Semantic Interoperability for *In Vitro* Diagnostic Systems

Report
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Introduction

This report provides guidance on achieving semantic interoperability for *in vitro* diagnostic (IVD) test results. The challenges associated with interoperability, describing current and past efforts, and presenting benefits associated with achieving semantic interoperability are discussed.

The report identifies common terminology required for the following data elements of an IVD test result to enable semantic interoperability:

- Test ordering or reporting identification
- Observation values
- Units of measure
- Specimen identification
- IVD reagent kit and instrument identification

The following standards and representations can be used to provide common terminology, consistent test result data, and consistent transmission for these data elements:

- Logical Observation Identifiers Names and Codes (LOINC®[a])[1]
- Unified Codes for Units of Measure (UCUM)[2]
- Systematized Nomenclature of Medicine—Clinical Terms (SNOMED CT®[b])[3]
- Japan Laboratory Analysis Code version 10 (JLAC10)[4]
- International Classification of Diseases (ICD)[5]
- Nomenclature for Properties and Units (NPU)[6]
- Integrating the Healthcare Enterprise (IHE) Laboratory Analytical Workflow (LAW) profile[7] (CLSI document AUTO16[8])
- LOINC® *In Vitro* Diagnostic (LIVD)[9]
- Health Level Seven version 2 (HL7®[c] v2)[10]
- HL7® Fast Healthcare Interoperability Resources (FHIR®[c]) standard[11]

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With this information, readers of the report will have a better understanding of how they can implement or leverage IVD test result semantic interoperability in their area of expertise.

Uses of CDA®,[c] FHIR®, HL7®, LOINC®, RELMA®,[a] SNOMED CT®, and SNOMED RT®[b] in this report are not endorsements on the part of CLSI.

Scope

This report provides information on navigating the existing standards and guidelines that promote interoperability of IVD test results. It also highlights the importance of adopting common terminologies to describe the same IVD test result in the same way across the digital health care ecosystem. AUTO17 documents semantic interoperability and the landscape of applicable standards, identifies existing gaps (because the health care ecosystem is in the early stages of the establishment of semantic interoperability), and provides recommendations on resolving those gaps as of the year 2023. If all actors proposed and requested implementation of the standards highlighted in this report, the health care ecosystem could achieve a significant level of laboratory data interoperability.

Although this report uses the experience and knowledge of health care industry and laboratory experts to provide guidance on achieving semantic interoperability for IVD test results, the authors acknowledge that laboratory testing is not limited to US Food and Drug Administration (FDA)–approved IVD tests that are performed in the intended-use setting. For example, laboratory-developed tests (LDTs) may be developed based on the laboratory's expertise. However, laboratory data information systems are used for reporting all test results, so the same data elements and standards should be used to describe LDTs to achieve interoperability and the other benefits identified in this report.

This report is not intended to guide clinical practice (eg, test ordering, application of IVD test results to patient care), laboratory methodology harmonization efforts, or reimbursement. It does not create additional standards but clarifies the use of existing standards. Additionally, it does not cover legal data ownership and data access.

Intended User

The intended users of this report are:

- Pathologists and medical laboratory personnel
- IVD manufacturers (eg, instruments and test kits)
- IVD software system vendors (including middleware and LIS)
- Individuals responsible for laboratory and health care information systems (eg, LIS, EHRs, and electronic medical records)
- Government and regulatory agencies
- Any consumer of IVD test results