ARE YOU READY FOR THE NEW INSTRUMENT INTERFACE STANDARD?

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

The IICC standard is documented in the IHE **Laboratory Analytical Workflow Profile** (LAW). This profile provides the following capabilities, most of which are not supported by the current LIS2 (ASTM) standard:

- 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/reject orders
- Improved device 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 runs
- Support for hematology images, graphs, and plots
- Support for transmission of raw values

You should plan ahead to adopt the IICC/IHE LAW profile as it

- Is a global standard
- Substantially reduces connectivity installation cost and time
- Supports federal guidelines on Meaningful Use
- Improves integrity of patient data
- Standardizes the data flow of IVD patient and QC test work order steps and results between instruments, middleware, and LIS or LAS systems
- Supports rerun and reflex testing
- Is HL7 2.5.1 based
- Supports LOINC® and JLAC10 vocabularies
- Has extensive implementation and test resources available

Laboratories should ask their vendors which of their products will support the new LAW Profile.

Participating 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.

Vendors interested in implementing and testing the new standard can participate in the **IHE Connectathons** held annually in Asia, Europe and North America, or can use **IHE Gazelle**, for online interoperability and conformance testing.

FOR MORE INFORMATION

IVD Industry Connectivity Consortium

http://www.ivdconnectivity.org

Laboratory Analytical Workflow (LAW) Information on IHE.com

http://wiki.ihe.net/index.php?title=Laboratory_Analytical_Workflow

Laboratory Analytical Workflow (LAW) testing on IHE Gazelle

http://gazelle.ihe.net/content/pre-connectathon-tests/law

UPCOMING MILESTONES	
Receive CLSI Approval for LAW Standard Development Project	Q3 2014
Publish LAW Supplement v1.4	Q3 2014
IHE Japan Connectathon	Q3 2014
Initiate CLSI Document Development Committee for LAW Standard	Q4 2014
IHE North America Connectathon	Q1 2015
Publish LAW R2 as part of IHE LAB TF	Q1 2015
IHE Europe Connectathon	Q2 2015
Publish CLSI LAW Standard	Q1 2016

IICC™

www.ivdconnectivity.org

AACC POSTER B-009

New Instrument Interface Standard to Enable Improved Interoperability with Integrated Information

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S. Jonnaert, Tensei LLC, San Clemente, CA
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PURPOSE

To create and ensure adoption of an interoperable connectivity paradigm to reduce the complexity and variability of data exchange between IVD testing systems and healthcare informatics systems.

INTRODUCTION

The In Vitro Diagnostic (IVD) Industry Connectivity Consortium (IICC) has worked with several standards organizations to develop a new interoperability (i.e. instrument interface) standard that provides plug-n-play connectivity between IVD analyzers and IT systems, eliminating the need for unique analyzer interfaces.

Currently, the Clinical and Laboratory Standards Institute (CLSI) LIS1 and LIS2 specifications (ASTM) provide limited guidance on the structure and content of the data being exchanged. These older standards are highly flexible and have been implemented in many different ways thus creating barriers to integration and interoperability. In addition laboratories must validate these unique interfaces every time a new analyzer is installed, and often encounter lengthy implementation cycles before they can go "live".

