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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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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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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.