

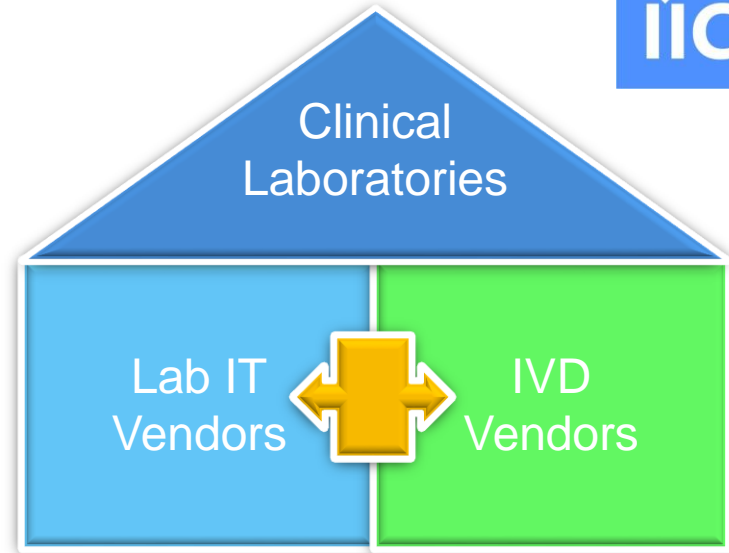


**Specification: Digital Format for
Publication of LOINC to IVD
(LIVD) Test Results**

What is the IVD Industry Connectivity Consortium?



- Mission
 - Modernize connectivity between laboratory IT systems and analyzers
 - Enable clinical laboratories to achieve more and spend less
- **Members:** 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 Syslab Technologies SA.



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"

Scope of IVD Specification



- Establishes industry content for publication of LOINC codes for vendor IVD test results
 - Human readable format for use by laboratory personnel
 - Electronic format for use by IVD software systems
- Supports IVD instrument and manual tests
- Mapping only of IVD test result identifiers
 - Mapping of IVD test orders requires additional information and alignment on a standardized coding system for orders
 - IVD Test Order mapping should be provided by separate mapping content

Expected Benefits



- Human-readable content allows laboratories to manually select appropriate LOINC codes for vendor IVD test results used by their laboratory
- Electronic content allows IVD software systems to automate laboratory mapping of IVD vendor test results to a LOINC code
- Other indirect benefits are also possible

Data Definition Type – Vendor Publication



Data Element	Description
Publisher	Entity publishing the mapping
Publication Version ID	Version of the mapping
LOINC Version ID	e.g. LOINC 2.59
LOINC Copyright	LOINC attribution statement
Localization	e.g. “en-US”
Region	Additional localization information

- Distinguishes between multiple vendor LOINC publications
- Supports localization

Data Definition Type – Equipment



Data Element	Description
Manufacturer	The vendor
Model	The instrument or manual test kit
UID	Universal identifier for the instrument
UID Type	The source of the UID

- Distinguishes between multiple vendor IVD instruments or manual test kits
- Supports Unique Device Identifier (UDI)

Data Definition Type – IVD Test Result



Data Element	Description
Vendor Analyte Code	Vendor transmission code for LIS reporting or Analyte Identifier for manual tests
Vendor Analyte Name	The human-readable test result name
Vendor Specimen Description	Is it serum, plasma, urine, etc.
Vendor Result Description	mg/dL, mmol/L, Binary (positive/negative)
Vendor Reference ID	For example, a reference to a package insert
Vendor Comment	Any further clarification to help IVD test identification by a human

- Captures the vendor's test result identification information
- Establishes the content for the LOINC relationship

