

IICC Technical Overview

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IICC Mission

- *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*
 - Laboratory Analytical Workflow (LAW) is the culmination of the technical team's efforts to define the data exchange
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LAW Profile

- Developed in partnership with IHE Laboratory
 - Analytical Work Order Steps (AWOS) only
 - Pre (sorters, decappers) and post (cappers, storage) devices covered by Laboratory Device Automation (LDA) Profile
 - Actors
 - Analyzer (Instrument)
 - Analyzer Manager (Middleware, LIS)
 - Transactions
 - LAB-27 Query for AWOS
 - LAB-28 AWOS Broadcast
 - LAB-29 AWOS Status Change
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LAW Profile

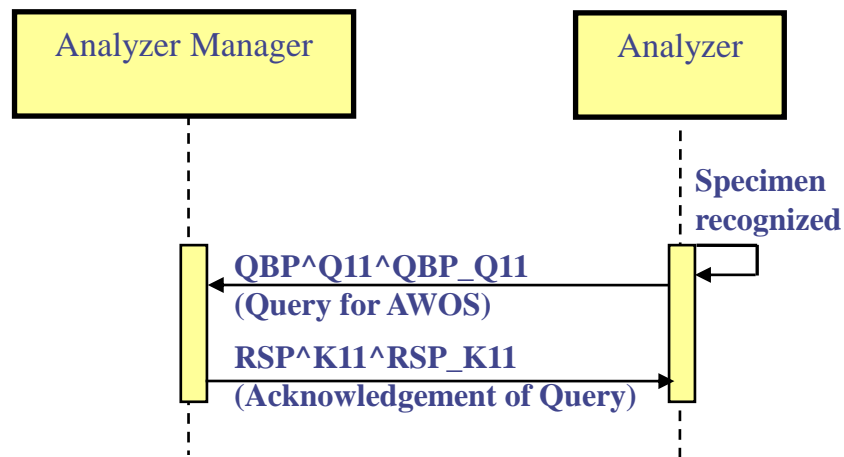
- Messaging
 - Based on HL7 v2.5.1 Messages
 - Pre-adoption of elements of v2.7, v2.8, and v2.9

LAW Use Cases

- AWOS transfer to the Analyzer before specimen arrival
 - AWOS broadcast by the Analyzer Manager before specimen arrival
 - AWOS query by the Analyzer for ALL specimens before specimen arrival
 - AWOS Query by the Analyzer at specimen arrival
 - AWOS created at the Analyzer
 - Rerun
 - Rerun decided on the Analyzer immediately after the first run
 - Rerun decided during technical validation on the Analyzer Manager
 - Rerun decided during clinical validation on the Order Filler
 - Reflex
 - Reflex decided on the Analyzer
 - Reflex decided during technical validation on the Analyzer Manager
 - Reflex decided during clinical validation on the Order Filler
 - Retransmit results from Analyzer
 - QC Performed on an Analyzer
 - Pooling of Patient Specimens
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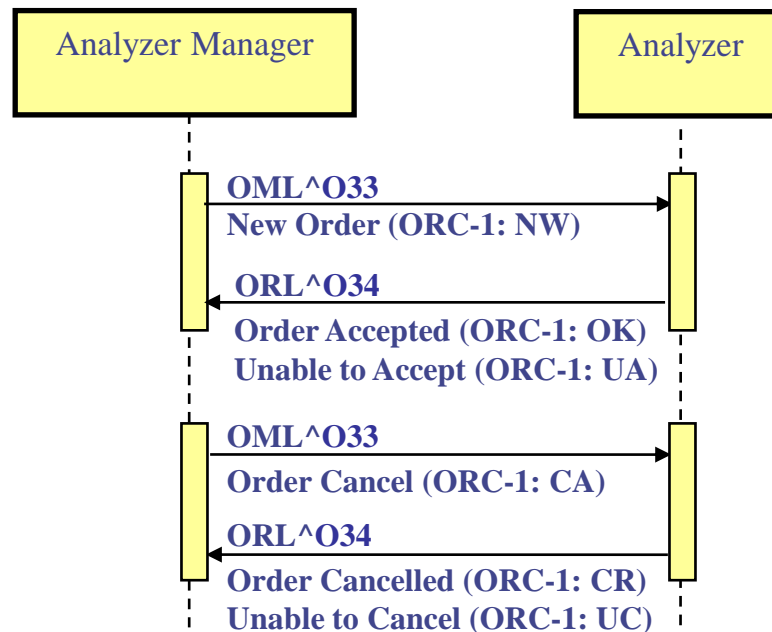
LAB-27 Query for AWOS

