Digital Format for Publication of LOINC® to Vendor IVD Test Results 2nd Edition

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Background

Entities from government, industry, and academia have long recognized the essential role of semantic interoperability of *in vitro* diagnostic (IVD) test results in health care information technology. This discussion paper adopts the same definition of interoperability laid out by the Office of the National Coordinator for Health IT (ONC) in its Shared Nationwide Interoperability Roadmap[1]. Specifically, interoperability is intended to mean: the ability of a system to exchange electronic health information with, and use electronic health information from, other systems without excessive effort on the part of the user. For semantic interoperability, it is the ability of this data to be shared with unambiguous meaning and without separate negotiations between sender and receiver. Many successful efforts have thus far made substantial contributions to different aspects of semantic interoperability, with LOINC® (Logical Observation Identifiers Names and Codes), SNOMED CT® (Systematized Nomenclature of Medicine – Clinical Terms), and UCUM® (Unified Code for Units of Measure) perhaps most recognizable. With the increased use of software systems in the health care environment, it is now critical for IVD instruments and IVD software systems to have the capability to efficiently and unambiguously exchange IVD test results, regardless of their location or setting (e.g., hospital-based laboratories, reference laboratories, physician office laboratories, home use testing, etc.).

2015 & 2016[2] public workshops, focused on the advancement of the interoperability of IVD test results, proposed promoting greater adoption of standardized codes and terminologies. This was further endorsed by the SHIELD (Systemic Harmonization and Interoperability Enhancement for Laboratory Data)[3] project managed under an MDIC (Medical Device Innovation Consortium)[4] private-public partnership. The proposed work involved facilitating the following model:

1. Vendor IVD tests results would be associated with a set of predefined LOINC® terms that identify the distinct observations produced by the test
2. Observations with numeric values would be associated with the UCUM® representation of their reporting units
3. Observations with categorical (multiple choice) values would be associated with a response set that defined the possible values, with the response set drawn from appropriate code systems such as SNOMED CT®

In addition, the public workshops and SHIELD recognized that defining methods for distributing the standard codes associated with a measure could have an immediate impact on laboratory interoperability. For example, doctors often need to observe laboratory results for their patients over a prolonged period

[1] https://www.healthit.gov/topic/interoperability/interoperability-roadmap ; last accessed April 2020
[2] http://wayback.archive-it.org/7993/20171114130548/https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm523316.htm ; last accessed April 2020
[3] https://mdic.org/program/systemic-harmonization-and-interoperability-enhancement-for-lab-data-shield/; last accessed May 2020
[4] https://mdic.org/; last accessed April 2020

to assess the patient's disease progression. Often these results come from different laboratories and can be run on different IVD instruments using different test configurations. For doctors, it is therefore important to know whether a result was measured using the same sample type and method as the previous or the following result. Otherwise they will not be able to consistently interpret and compare test results to make a proper diagnosis and treatment recommendations.

In support of these concepts, this paper proposes an industry-defined format to publish the LOINC terms associated with the distinct observations that may be produced by an IVD instrument, through the execution of vendor-defined manual IVD test kits or by a test kit that may be run on either one dedicated IVD system or accommodate several such systems (possibly from different manufacturers). IVD vendors would voluntarily adopt this format to establish IVD vendor test result to LOINC mappings in a standardized manner. Ultimately, this could reduce differences of coding between vendors for similar test results and align codes between labs using similar classes of systems to achieve comparable operational outcomes.

This file format may also be used by organizations to aggregate manufacturer defined LOINC terms for specific needs, for example at the disease level for operational or public health reporting needs.

Example benefits may include:

- Decreasing the time required for a lab's deployment of IVD instruments.
- Facilitating electronic clinician decision support on test outcomes from disparate sources.

The IVD Industry Connectivity Consortium (IICC) is publishing this paper in support of its 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

IICC collaborated with the IHE Pathology and Laboratory Medicine (PaLM) domain to develop the Laboratory Analytical Workflow (LAW) Profile[5] that defines the next generation interface between IVD Analyzers and Analyzer Managers. The LAW Profile establishes use cases, transactions, and message definitions based on the HL7® Messaging Standard v2.5.1. LAW was published as the CLSI AUTO16 standard[6] for the exchange of analytical testing data between in vitro diagnostic instruments and health care informatics systems.

