

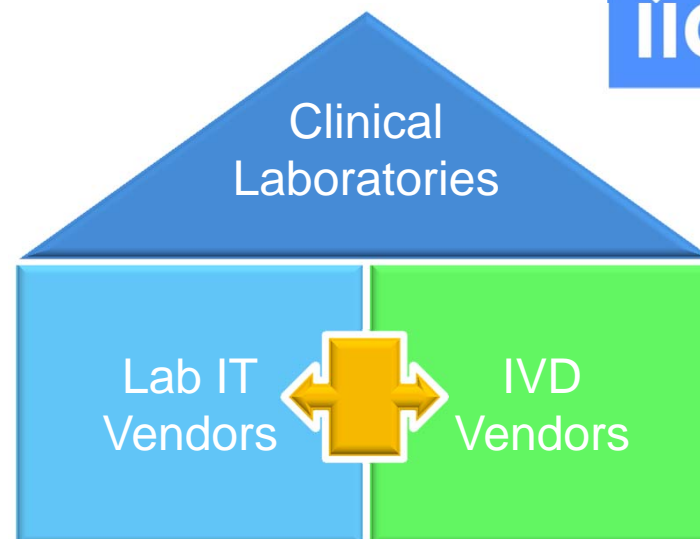


IICC Proposal for a Digital Format Used to Publish LOINC Codes for Vendor IVD Tests



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 Proposal



- Establish industry format for publication of LOINC codes for vendor IVD tests
 - Easily transformed into human readable format for use by laboratory personnel
 - Electronic format for use by IVD software systems
- Support IVD instrument tests and manual tests

Expected Benefits



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

Data Definition – Publication Content



- Summary
 - Version ID
 - LOINC Copyright
- Distinguishes between multiple vendor publications

Data Definition – Vendor Test Content



| Data Element | Description |
|-----------------------------|--|
| Manufacturer | The vendor |
| Model | The instrument, or manual test |
| UID | Universal identifier for the instrument |
| Vendor Transmission Code | Vendor code for LIS reporting |
| Vendor Specimen Description | Is it serum, plasma, urine, etc. |
| Vendor Result Description | mg/dL, mmol/L, Binary (positive/negative) |
| Localized Analyte Name | The test name |
| Vendor Reference ID | For example, a reference to a package insert |
| Vendor Comment | Any further clarification to help IVD test identification by a human |

Data Definition – Vendor Test Content



- Reduces effort for human identification of IVD tests
- Establishes the content for the LOINC relationships