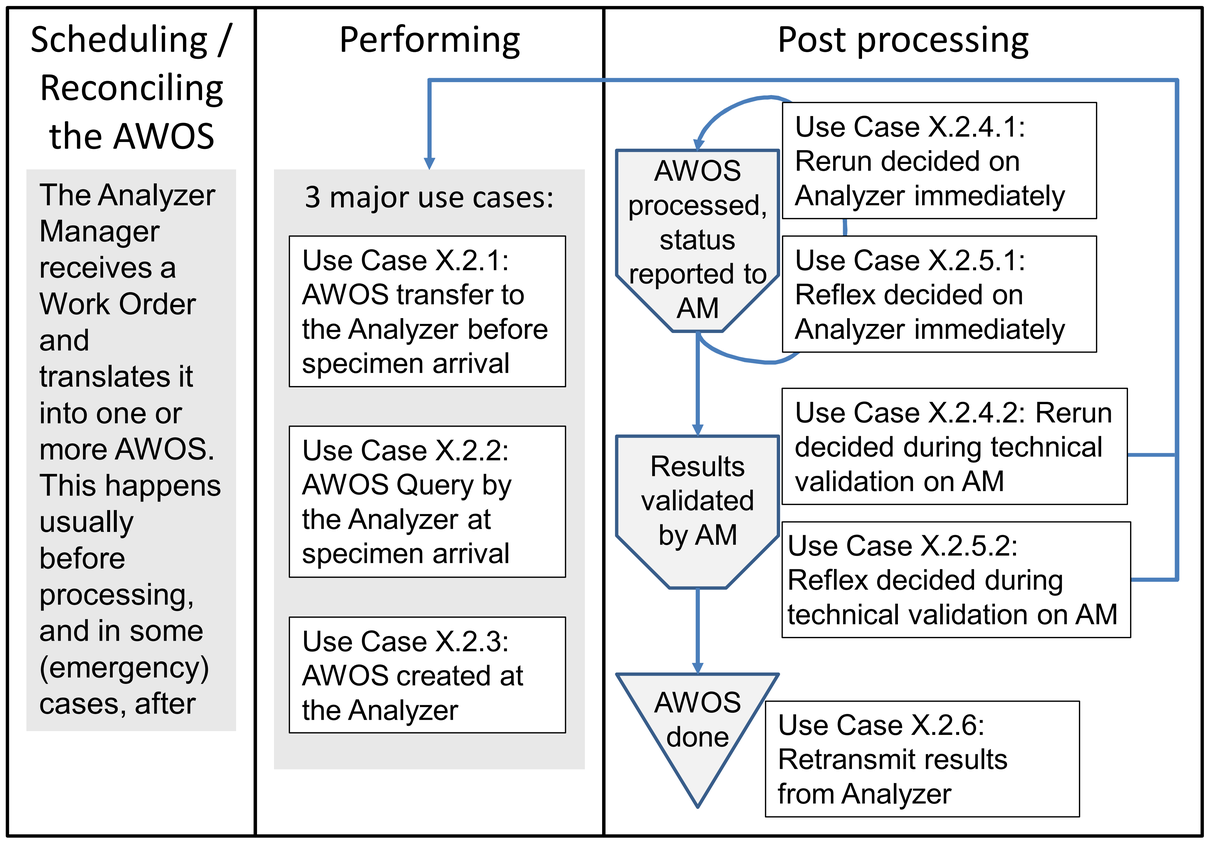

Figure 1 *Use Case Scenarios defined in the IHE Laboratory Analytical Workflow (LAW)*

METHOD

Initial analysis identified a common set of use cases that describe the common interactions between IVD instrument and IT systems *(Figure 1)*:

- Order transfer to the IVD instrument before specimen arrival
- Order query by the IVD instrument at specimen arrival
- Order created at the IVD instrument
- Transfer of results
- Rerun/reflex testing
- Retransmission of results
- QC performed on the IVD instrument
- Pooling of Patient Specimens

IICC established partnerships with the CLSI, IHE (Integrating the Healthcare Enterprise), and HL7 (Health Level 7) standards organizations in order to leverage existing work, accelerate the creation of a plug-n-play standard, and promote worldwide adoption.

The resulting IICC standard is documented in an IHE Laboratory Analytical Workflow (LAW) profile. This profile provides the following capabilities, most of which are not supported by the LIS2 (ASTM) standard:

- 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/reject orders
- Improved device identification for test logging
- Contributing substance identification for test logging
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- Support for LOINC to identify test requests and observations
- Unique identification of runs
- Support for hematology images, graphs, and plots
- Support for transmission of raw values

RESULTS

To confirm that the LAW profile could support plug-n-play connectivity, vendors representing seven IVD analyzer and three IVD IT systems participated in the IHE 2012 European and 2014 North American "Connectathons". The IHE team defined ten test cases representing major LAW scenarios and focused on immunoassay, clinical chemistry, and hematology, and microbiology testing. Each IVD analyzer tested interoperability with each IVD IT system through the execution of the test cases. The testing was monitored by IHE independent representatives. Each IVD IT system used the same interface implementation to communicate with each of the instruments.