The LAW profile supports the transmission of LOINC, and IICC recognized the importance of this industry initiative for the adoption of standardized codes and terminologies. When possible, data elements discussed in this proposal were aligned with similar data elements defined by the LAW profile.

[5] https://www.ihe.net/uploadedFiles/Documents/PaLM/IHE_PaLM_TF_Vol2c.pdf ; last accessed June 2020
[6] https://clsi.org/standards/products/automation-and-informatics/documents/auto16/; last accessed June 2020

Scope

The objective of this analysis is to define a joint Public Health authorities & IVD industry format to facilitate the publication and exchange of LOINC terms

- For vendor IVD test results, based on either vendor IVD test transmission codes or manual test identification, for use by laboratory personnel or laboratory applications. It is not intended to cover information for other related activities, such as purchasing tests from a vendor. Expected systems include Laboratory Information Systems (LIS), clinical middleware applications, databases, and terminology servers.
- For organizations (e.g. public health) aggregating LOINC terms from several IVD manufacturers for a particular need (such as SARS-CoV-2).

This proposal will define a digital format that can be used as-is by IVD software systems to automate the mapping between vendor IVD test transmission codes and LOINC terms. It can also easily be transformed into an alternate format, such as an Excel spreadsheet, to support the manual selection of LOINC terms for results produced by vendor IVD tests used by the laboratory.

Vendor-defined IVD tests performed by a vendor IVD instrument, vendor-defined manual IVD tests, or vendor-defined test kits that may be run on a dedicated IVD system or several such systems (possibly from different manufacturers) are in scope.

This proposal will provide specific guidance on how the digital content should be structured, i.e. recommendations for the combining of test mapping records into aggregates.

Outcomes out of scope

- This proposal does not address the mapping of IVD Test Orders, which requires additional data and alignment on a standardized coding system for orders. Although IVD Test Orders and IVD Test Results are related, information required for IVD Test Order mapping should be provided by a separate mapping table.
- This proposal does not address any long-term or common storage locations vendors may agree upon to host the published LOINC terms or regulatory impacts of vendors providing LOINC terms for their IVD tests.
- This proposal does not address the use of specific protocols or technologies that could be used to transmit the industry-defined digital content between IVD systems.
- This proposal does not include transmitting LOINC terms directly from IVD instruments, leaving that content to be represented by vendor-defined codes due to issues in achieving one-to-one appropriate LOINC terms, as discussed in the Data Definition section.
- This proposal does not address which LOINC terms publishers should choose for their tests, or what content is needed to make this decision; readers should refer to the guides offered by LOINC

for this purpose[7]. It only addresses the format used to publish these associations, for use by laboratory personnel or laboratory applications.

- This proposal does not address what information is required to automatically set up a configuration between an IVD instrument and an IVD software system.

[7] https://loinc.org/guides

Data Definition

The following data definition is proposed as the content for the publication of LOINC terms for vendor IVD test results. The data definition supports the following mappings:

- One vendor IVD Test Result to many **LOINC**s
  - This is a very common occurrence. For example, an IVD test for serum glucose could map to a LOINC term for a mass concentration (e.g. mg/dL) or one that defines a substance concentration (e.g. mol/L). Or, a urine albumin could map to a LOINC test for a 24 hour excretion rate with units of mg/(24.h), versus one for a random urine with unit of md/dL. The structure of the data definition naturally supports this relationship.

- One **LOINC** to many vendor IVD Test Results
  - This is a much less common occurrence for IVD Test Results published by a single vendor.
    - For example, an IVD instrument may distinguish stat tests from routine tests by the IVD test code. In this case, the LOINC [13969-1] *Creatine kinase.MB [Mass/ volume] in Serum or Plasma* is associated with two IVD Test Results, depending if the test is routine or stat (prioritized).
    - Or, consider a susceptibility test that has different IVD Test IDs based on the original specimen source. In this case, the LOINC [6932-8] *Penicillin [Susceptibility] by Minimum inhibitory concentration (MIC),* which is named for testing on the isolate, could be associated with multiple IVD Test Results for one IVD Instrument depending on the clinical context. For example, the break points are different for suspected meningitis versus blood infections and to date LOINC has only distinguished test codes by suspected source of infection for some antibiotic susceptibility codes.