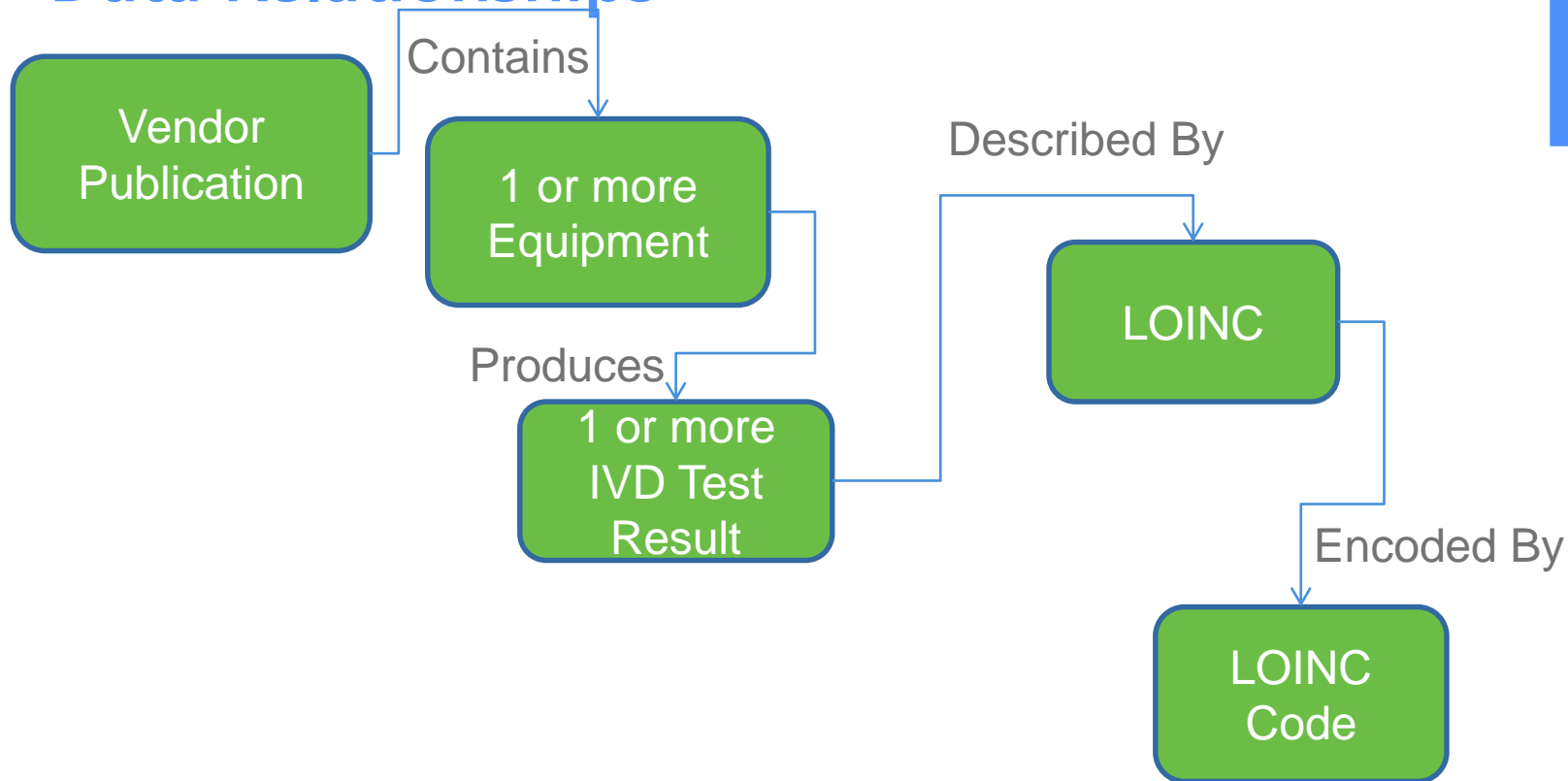
Data Definition Type – LOINC



Data Element	Description
LOINC Code	Content defined by LOINC Users' Guide
LOINC Long Name	Content defined by LOINC Users' Guide
Component	Content defined by LOINC Users' Guide
Property	Content defined by LOINC Users' Guide
Time	Content defined by LOINC Users' Guide
System	Content defined by LOINC Users' Guide
Scale	Content defined by LOINC Users' Guide
Method	Content defined by LOINC Users' Guide

