CLINICAL AND LABORATORY STANDARDS INSTITUTE®

1st Edition

AUTO16

Next-Generation *In Vitro* Diagnostic Instrument Interface

This standard applies to the exchange of analytical testing data between *in vitro* diagnostic instruments and health care informatics systems.

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

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Next-Generation *In Vitro* Diagnostic Instrument Interface

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Abstract

Clinical and Laboratory Standards Institute standard AUTO16—*Next-Generation* In Vitro *Diagnostic Instrument Interface* defines a connectivity standard based on the Laboratory Analytical Workflow (LAW) Profile[1] of the Integrating the Healthcare Enterprise organization, which originated from the work of the IVD Industry Connectivity Consortium. In addition to the LAW Profile, this standard includes implementation and integration guidance, security considerations, examples, and other supplemental information. The intended users of this standard are *in vitro* diagnostic system manufacturers, as well as the personnel and information technology management of medical laboratories.

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Contents

Foreword

This standard is a successor to CLSI documents LIS01[2] and LIS02[3] (see Appendix A for a description of differences) for the next generation of *in vitro* diagnostic (IVD) instruments and discusses the connectivity challenges present in medical laboratories. This standard leverages the work of the IVD Industry Connectivity Consortium and Integrating the Healthcare Enterprise (IHE) organizations through the use of the Laboratory Analytical Workflow (LAW) Profile. Benefits of this new IVD system connectivity protocol include:

- Improved interoperability through the use of modern health care connectivity protocols and network technologies
- A more consistent interface across instruments with differing capabilities
- Substantial reduction in connectivity installation cost and time
- Improved integrity of patient result data
- Standardized data flow of IVD patient and quality control test work order steps and results between instrument, middleware, and laboratory information systems or laboratory automation systems
- Support for common testing workflows, such as rerun and reflex testing
- The availability of extensive resources for use during implementation and testing

In addition, this standard supplements the LAW Profile by:

- Providing guidance to vendors on implementing the LAW Profile
- Providing guidance to health care providers on integrating IVD systems implementing the LAW Profile
- Consolidating the LAW elements of the IHE Laboratory Technical Framework to improve profile usability
- Offering guidance on securing the interface

NOTE: The content of this standard is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

Key Words

Analyzer, HL7, IHE, interoperability, interface, IVD instrument, LAW Profile, security

Uses of HL7®, LOINC®, CDA®, and SNOMED CT® in this standard are not endorsements on the part of CLSI.

Next-Generation *In Vitro* Diagnostic Instrument Interface

Chapter 1: Introduction

This chapter includes:

- Standard's scope and applicable exclusions
- Background information pertinent to the standard's content
- "Note on Terminology" that highlights particular use and/or variation in use of terms and/or definitions
- Terms and definitions used in the standard
- Abbreviations and acronyms used in the standard

1.1 Scope

This standard specifies requirements for the data exchange associated with the analytical workflow between medical laboratory *in vitro* diagnostic (IVD) instruments and the systems managing their work. This data exchange includes test orders and test results for both patients and QC specimens. Additional guidance is also provided to aid in the standard's adoption and implementation. This standard applies to all medical laboratory specialties (including blood bank testing). The intended users of this standard are IVD instrument vendors, IVD software systems vendors (LIS and middleware), and medical laboratory information technology (IT) personnel. This standard:

- Does not apply to point-of-care information exchange, which is already standardized by CLSI document POCT01[4]
- Does not apply to imaging information exchange, which is already standardized by digital imaging and communications in medicine (DICOM)
- Is not intended to standardize the features of IVD instruments or IVD software systems, only their external connectivity
- Does not apply to communication between systems already covered by other Integrating the Healthcare Enterprise (IHE) profiles (ie, laboratory testing workflow [LTW] and laboratory device automation [LDA])
- Does not cover calibration data, configuration information, standardization of test or analyte nomenclature (eg, LOINC®[a] [Logical Observation Identifiers Names and Codes]), or process status monitoring
- Does not discuss data privacy requirements

[a] LOINC® is a registered US trademark of Regenstrief Institute, Inc.

1.2 Background

Laboratories and their vendors spend a substantial amount of time and money connecting analyzers and IT systems to one another. This is a worldwide challenge resulting from inconsistency in the way data exchange standards are applied in most modern laboratory equipment.