All testing events were successfully completed, allowing all participating vendors to register an IHE Integration Statement documenting that their implementation successfully integrated with the other vendors through the use of the LAW profile *(Figure 2)*.

Completed Milestones	
Publish LAW Supplement for Trial Implementation	Q1 2012
Test LAW Profile at IHE EU Connectathon	Q2 2012
Publish LAW Supplement v1.2	Q4 2013
Demonstrate IHE Testing Infrastructure at 2013 AACC	Q2 2013
Publish LAW Supplement v1.3	Q3 2013
Test LAW at IHE Japanese Connectathon	Q3 2013
Test LAW at IHE NA Connectathon	Q1 2014
Test LAW at IHE EU Connectathon	Q2 2014

Future Milestones	
Receive CLSI Approval for LAW Standard Development Project	Q3 2014
Publish LAW Supplement v1.4	Q3 2014
Test LAW at IHE Japanese Connectathon	Q3 2014
Initiate CLSI Document Development Committee for LAW Standard	Q4 2014
Test LAW at IHE NA Connectathon	Q1 2015
Publish LAW R2 as part of IHE LAB TF	Q1 2015
Test LAW at IHE EU Connectathon	Q2 2015
Publish CLSI LAW Standard (15-month, Track 1 Document)	Q1 2016

Figure 2 *Interoperability verification events (Connectathons) and other IICC LAW milestones*

CONCLUSIONS

This new IICC instrument interface standard is now available for adoption by IVD instrument vendors (ivdconnectivity.org). Its use should greatly simplify interoperability between different IT systems in the more integrated healthcare continuum that is currently evolving under federal guidelines of "Meaningful Use".

www.ivdconnectivity.org

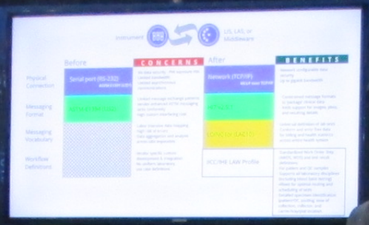
IICC

IVD Industry Connectivity Consortium

Global, nonprofit organization dedicated to creating and encouraging the adoption of a unified connectivity standard to reduce the cost and variability of data exchange between IVD devices and healthcare informatics.

IICC/IHE LAW Profile

- Global standard
- Substantially reduces connectivity installation cost and time
- Supports federal guidelines on Meaningful Use
- Improves integrity of patient test data
- Standardizes the data flow of IVD patient
- Supports
- Supports
- Extensible



www.ivdconnectivity.org

IICC

The IICC/IHE Laboratory Analytical Workflow LAW Profile is coming!

What are you waiting for?

Participating Companies

- Abbott Diagnostics
- A&T
- Beckman Coulter
- Becton Dickinson
- bioMérieux
- Data Innovations
- Hitachi
- IZASA SA
- Orchard Software
- Ortho Clinical Diagnostics
- Roche Diagnostics
- Samsung
- Siemens Medical Solutions
- Sunquest Information Systems
- Systelab Technologies SA

PROJECT PROPOSAL FORM

CLSI welcomes input from expert practitioners to identify specific topics for which a CLSI standard or guidelines is needed. Any person or organization, including CLSI committee participants or committees, may propose a new CLSI project.

Please complete this form and submit it to:
Clinical and Laboratory Standards Institute
940 West Valley Road, Suite 1400
Wayne, PA 19087-1898
E-Mail: projects@clsi.org
Fax:610.688.0700

DATE:	7/29/2014

SUBMITTER INFORMATION		PROPOSED PROJECT INFORMATION	
Name:	**Ed Heierman** **Rob Bush, Jamel Guima,** **Fred Huls, Andrzej Knafel** **Laurent Lardin**	Proposed Title: Next Generation IVD Instrument Interface	
Organization:	**Abbott Diagnostics**	Anticipated product will be (check one):	
Address:	**1921 Hurd Dr** **Irving, TX** **75038**	X	Consensus standard
			Consensus guideline
			Reference method
Telephone:	**972-518-7424**		Reference material specifications
Fax:			Other (please describe)
Email:	**ed.heierman@abbott.com**		
		Level of intended user:	
			Novice
			Intermediate
		X	Advanced

