-way digital transmission of remote requests and results between clinical laboratory instruments and information systems.

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

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Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems; Approved Standard—Second Edition

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Abstract

Clinical and Laboratory Standards Institute document LIS02-A2—*Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems; Approved Standard—Second Edition* addresses the two-way digital transmission of remote requests and results between clinical laboratory instruments and information systems. It enables any two such systems to establish a logical link for communicating text to send result, request, or demographic information in a standardized and interpretable form.

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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 NCCLS.

Following this transfer, nine standards (formerly ASTM E792; E1029; E1238; E1246; E1381; E1394; E1466; E1639; and E2118) were redesignated as NCCLS standards LIS1 through LIS9. This collection of former ASTM 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. LIS02 is a revision of the former ASTM E1394-97.

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 NCCLS Administrative Procedures. The area committee prioritized LIS2-A as the first standard from this collection to be updated, incorporated into the NCCLS document template, and advanced through the NCCLS 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.

The revisions in this version of the LIS02 standard are intended to delineate this document from the former ASTM version of this standard. 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 (i.e., LIS).

Key Words

Component field, delimiter, field, message, record, repeat field

Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems; Approved Standard—Second Edition

1 Scope

This standard covers the two-way digital transmission of remote requests and results between clinical laboratory instruments and information systems. It is intended to document the common conventions required for the interchange of clinical results and patient data between clinical laboratory instruments and information systems. This standard specifies the message content for transferring information between a clinical laboratory instrument and an information system. It enables any two such systems to establish a logical link for communicating text to send result, request, or demographic information in a standardized and interpretable form. This standard does not necessarily apply to general analytical instruments in an industrial analytical setting, or to a research and development setting.

This standard is intended to apply to the structure of messages exchanged between clinical laboratory instruments and information systems by means of defined communications protocols. Low-level communications protocols and data transfer requirements are beyond the scope of this standard. A separate specification is available detailing a standard for low-level data transfer communications (see NCCLS document LIS1—*Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems*).

This standard specifies the conventions for structuring the content of the message and for representing the data elements contained within those structures. It is applicable to all text-oriented clinical instrumentation. It has been specifically created to provide common conventions for interfacing computers and instruments in a clinical setting. It would also be applicable to interfacing instruments in clinical practice settings, such as physicians' offices, clinics, and satellite laboratories. The intended users of this standard are developers of clinical laboratory information systems and clinical laboratory managers.

2 Definitions

Battery – A group of tests ordered together, for example, an admitting battery; **NOTES:** a) The term *battery* is used in the document synonymously with the term *profile* or *panel*; b) The test elements within a battery may be characteristic of a single physiologic system, for example, liver function tests, or many different physiologic systems; c) The battery is simply a convention by which a user can order multiple tests by specifying a single name.

Component field – A single data element or data elements which express a finer aggregate or extension of data elements which precede it, for example, parts of a field or repeat field entry; **NOTES:** a) As an example, the patient's name is recorded as last name, first name, and middle initial, each of which is separated by a component delimiter; b) Components cannot contain repeat fields.

Download – Data transmitted from an information system to a clinical instrument.

Field – One specific attribute of a record which may contain aggregates of data elements further refining the basic attribute.

Message – A textual body of information consisting of a header (H) record through a message terminator (L) record.

Record – An aggregate of fields describing one aspect of the complete message.

Related NCCLS Publications

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.

LIS1-A **Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems (2003).** This specification describes the electronic transmission of digital information between the 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).

LIS3-A **Standard Guide for Selection of a Clinical Laboratory Information Management System (2003).** This guide covers the selection, purchase, use, enhancement, and updating of computer technology supplied by a vendor as a complete system in the clinical laboratory. The purpose of the guide is to assist hospitals, clinics, and independent laboratories through the entire automation project in order to minimize the risks and maximize the benefits. It also includes checklists of items and design aids to be considered at each stage of planning to assist in carrying out the project.

LIS4-A **Standard Guide for Documentation of Clinical Laboratory Computer Systems (2003).** This guide covers documentation (defined as the information needed to install, use, maintain, or modify the system) for a computer system operating in a clinical laboratory.

LIS5-A **Standard Specification for Transferring Clinical Observations Between Independent Computer Systems (2003).** This specification details how clinical observations can be transferred between independent computer systems.

LIS6-A **Standard Practice for Reporting Reliability of Clinical Laboratory Information Systems (2003).** This practice describes a system for collecting data, maintaining records, and reporting on the reliability of operating clinical laboratory computer systems. The reliability measure will be achieved by documenting the number, severity, cause, impact, and duration of the failures that a system experiences. This practice can be implemented with paper forms or computer records.

LIS8-A **Standard Guide for Functional Requirements of Clinical Laboratory Information Management Systems (2003).** This guide covers the capabilities needed for a Clinical Laboratory Information Management System (CLIMS). It was written so that both vendors/developers of CLIMS and laboratory managers would have a common understanding of the requirements and logical structure of a laboratory data system. This guide will also provide more uniformity in the way that requirements are expressed from one laboratory to another.

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