    The structure of the data definition supports this relationship through repeating LOINC data content across multiple IVD Test Results.

Conventions

Conventions for the Data Definition

(k) Used to identify the elements that identify a unique *IVD Test Result* to *LOINC* mapping. Each element is a member of the composite key.

1..1 The item is mandatory, and only one occurrence of the item must be included.

1..* The item is mandatory, and one or more occurrences of the items must be provided.

0..1 The item is optional. If provided, only one occurrence is included.

0..* The item is optional. If provided, one or more occurrences of the item may be included.

LIVD Publication

This information establishes the publisher of the document.

- **Publisher** is the entity publishing the mapping information.
- **Document Identifier** is the publisher's identifier for the document
- **Publication date** is the date of publication
- **Publisher URL** is to the publisher website
- **Publisher Statement** is a publisher statement about the document
- The LOINC License requires a statement of attribution and notice that LOINC content is copyrighted. The **LOINC Copyright** component holds the required attribution statement.
- **Localization** is the language used for this publication.
- **Region** is an optional vendor description for which geographic or administrative region this localization is valid, e.g. de-CH is self-explanatory, but not en-CH.

Component	Type	Card.	Reference	Comments
Publisher	String, 199	1..1		Vendor publishing the mapping
Document Identifier	String, 199	0..1		Vendor Document Identifier
Publication date	String, 199	0..1		Date of publication
Publisher URL	String, 199	0..1		URL to Publisher web site
Publisher Statement	String, 500	0..1		A statement from the publisher about the publication
LOINC Copyright	String, 500	1..1	LOINC License	LOINC attribution statement[1]
Localization	String, 10	1..1	RFC5646	e.g. “en-US”
Region	String, 199	0..1		e.g. “applicable to the United States”

1 The Attribution statement required by LOINC License when LOINC content is included. This statement was approved by Regenstrief Institute.

Equipment

The equipment elements, types, and cardinality are aligned with values reported in LAW OBX-18 Equipment Instance Identifier.

Equipment UID and **Equipment UID Type** can support the unique device identification system to identify medical devices through their distribution and use. When fully implemented, the label of most devices will include a unique device identifier (UDI) in human- and machine-readable form.

Component	Type	Card.	Reference	Comments
(k) Manufacturer	String, 20	1..1	LAW OBX-18.2	
(k) Model	String, 50	1..1	LAW OBX-18.1	Automated test: name of instrument Manual test: IVD Test Kit Name
Equipment UID	String, 199	0..*	LAW OBX-18.3	Can be used for equipment Unique Device Identifier (UDI)
Equipment UID Type	String, 6	0..1	LAW OBX-18.4	Use to identify the structure for the UID, e.g., FDA-accredited UDI[1] or an alternative structure

1 Specify if the UID represents the Device Identifier (DI) per the FDA unique device identification (UDI) system or an alternate type of device identification system. For additional information regarding the FDA UDI system and the FDA Global Unique Device Identification Database (GUDID), see *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/*.

IVD Test Performed

The **IVD Test Performed** establishes that test that was performed to produce the IVD Test Result. The **IVD Test Performed** components are aligned with values reported in OBX-3 Observation Identifier as applicable. **Vendor Specimen Description, Vendor Result Description**, and **Vendor Comment** are included to assist a laboratory in selecting the appropriate LOINC term (s) for the vendor IVD tests used by the laboratory. This information is not intended to be parsed by an IVD Software System that automates the mapping of vendor IVD transmission codes to LOINC terms. The inclusion of this information should reduce errors in the manual selection of LOINC terms by a laboratory.

- **Publication Version ID** is human-readable information provided by the vendor that can be used to differentiate mapping publication versions.
- **Vendor Analyte Code** is one of two possible values
    - For an automated test performed, it contains Vendor Transmission Code used by the instrument when sending the test result to a health information system, such as an LIS.