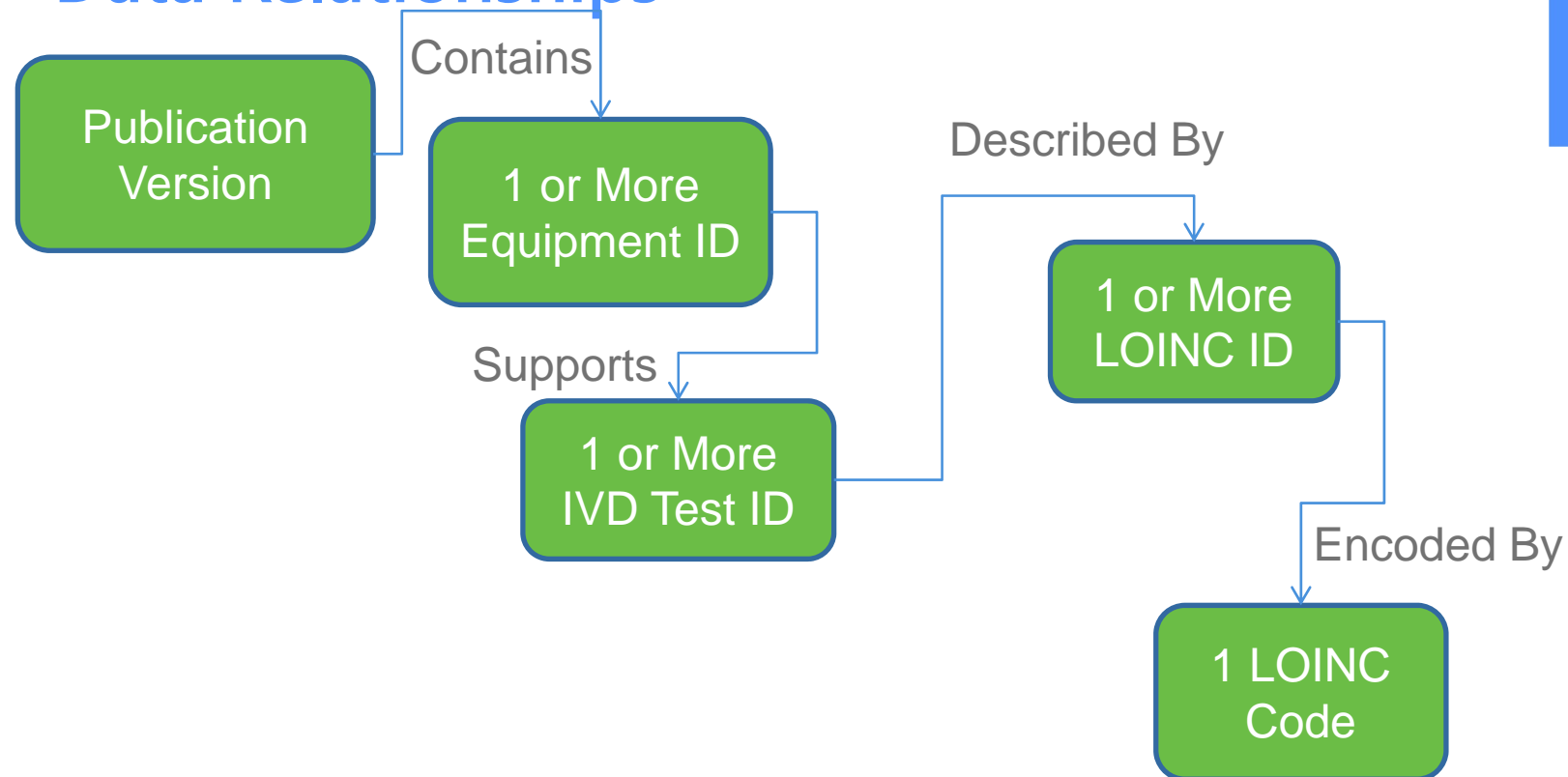


Data Definition – LOINC Content

- Summary of content
 - LOINC Code
 - LOINC Parts
- Establishes the LOINC code for a specific configuration of an IVD test
 - The analyte
 - Type of specimen tested
 - Type of result reported



Data Relationships





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



JSON Example

- Will look something like this...

```
"Version ID": "1.0",
"Equipment ID": {
  "Manufacturer": "Vendor1",
  "Model": "Model1",
  "UID": "0103573026555504801209.01.00"
},
"IVD Test ID": [{
  "Vendor Transmission Code": "CODEA",
  "Vendor Specimen Description": "All",
  "Vendor Result Description": "Vendor description" of the result type",
  "Vendor Reference ID": "Reference 123",
  "Localized Analyte Names": [{
    "Localization": "us-en",
    "Analyte Name": "CREA"
```

JSON Example



- continued...

```
    }, {  
      "Localization": "ch-ge",  
      "Analyte Name": "KREA"  
    }],  
    "Vendor Comment": "Vendor Comment",  
    "LOINC ID": [{  
      "LOINC Code": "2345-7",  
      "Component": "Glucose",  
      "Property": "MCnc",  
      "Time": "Pt",  
      "System": "Ser/Plas",  
      "Scale": "Qn",  
      "Method": "XX"  
    }]  
  }  
}
```



Next Steps

- Complete proposal
 - Review content for manual tests
 - Discuss supporting UID for IVD test
 - Discuss supporting LOINC long name
 - Finalize field names
 - Finalize description of data definition
 - Finalize examples
- Identify activities to formalize the data definition
- Promote adoption

Contributors



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Thank You!

www.ivdconnectivity.org