PART I:

PROPOSED PROJECT DESCRIPTION
• **Provide a rationale for the project and describe its potential impact on healthcare.** The LIS1 and LIS2 standards were developed over 20 years ago and describe specifications based on RS-232 (serial) communication for interfacing with an IVD instrument. Although later updated to support TCP/IP communication, the protocols described by the standards essentially remained the same. In addition, the variability allowed by the LIS2 standard has resulted in unique instrument vendor implementations, requiring LIS/middleware vendors to develop interfaces tailored to each specific instrument. This project proposes leveraging the work of the IVD Industry Connectivity Consortium (IICC) and Integrating the Healthcare Enterprise (IHE) organizations to publish a successor to the LIS1 and LIS2 standards. This new standard will improve IVD instrument connectivity by defining an interface that is more consistent across instruments and leverages modern healthcare connectivity protocols and network technologies.
• **Describe the scope in a draft introduction section for the proposed project.** This project would leverage the Laboratory Analytical Workflow (LAW) profile developed by the IHE

Laboratory technical committee and IICC technical team members. The LAW supplement provides use cases, transactions, data flows, HL7 messaging conventions, and HL7 message definitions. No modifications to the LAW work will be necessary.

The project would use the completed work from the IHE organization, develop a standard around the Law profile, and submit it through the CLSI consensus project. The effort to create the new standard would be significantly less than most document projects. This approach is similar to the development of AUTO3, which includes HL7 v2.x Chapter 13 as part of the standard.

PART I (continued):

- **Outline the chapter headings/topics.**

1. Introduction
2. Scope
3. Definitions
4. Background
   - Extent of challenges with the current LIS1 and LIS2 serial-based protocols
   - Collaboration of IICC, IHE, HL7
   - Analysis that led to selection of HL7 and IHE
5. Use Case/Behavior for messaging (IHE Laboratory Technical Framework Volume 1, LAW Integration Profile)
6. Message Definitions (IHE Laboratory Technical Framework Volume 2, LAW Transactions)
7. Security Considerations
8. Summary

- **Provide other important factors for consideration related to the proposed project.**

The LAW Integration Profile is under development by the IHE Laboratory technical committee. The profile is currently implemented as a Supplement for Trial Implementation, and was tested at the IHE Europe Connectathon held in May 2012 and the IHE North America Connectation held in January 2014. It is expected the profile would be published in final form in Q4 2014 and published as part of the IHE Laboratory Technical Framework in Q1 2015. It is recommended that the document development committee be formed in Q4 2014 to align with the IHE publication schedule. The DDC would have several months to establish the foundation for the standard prior to the final release of the LAW profile. The DDC will need to closely monitor the progress of the LAW profile for any delays that impact the CLSI schedule.

The IHE Laboratory Technical Framework consists of multiple volumes and supplements. The LAW profile is currently implemented as a supplement, but will eventually be incorporated into Volume 1 and Volume 2 of the technical framework. Because of the organization of the IHE technical framework documents, some analysis will be necessary to produce a clear and concise CLSI standard from the IHE and IICC work. The LAW profile does not provide any background discussions on how the new interface relates to the existing LIS1/LIS2 interfaces, or any discussions on security. This information will be important to implementers of the interface, as well as to health care providers so they understand the impact and benefits of the new interface on their laboratory environment.

IHE makes all of its profiles available free of charge. However, the CLSI standard is still necessary because it provides the following additional benefits:

- Resistance to moving from LIS1/LIS2 to a new HL7-based interface is expected. Background information will be provided on the benefits of the new interface over the existing LIS1/LIS2 interfaces that will not be available from the LAW profile.
- As noted above, the organization of the existing IHE Laboratory Technical Framework documents and content do not make it easy to review the content associated only with the implementation of an LAW conforming interface. The CLSI standard will be easier to use than the IHE Technical Framework documents.
- The security needs for IVD analyzers are greatly increased with the use of the LAW profile. Many analyzers currently only provide a serial interface to external systems. LAW requires the use of TCP/IP, which exposes the analyzer to additional threats. However, security considerations are out of scope for the LAW profile. The standard will address security by relying on AUTO11 *IT Security of In Vitro Diagnostic Instruments and Software Systems* to define security

requirements.

