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# Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems

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

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# NCCLS...

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NCCLS is an international, interdisciplinary, nonprofit, standards-developing, and educational organization that promotes the development and use of voluntary consensus standards and guidelines within the healthcare community. It is recognized worldwide for the application of its unique consensus process in the development of standards and guidelines for patient testing and related healthcare issues. NCCLS is based on the principle that consensus is an effective and cost-effective way to improve patient testing and healthcare services.

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- the revision of documents in response to comments by users
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the need for field evaluation or data collection, documents may also be made available for review at an intermediate (i.e., "tentative") consensus level.

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### VOLUNTEER PARTICIPATION

Healthcare professionals in all specialties are urged to volunteer for participation in NCCLS projects. Please contact the NCCLS Executive Offices for additional information on committee participation.

## **Preface**

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 explore the option of transferring responsibility for nine E31.13 standards to NCCLS.

The NCCLS Area Committee on Automation and Informatics, at its meeting in April 2002, reached a positive assessment of the value of the ASTM standards and encouraged the NCCLS Executive Offices staff to pursue negotiations with ASTM on transferring these standards to NCCLS.

Following this transfer, these nine standards (formerly ASTM E792; E1029; E1238; E1246; E1381; E1394; E1466; E1639; and E2118) have been redesignated as NCCLS standards LIS1 through LIS9.

The Area Committee on Automation and Informatics has assumed responsibility for maintaining the documents and will revise or update each document in accord with NCCLS Administrative Procedures.

This document is the equivalent of ASTM E1381-02 but has been redesignated and is now maintained by NCCLS. This document has been approved as an American National Standard (ANSI/ASTM E1381-02).

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## Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems

### 1. Scope

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

1.2 The terminology of the Organization for International Standards (ISO) Reference Model for Open Systems Interconnection (OSI) is generally followed in describing the communications protocol and services. The electrical and mechanical connection between instrument and computer is described in the Physical Layer section. The methods for establishing communication, error detection, error recovery, and sending and receiving of messages are described in the Data Link Layer section. The data link layer interacts with higher layers in terms of sends and receives "messages," handles data link connection and release requests, and reports the data link status.

1.3 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 NCCLS document LIS1-A. Topics are found in the following sections:

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