LABORATORY CONNECTIVITY GUIDE

The IVD Industry Connectivity Consortium (IICC) is a global, nonprofit organization that has collaborated with several government bodies and industry organizations to develop two standards that together allow for true plug & play connectivity of IVD instruments to Middleware and Laboratory Information Systems (LIS).

LAW Laboratory Analytical Workflow Profile

The LAW Profile defines the physical connection, message definitions (based on the HL7 Messaging Standard v2.5.1), and workflow definitions between instruments, middleware, and LIS systems in the laboratory. IICC collaborated with the IHE Pathology and Laboratory Medicine (PaLM) domain to develop the LAW Profile. LAW is currently being implemented by all major IVD companies.

- Support for IA, CC, 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 identification for test logging
- Contributing substance identification for test logging
- Basic and enhanced message interface to support IVD instrument
- LOINC identification of test requests and observations (LIVD)
- Unique identification of runs
- Support for hematology images, graphs, and plots
- Support for transmission of raw values
- Support for rerun and reflex testing
- HL7 2.5.1 based
- Supports LOINC® , JLAC10 , and UCUM

LAW also selected by the European Union to be part of the eHealth European Interoperability Framework (eEIF) and will be the basis for the upcoming Clinical and Laboratory Standards Institute (CLSI) AUTO16 standard for next generation In Vitro Diagnostic (IVD) instrument interfaces.

To download the LAW profile specifications go to **http://bit.ly/iicc_law**

LIVD LOINC for In Vitro Diagnostics

LIVD defines the digital publication of LOINC using vendor defined IVD tests associated with a set of predefined LOINC codes. LIVD assures that laboratory personnel select the appropriate LOINC codes for IVD test used by their laboratory. It also allows LIS systems to automatically map the correct IVD vendor test result to a LOINC code.

To download the LIVD specifications go to **http://bit.ly/iicc_livd**

LIVD was developed in collaboration with

Why are LAW and LIVD important for clinical laboratories?

LAW and LIVD should have a significant positive impact on laboratory operations. Clinical laboratories are encouraged to ask their instrument, middleware, and LIS vendors about their current or planned support for the IICC/IHE Laboratory Analytical Workflow (LAW) and LIVD.

- LAW and LIVD will significantly reduce the time and cost involved with deploying, connecting, and updating instruments in the laboratory by eliminating the need for vendor customized connectivity implementations, favoring vendors that adopt the specifications and pass the savings to their customers.
- Addresses all the shortcomings of outdated laboratory connectivity standards such as CLSI LIS1-A (ASTM 1391) and CLSI LIS2 (ASTM E1394).
- LAW will be a global standard (CLSI AUTO16).
- LAW and LIVD support federal guidelines on Meaningful Use.
- LAW and LIVD improve the integrity of patient data.

The LAW and LIVD specifications are available for download and do not require any licensing or fees for implementation.

For IVD Companies

IHE provides extensive documentation and test resources to support your efforts. IVD vendors interested in implementing and testing the LAW Profile should

1. Download the LAW Profile **http://bit.ly/ihe_law_profile**

   Additional information can be found on the IHE Pathology and Laboratory Medicine (PaLM) domain **http://bit.ly/ihe_palm**

	Before	CONCERNS	After	BENEFITS
Physical Connection	Serial port (RS-232) **ASTM E1391 (LIS1)**	· No data security - PHI exposure risk · Limited bandwidth · Limited asynchronous communications	Network (TCP/IP) **MLLP over TCP/IP**	· Network configurable data security · Up to gigabit bandwidth
Messaging Format	ASTM-E1394 (LIS2)	· Limited message exchange patterns · Vendor enhanced ASTM messaging lacks conformity · High custom interfacing cost	Hl7 v2.5.1	· Constrained message formats to 'package' clinical data · Adds support for images, plots, and resulting details
Messaging Vocabulary		· Labor intensive data mapping · High risk of errors · Data aggregation and analysis across labs impossible	**IICC LIVD**, JLAC10, or customer defined	· Universal definition of lab tests · Conform and error free data for billing and health statistics across entire health system
Workflow Definitions		· Vendor specific custom development & integration · No uniform laboratory use case definitions	**IICC/IHE LAW Profile** (CLSI AUTO16)	· Standardized Work Order Step (AWOS, WOS) and test result definitions · For patient and QC samples · Supports all laboratory disciplines (including blood bank testing) · Allows for optimal routing and scheduling of tests · Detailed specimen identification (patient/QC, pooling, time of collection, collector, and carrier/tray/plate location)

Clinical laboratory connectivity before and after LAW and LIVD

2. Implement the LAW Profile on your instrument, middleware, or LIS
3. Test your implementation online using the IHE Gazelle platform **https://gazelle.ihe.net**
4. Participate to an IHE Connectathon event in North America, Europe, or Asia **http://bit.ly/ihe_connectathon**
5. Assess the conformity of your LAW Profile implementation by an independent ISO17025 accredited laboratory **http://bit.ly/ihe_conformance**

About the IVD Industry Connectivity Consortium

The IVD Industry Connectivity Consortium (IICC) is a global, nonprofit organization that has worked with CLSI, IHE, and HL7 to accelerate the development of an interoperability standard that provides plug-n-play connectivity between instruments, middleware, and LIS systems.

Member companies include: Abbott Laboratories, A&T, Beckman Coulter, Beckton Dickinson, bioMérieux, Data Innovations, Hitachi, IZASA SA, Orchard Software, Ortho Clinical Diagnostics, Roche Diagnostics, Samsung, Siemens Healthcare Diagnostics, Sunquest Information Systems, and Systelab Technologies SA.

UPCOMING EVENTS

Japan Connectathon 2017
September 24-29, 2017
Tokyo, Japan
http://bit.ly/cjpn2017

North American Connectathon 2018
January 8-12, 2018
Cleveland, OH USA
http://bit.ly/cna2018

IHE European Connectathon 2018
April 16-20, 2017
Den Haag, Nederand
http://bit.ly/ceu2018

The IHE Connectathons are a cross-vendor, live, supervised, and structured testing event for engineers and IT architects. Participants can test their products against multiple vendors using real-world clinical scenarios contained in IHE's Integration Profiles.