- The CLSI consensus process provides additional credibility to the LAW profile, because the process is more rigorous than the IHE approval process. In addition, CLSI has more recognition and customer awareness. Vendors and laboratories are more likely to look to CLSI for the standard rather than IHE because of these factors.

The development of the CLSI standard will require close coordination with IICC and IHE. However, consensus committee members Ed Heierman and Andrzej Knafel are members of IICC and IHE. These individuals have been major contributors to the LAW profile work.

This committee will also need to coordinate with the committee updating AUTO 11. Consensus committee members Ed Heierman and Andrzej Knafel are members of the document development committee updating AUTO11.

IICC is willing to fund the development of the standard, similar to how the POCT1-A standard was funded by the CIC (Connectivity Industry Consortium). IICC was formed through contributions made by its members, and these funds could be allocated to the development of the CLSI standard.

PART II:

RECOMMENDED TIMELINE FOR PROJECT DEVELOPMENT	
X	**Track 1 (no more than 15 months)**
	Track 2 (no more than 25 months)

Rationale for Track 2

PART III:

PROPOSED COMPANION PRODUCTS

Please indicate those companion products listed below that could be developed with this proposed document. The concept for potential products could be defined during the document development process. After publication of the document as an approved standard or guideline, the companion product could be prepared by CLSI staff in consultation with the committee. The objectives of developing companion products based on CLSI documents are to aid in the understanding of the documents; facilitate implementation of CLSI standards and guidelines into practice; and/or serve as handy reminders for performing and/or interpreting laboratory procedures.

- [ ] **Quick Guides** (Handy reminders that put information at the user's fingertips)
  Includes: Laminated sheets, wall charts, and pocket guides
- [ ] **Checklists** (For use in reporting completed required activities and/or assessments)
- [ ] **Video/DVD (**Instructional video presentation)
- [ ] **Toolkits (**Electronic templates)
- [ ] **Software (**Includes: Databases and software for method evaluation)
- [ ] **Educational Presentations**
- [ ] **Article in a professional journal(s) (List name of appropriate journals below):**
- [ ] **Presentations/Workshops at professional meetings (List appropriate professional organizations and associated meetings below):**

  _____

  _____
- [ ] **Web/audio conference**
- [x] **Other**
  Collaboration with IHE and IICC on press releases, articles in journals, etc.

PART IV:

INTENDED USERS FOR PROPOSED PROJECT		
Please list the intended users that would find this CLSI document valuable and identify the professional organizations in which they are likely to be actively involved and the publications to which they subscribe.		
Target Audience(s) /Intended user(s)	**Professional Organizations**	**Professional Publications**
IVD Instrument vendors		
LIS/Middleware vendors		
Clinical Laboratory IT organizations		

PART VI:

DOCUMENT DEVELOPMENT COMMITTEE MEMBERSHIP
Describe <u>specific</u> <u>expertise</u> needed on a document development committee for development of this proposal. IVD Instrument Interfaces Middleware & Laboratory Information System (LIS) Interfaces HL7 Standards IHE Laboratory Technical Framework Network Communication Protocols
CLSI follows an established "Call for Nominations" procedure for soliciting nomination from its member organizations and the public to serve on project development committees. Nominees' supporting documentation (CV and Disclosure of Interests form) are reviewed by the new project chairholder designate, and the appropriate consensus committee chairholder. Committee formation is based upon the expertise and balanced representation required for development of the new CLSI document. The document development committee roster is reviewed and approved by CLSI's President Elect and the Chairholders Council. Individuals may submit nominations or self-nominate for consideration to serve on CLSI committees. More information about volunteer opportunities is available on the CLSI (www.clsi.org)

To be completed by CLSI
PART VII: Consensus Committee Review and Recommendation Responsible Consensus Committee: Comment on intended users, impact on health care, and priority of project.

Consensus Committee Chairholder