The purpose of the IHE Laboratory Analytical Workflow (LAW) Profile is to improve interoperability between IVD testing systems and health informatics systems by reducing complexity and variability in the exchange of information related to patient and QC test orders and to the results thereof. The IHE LAW Profile provides the following capabilities, most of which are not supported by CLSI documents LIS01[2] and LIS02[3]:

- Support for immunoassay, clinical chemistry, hematology, microbiology, and molecular testing
- Unique identification of each order request at the test or test panel level
- Improved query for orders
- Selection of query as the default mode
- Simplified order download
- Ability for an analyzer to accept or reject orders
- Improved device and disposable identification for test logging
- Contributing substance identification for test logging
- Basic and enhanced message interface to support IVD instrument rule evaluation
- Support for LOINC® to identify test requests and observations
- Unique identification of each reported observation and differentiation between runs of the same test
- Support for hematology images, graphs, and plots
- Support for transmission of raw values

1.2.1 History

The existing CLSI documents LIS01[2] and LIS02[3] were developed when laboratories connected IVD instruments to IVD software systems over serial RS-232 electronic connections. A limited amount of data was exchanged so that the IVD software system could collect test results from the IVD instrument and report the results to other health care systems.

The laboratory environment has changed dramatically and now demands an exchange of greater amounts of data. IVD instrument vendors created specialized interfaces based on CLSI document LIS02,[3] which supported their instrument data. Thus, IVD software systems must support numerous but distinct interfaces based on CLSI document LIS02[3] to communicate with the variety of IVD instruments deployed at a facility. Laboratories must validate these unique interfaces every time a new analyzer is installed and often encounter lengthy implementation cycles before they can go test-of-record. Connecting an IVD instrument to an IVD software system has become a challenging and time-consuming activity for vendors and health care organizations (HCOs), creating barriers to integration and interoperability.

In response to this challenge, IVD industry vendors formed the IVD Industry Connectivity Consortium (IICC) to eliminate the gaps in instrument interfaces based on CLSI documents LIS01[2] and LIS02[3] (see Appendix A). IICC worked with several standards organizations to develop an interoperability standard that provides plug-and-play connectivity between IVD analyzers and IT systems, eliminating the need for unique analyzer interfaces.

Chapter 2: Implementation Roadmaps

This chapter includes:

- Vendor guidance on implementing the LAW Profile interface on:
  - IVD instruments (ie, analyzer)
  - IVD software systems (ie, analyzer manager)
- Vendor and HCO guidance on integrating LAW Profile–conforming IVD systems

2.1 Vendor Guidance on Implementing the Laboratory Analytical Workflow Profile Interface

2.1.1 Becoming Familiar With HL7® v2.x Fundamentals

Because AUTO16 and the IHE LAW Profile use HL7® v2.5.1[5] as a baseline standard (with a few adopted elements from v2.7,[14] v2.8.2,[15] and v2.9[16]), it is important to become familiar with HL7® v2.x fundamentals before studying the LAW Profile. For those who need to become familiar with the HL7® v2.x fundamentals, the following resources are available:

- HL7® v2.5.1[5]:
  - Chapter 1: Introduction
  - Chapter 2: Control
  - Chapter 2.A.1: Data Types
  - Appendix A: Data Definition Tables
- HL7® v2.3.1[17]:
  - Appendix C, Section C.4: Minimal Lower Layer Protocol
- Training courses

The fundamentals to master include:

- Understanding HL7® v2.x standards
- Reading and writing HL7® v2.x messages
- Understanding message triggers

2.1.2 Becoming Familiar With Integrating the Healthcare Enterprise Fundamentals

Because AUTO16 and the IHE LAW Profile are structured and documented using IHE conventions and terminology, it is important to become familiar with IHE fundamentals before studying the LAW Profile. For those who need to become familiar with the IHE fundamentals, the following resources are available:

- General information about IHE: http://www.ihe.net/
- Information about the IHE Pathology and Laboratory Medicine (PaLM) domain: http://www.ihe.net/IHE_Domains/ and http://www.ihe.net/IHE_Pathology_and_Laboratory_Medicine/

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