- Two-part message exchange
 - LAB-27 (query) followed by LAB-28 (AWOS Broadcast)
 - Allows Analyzer to continue while Analyzer Manager processes the query
 - Allows Analyzer to accept/reject AWOS



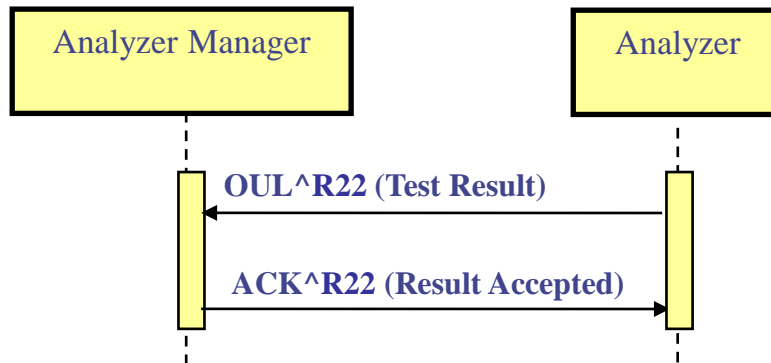
LAB-28 AWOS Broadcast

- New and Cancel AWOS
- Modify is cancel followed by new
- Requires Analyzer response to request



LAB-29 AWOS Status Change

- Test results
- Test exceptions



Options

- Orders (Bi-directional communication)
 - Some Analyzers do not support orders (e.g. instrument with fixed tests)
 - A profile option for Analyzers
 - Query is default mode when orders are supported
 - Basic and enhanced message interfaces
 - All Analyzers must support basic interface to transmit results
 - ♦ Basic interface elements are mandatory for Analyzers and Analyzer Managers
 - ♦ Basic elements are tested for conformance
 - Some Analyzers support additional information (e.g. patient information) to further evaluate results
 - ♦ Analyzer Managers must support enhanced elements
 - ♦ Analyzers may support enhanced elements based on capabilities (options)
 - ♦ Enhanced elements are not part of conformance testing for Analyzers
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LAW Special Topics

- AWOS ID
 - Every AWOS request is assigned a unique ID by the Analyzer Manager
 - No AWOS ID is assigned for AWOS requests created at the Analyzer
 - Sample identification
 - Sample container is used for identification
 - Specimen identification is optional
 - Standard vocabulary support
 - Universal Service Identifier - Logical Observation Identifiers Names and Codes (LOINC)
 - JLAB10 - Japanese standard clinical test code
 - Units of Measure - Unified Code for Units of Measure (UCUM)
 - Device Identification
 - Vendor model and serial number
 - Support for Universal Device Identifier (UDI)
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LAW Special Topics

- Orders
 - AWOS Query
 - Related observations
 - Prior observations
 - Clinical information
 - AWOS acceptance
 - AWOS cancellation

LAW Special Topics

- Observations
 - AWOS (order) status
 - Result status
 - Identification of runs
 - Unique identification of results (Microbiology)
 - Result Fragments
 - ◆ Quantitative (10.3)
 - ◆ Qualitative (Positive, > 100)
 - Supplemental Observations
 - ◆ Plots
 - ◆ Images
 - ◆ Raw values
 - Contributing substances
 - Analyzer initiated reflex
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Law Special Topics

- Message handling
 - Identification
 - Acknowledgement
 - Connectivity
 - HL7 MLLP
 - Two TCP/IP Connections
 - ◆ Sender
 - ◆ Receiver
 - Connection persistence
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LAW Special Topics

- Error handling
 - Malformed messages
 - Messages with incorrect content
 - Reject a message
 - Messages with content inconsistent with previous messages
 - Managing patient demographic data

Important Links

- IHE Laboratory Wiki

<http://wiki.ihe.net/index.php?title=Laboratory>

- LAW Wiki

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

- LAW Supplement for Trial Implementation

http://www.ihe.net/Technical_Framework/upload/IHE_LAB_Suppl_LAW.pdf

- IICC Website

<http://www.ivdconnectivity.org/>