  - For a manual test performed, it is the Vendor Analyte Identifier for the test result produced by the Test Kit.
- **Vendor Analyte Name** is human-readable text the vendor used to identify the analyte. The text might be displayed by the instrument or could be used within an assay insert.
- **Vendor Specimen Description** is human-readable text that provides information about the specimen used for the test, such as “Serum or Plasma.” The field is used to document the vendor description of the specimen used for the IVD test.
- **Vendor Result Description** is human-readable text that provides information about the result that is produced.
  - For non-numeric results, this field should describe the result by including one of the following
    - **Binary** – pos/neg, reactive/non-reactive.
    - **Ordinal** – none, few, many.
    - **Nominal** – the test can report none found or one or more possibilities from a taxonomy of choices, such as organism names.
  - Numeric results and associated units of measure:
    - For numeric results, this field should describe the result by including a representative unit of measure, preferably represented as a UCUM unit.
    - If one unit of measure is reported, then include it in this field.
    - If multiple units can be reported that can be converted to one another by a multiplicative scale factor independent of the analyte (such as mg/L and ug/dL), select one of the units as a representative unit.
    - If multiple units can be reported that cannot be converted by an analyte-independent scale factor (such as mol/L and as mg/L), then define a mapping for each unit. These different types of numeric results require their own LOINC terms– one for the test reported as molar concentration and one for the test reported as mass concentration. Similarly, the results of a urine analyte (e.g. Sodium) reported as either mmol/L (spot urine) versus mmol/(24.h) (24 hour urine) have different LOINC properties and map to two different LOINC terms. The same is true for viral loads which can be reported in units of copies/mL, Log (copies/mL), IU/mL and Log (IU)/mL; and none of which can be converted by a simple scale factor. These result types have different properties and thus different LOINC terms. In such cases, define a mapping for all units that are appropriate for this IVD test.
  - In some cases, the same IVD Test may be reported as a **Binary** result, or a spot numeric result of the mass concentration, etc. In such instances, the same **IVD Test Performed** will map to multiple **LOINC**s. The **Vendor Result Description** should be used to assist the laboratory in manually selecting the appropriate LOINC for their laboratory.
- **Vendor Reference ID** is a vendor identifier, such as an identifier that can be used to locate the associated assay insert published by the vendor. This attribute may contain the material number used to order the product from the manufacturer.

- **Testkit UID** is a unique identifier from a system that identifies the IVD Test Performed. The identifier may be a unique device identifier (UDI), a EAN/GTIN, or another unique identifier depending on the jurisdiction.
- **Testkit UID Type** is used to identify the unique identifier system.
- **Vendor Comment** is human-readable text clarification, such as "This is a STAT (prioritized) version of the test".

Component	Type	Card.	Reference	Comments
Publication Version ID	String, 199	1..1		Publisher -defined version
(k) Vendor Analyte Code	String, 20	1..1	LAW OBX-3.1	Automated test: Vendor Transmission Code used for identification through an instrument interface, such as LAW. Manual test: Vendor Analyte Identifier
Vendor Analyte Name	String, 199	1..1	LAW OBX-3.2	
Vendor Specimen Description	String, 199	1..1		Vendor description of specimen
Vendor Result Description	String, 199	1..1		Vendor description of the result
Vendor Reference ID	String, 20	0..1		Additional vendor reference
Testkit UID	String, 199	0..1		Can be used for a Test Performed Unique Identifier
Testkit UID Type	String, 199	0..1		Use to identify the structure for the UID, e.g., FDA-accredited UDI[1] or an alternative structure such as a EAN / GTIN
Vendor Comment	String, 199	0..1		Vendor comment

1 Specify if the UID represents the Device Identifier (DI) per the FDA unique device identification (UDI) system or an alternate type of device identification system. For additional information regarding the FDA UDI system and the FDA Global Unique Device Identification Database (GUDID), see *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/*.

LOINC

This information captures the LOINC information established by the publisher for the associated IVD Test Result.