- Establishes the LOINC code for a specific configuration of an IVD Test Result

Data Relationships



Data Definition Content



Element	Card.	Comments
IVD LOINC Publication	1..1	The mapping publication
	Vendor Publication	1..1 Vendor version information
	Vendor Equipment	1..* Mappings may be defined for multiple equipment
	Equipment	1..1 The equipment or manual test
	IVD Test Mapping	1..* One or more LOINC mappings
	IVD Test Result	1..1 Must provide a test result
LOINC	0..1 LOINC is optional	

Data Format – Table



- The spreadsheet will contain a worksheet with the following content that establishes the publisher and the right to use LOINC
 - Publisher
 - LOINC Version
 - LOINC Copyright
 - Localization
 - Region

Data Format – Table



- The spreadsheet will provide another worksheet containing the mapping content, with each row of the worksheet containing the following data definition content
- It should be possible for a laboratory to combined spreadsheets from multiple vendors into a single spreadsheet

Data Format – Table Columns



Column Header	Comments
Publication Version ID	
Manufacturer	Sortable column could be used if spreadsheet form multiple manufacturers are combined into one
Model	
Equipment UID	Leave empty if no universal ID
Equipment UID Type	Leave empty if no universal ID
Vendor Analyte Code	
Vendor Analyte Name	
Vendor Specimen Description	
Vendor Result Description	
Vendor Reference ID	Leave empty if no additional vendor reference
Vendor Comment	Leave empty if no vendor comment
LOINC Code	Leave empty if no LOINC mapping
LOINC Long Name	Leave empty if no LOINC mapping
Component	Leave empty if no LOINC mapping
Property	Leave empty if no LOINC mapping
Time	Leave empty if no LOINC mapping
System	Leave empty if no LOINC mapping
Scale	Leave empty if no LOINC mapping
Method	Leave empty if no LOINC mapping

Data Format – JSON



- JSON (JavaScript Object Notation)
- Industry standard for describing digital content
- Human readable
- Lightweight
- Simple syntax
- Designed for data exchange
- Ease of use by IVD Systems and tooling
- International format that is independent of interoperability standards

Next Steps



- Published specification on 6/1/2017
- Formalize the data definition
 - HL7 Orders and Observations Working Group
 - LOINC to IVD (LIVD) Test Result Project
- Promote adoption
 - Announcement:
http://ivdconnectivity.org/iicc_announces_livd_specification/
 - IICC booth at AACC: AACC Annual Scientific Meeting & Clinical Lab Expo in San Diego, CA (July 30–August 3) at the IICC booth #1955

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Participating Organizations



- Abbott Laboratories
- Advanced Medical Technology Association (AdvaMed)
- Association of Public Health Laboratories (APHL)
- BD Life Sciences
- bioMerieux
- Cerner Corporation
- Epic
- Geisinger Health System
- Health Level Seven® (HL7®)
- IHE Pathology and Laboratory Medicine (PaLM) Technical Committee
- Intelligent Medical Objects, Inc
- Medical Device Innovation Consortium (MDIC)
- Orchard Software
- Phast
- Regenstrief Institute, Inc.
- Roche Diagnostics International, Ltd
- Swiss Laboratory Interoperability Interest Group (Joint Venture of FAMH.ch, IHE-Suisse.ch, HL7.ch, SULM.ch)
- U.S. Centers for Disease Control and Prevention (CDC)
- U.S. Food and Drug Administration (FDA)
- U.S. National Library of Medicine, National Institutes of Health (NLM/NIH)
- Vernetzt, LLC



Thank You!

www.ivdconnectivity.org