CLINICAL AND LABORATORY STANDARDS INSTITUTE®

2nd Edition

CLSI AUTO16™

Next-Generation *In Vitro* Diagnostic Instrument Interface

CLSI AUTO16 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.

CLSI AUTO16-Ed2
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Replaces CLSI AUTO16-Ed1

Next-Generation *In Vitro* Diagnostic Instrument Interface

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Abstract

CLSI 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 *In Vitro* Diagnostic (IVD) Industry Connectivity Consortium. In addition to the LAW Profile, CLSI AUTO16 includes implementation and integration guidance, security considerations, examples, and other supplemental information. The intended users of CLSI AUTO16 are IVD system manufacturers, as well as the personnel and information technology management of medical laboratories.

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Contents

Foreword

CLSI AUTO16 is a successor to CLSI LIS01[2] and CLSI 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. CLSI AUTO16 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 QC test work order steps and results between instrument, middleware, and LIS 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, CLSI AUTO16 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 Pathology and Laboratory Medicine (PaLM) Technical Framework to improve profile usability
- Offering guidance on securing the interface

Overview of Changes

CLSI AUTO16-Ed2 replaces AUTO16-Ed1, published in 2019. This edition incorporates updates made to the LAW Profile as of IHE PaLM Technical Framework Revision 11.0. These updates include:

- Correcting the result predicate in LAB-29
- Clarifying the Health Level Seven version used for OBX-2
- Supporting Additional Result Identifiers in OBX-3
- Adding details for providing Container Identifier, Carrier Identifier, and Position in Carrier in a query
- Aligning conformance lengths
- Correcting the placement of PATIENT Group in LAB-29

NOTE: The content of CLSI AUTO16 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
***in vitro* diagnostic instrument**
LAW Profile
security

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[e] DICOM® is a registered trademark of the National Electrical Manufacturers Association.

Chapter 1

Introduction

Next-Generation *In Vitro* Diagnostic Instrument Interface

1 Introduction

1.1 Scope

CLSI AUTO16 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. CLSI AUTO16 applies to all medical laboratory specialties (including blood bank testing). The intended users of CLSI AUTO16 are IVD instrument vendors, IVD software systems vendors (LIS and middleware), and medical laboratory information technology (IT) personnel. CLSI AUTO16:

- Does not apply to point-of-care information exchange, which is already standardized by CLSI POCT01[4]
- Does not apply to imaging information exchange, which is already standardized by digital imaging and communications in medicine (DICOM®[a])
- 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, Logical Observation Identifiers Names and Codes [LOINC®[b]]), or process status monitoring
- Does not discuss data privacy requirements

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 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 LIS01[2] and CLSI 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

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