- The LOINC parts are included for information, so that laboratory personnel may not need additional tooling or references to interpret the content of the associated ***LOINC term***. Nevertheless, it shall be noted that *ONLY* the official LOINC data base release is the authoritative source to specify the actual part breakdown of any LOINC term.
  The **LOINC Long Name** associated with the **LOINC term** is included to assist the manual selection of the **LOINC term** for the **IVD Test Result**.
- **LOINC Version ID** is the version of LOINC that was used for the initial mapping or revised mapping. The LOINC version is the version as described by Regenstrief Institute. The format may be "<LOINC-next version ID>-pre" when terms are assigned before the next official release.

All those fields should come from the LOINC database as published by the Regenstrief Institute.

Component	Type[8]	Card.	Reference	Comments
(k) LOINC term	String, 10	1..1	LOINC	Content defined by LOINC Users' Guide
LOINC Long Name	String, 255	1..1	LOINC	
Component	String, 255	1..1	Component /Analyte – 1st part	
Property	String, 255	1..1	Kind of Property – 2nd part	
Time	String, 255	1..1	Time Aspect – 3rd part	
System	String, 255	1..1	System (Sample) Type – 4th part	
Scale	String, 255	1..1	Type of Scale – 5th part	
Method	String, 255	0..1	Type of Method – 6th part	
LOINC Version ID	String, 20	1..1	Regenstrief Institute	e.g. LOINC 2.59

[8] See LOINC Users's Guide, Appendix A « LOINC Database Structure » ; https://loinc.org/download/loinc-users-guide/ ; last accessed April 2020

Data Definition Content

- The **LOINC** element can be left null for the case where no **LOINC term** is available for this specific **IVD Test Performed**.
- The combination of **Manufacturer**, **Model**, **Vendor Analyte Code** (represents the **Vendor Transmission Code** or **Vendor Analyte Identifier**), and **LOINC term** must be unique based on the mandatory items identified for each element**.**
- The definition accommodates automated IVD instruments and tests kits. For a test kit, the following is required:
  - **Model** will be populated with the vendor Test Kit Name.
  - **Vendor Analyte Code** will be populated with **Vendor Analyte Identifier**.

The following data definition table describes the data elements of an LIVD mapping publication. The *italic* items are used to provide grouping of the data elements, while the **bold** items are actual data elements of the definition.

Element			Card.	Comments
IVD LOINC Publication			1..1	The mapping publication
	LIVD Publication		1..1	Vendor version information
	Vendor Equipment Mapping		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 Performed	1..1	The test performed that is mapped
		LOINC	0..1	Must provide if LOINC available

Data Format

A table and digital format are defined.

Criteria

The following criteria were established for the format:

- Widely used and accepted
- Used internationally
- Common tooling available for producing and parsing the format
- Support human readable content
- Support exchange with or consumption by machines (LIS vendors, etc.)

Table Format Recommendation

A spreadsheet is recommended as the table format. Spreadsheets can be used to filter the publication content as part of a manual activity to select the LOINC terms. It is also possible to create the spreadsheet content based on the digital content described below. In addition, table content from multiple vendors can be merged into a single spreadsheet.

The spreadsheet will contain

- a first worksheet (named “LIVD Publication”) containing information of the **LIVD Publication** data element from the “Data Definition” section,
- a second worksheet (named “LOINC mapping”) containing the mapping content. The table is normalized based the structure for **Equipment**, **IVD Test Performed** and **LOINC** from the “Data Definition Content”.

Each row of the second worksheet contains the following data definition content:

Column Header	Comments
Publication Version ID	Sortable column could be used if mapping from multiple publications are combined into one
Manufacturer	Sortable column could be used if mapping from multiple manufacturers are combined into one
Model	Name of instrument or IVD Test Kit Name
Equipment UID	Leave empty if no Universal ID
Equipment UID Type	Leave empty if no Universal ID
Vendor Analyte Code	Transmission Code or Analyte Identifier
Vendor Analyte Name	
Vendor Specimen Description	
Vendor Result Description	
Vendor Reference ID	Leave empty if no additional vendor reference
Testkit UID	Leave empty if no Universal ID
Testkit UID Type	Leave empty if no Universal ID
Vendor Comment	Leave empty if no vendor comment
LOINC term	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
LOINC Version ID	Leave empty if no LOINC mapping

Digital Format Recommendation

JSON (JavaScript Object Notation) is recommended as the digital format. JSON was chosen because it provides the following benefits:

- Industry standard for describing digital content
- Human readable
- Lightweight
- Simple syntax
- Designed for data exchange
- Ease of use by IVD Systems and tooling
    - Consumption of JSON by IVD software systems
    - Conversion of JSON into spreadsheet format
    - Conversion of JSON into future FHIR® format
- International format that is not tied to any specific interoperability standard. The format could be easily integrated into or used by existing protocols and standards.

It was recognized that multiple formats, protocols, and standards exist that could be used to publish the LOINC for Vendor IVD Tests. The following possible options were considered, but not selected:

- eDOS – Electronic Delivery of Service
  - Does not support human readable (data at rest) representation
  - Includes message-level content
- SPL – Structured Product Labeling
  - Established for pharmaceutical products
  - Also used for GUID
- IHE PaLM Laboratory Code Set Distribution (LCSD)/HL7® v2.5.1Master Files
  - Does not support human readable (data at rest) representation
  - Includes messaging-level content
- CSV – Comma Separated Values
  - The combination of multiple vendor names with multiple LOINC will require a significant pivot table
- XML – Extensible Markup Language
  - Excellent for data representation (documents)
  - Cumbersome for data exchange

Digital Format Schema

The schema for the JSON Digital Format is being developed as a FHIR® (Fast Healthcare Interoperability Resources®) Resource, which provides:

- Solid ontology-based analysis with a rigorous formal mapping for correctness
- Support for light-weight RESTful architectures and seamless exchange of information using messages

Please see https://build.fhir.org/ig/HL7/livd/index.html for details about the HL7 definition and current status.

LOINC Publication Example

Table Format

The table format is useful when the LIVD publication is reviewed by a human. A spreadsheet version was created using the *Table Format Recommendations* above. The rows in the LIVD example worksheet describe a unique IVD Test Mapping for a vendor IVD Test Performed to LOINC relationship. Filters have also been added to the table columns. The table content can be constructed from a JSON Digital Format. The example Microsoft® Excel LIVD Table Format is downloadable from this site.

Summary

This document proposes a data definition and digital format, for IVD manufacturers to use when publishing LOINC terms for their IVD Tests. This format is also intended to be used when a health authority or any other organization intend to aggregate LOINC terms from different manufacturers publications for a specific need.

The proposed format is human readable, and can be easily produced as a table format, such as Microsoft Excel, that further simplifies its use within a laboratory setting. In addition, the digital format is suitable for use by IVD software systems, such as a Laboratory Information System (LIS), that automate Vendor IVD Test to LOINC mappings.

By voluntarily adopting the format described here as an industry convention, IVD manufacturers will understand what data and in what format they should provide when publishing LOINC for their IVD Tests. By doing so, this work will significantly reduce the variability of the content and format of the multiple publications received by laboratory environments, further reducing the time and effort required by laboratories to review and integrate this information into their laboratory software systems. The format includes additional vendor information, such as a description of the result and specimen description, used to easily discriminate between multiple LOINC terms for the same IVD Test.

Ultimately, it is expected that the LOINC terms selected by manufacturers would be reviewed by a common party (e.g. LOINC, Regenstrief Institute) for correctness and consistency across vendors, and also that the industry would establish conventions for the storage and access of the IVD vendor LOINC publications. The effort required for these objectives will also be reduced by having this standard publication format and associated content.

Revision History

Version	Date	Modifications
1.0	2017	Initial version
2.0	2021	The content of multiple sections was updated to improve readability and provide clarifications The LIVD *Data Definition* was updated as follows: - **Document Identifier**, **Publication Date**, **Publication URL**, and **Publication Statement** were added to the *LIVD Publication* Data Structure to provide additional information from the publisher about the document - The **LOINC Version ID** was moved to the *LOINC* Data Structure so that a LOINC version can be established for each mapping - **Testkit UID** and **Testkit UID Type** fields were added to the *IVD Test Performed* Data Structure for test kit identification The IICC developed JSON definition was replaced with a reference to the HL7 FHIR LIVD definition A section was added for the *Public License*

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In memoriam
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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

IVD Industry Connectivity Consortium (IICC)

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