The following comments are submitted by the American Clinical Laboratory Association (ACLA)

Thank you for the opportunity to comment on the ISA.

General comment:
For any reference to ‘lab’ we suggest changing to ‘laboratory’ to promote usability of the guide.

Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications
Representing Laboratory Tests
https://www.healthit.gov/isa/representing-laboratory-tests

### 2021-09-13 screen print

<table>
<thead>
<tr>
<th>Type</th>
<th>Standard / Implementation Specification</th>
<th>Standards Process Maturity</th>
<th>Implementation Maturity</th>
<th>Adoption Level</th>
<th>Federally required</th>
<th>Cost</th>
<th>Test Tool Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard for observations</td>
<td>LOINC</td>
<td>Final</td>
<td>Production</td>
<td>Feedback requested</td>
<td>Yes</td>
<td>Free</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**Limitations, Dependencies, and Preconditions for Consideration**

- Laboratory test and observation work in conjunction with values or results which can be answered numerically or categorically. If the value/results/answer to a laboratory test and observation is categorical that answer should be represented with the SNOMED CT® terminology.
- A single laboratory test with a single result will have the same LOINC® code for the order and the result or will have a more specific code for the result. For example if the order code was method less or did not declare the system property A panel order will have an order LOINC® code and multiple result LOINC® terms for each result in the panel.
- Guidance is available for using SNOMED CT® and LOINC® together.
- LOINC code availability is contingent on assignment by Regenstrief.
- For more information about representing laboratory tests as a procedure, see the Representing Medical Procedures page.
- See LOINC projects in the Interoperability Proving Ground.
- For more information about observations and observation values, see Appendix III for an informational resource developed by the Health IT Standards Committee.

**Applicable Value Sets(s) and Starter Set(s)**

- LOINC Top 200® Lab Observations - US Version OID: 1.3.6.1.4.1.2009.10.2.3

### 2021 ISA for 2022 publication

**ACLA Comment:**

- In the Limitations, Dependencies, and Preconditions for Consideration, second bullet, please change ‘will’ to ‘may’. In Conformance language ‘may’ is equivalent to ‘optional’ and ‘will’ is not defined as a conformance verb in RFC 2119. A LOINC code may not be immediately available from or published by Regenstrief, therefore a laboratory may have to use a local code until an appropriate LOINC code is available and deployed to applicable LIS and EHR systems.
  - Extract from RFC 2119: The key words "MUST", "MUST NOT", "REQUIRED", "SHALL", "SHALL NOT", "SHOULD", "SHOULD NOT", "RECOMMENDED", "MAY", and "OPTIONAL" in this document are to be interpreted as described in RFC 2119.

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## Topic: Representing Patient Sex (At Birth)


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<tr>
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<tr>
<td>Standard for Observations</td>
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<td>Production</td>
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<td>Standard for observation values</td>
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<td>Yes</td>
<td>Free</td>
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</tbody>
</table>

### Limitations, Dependencies, and Preconditions for Consideration

- Patient Sex (at birth) or Assigned Sex is sex that is sex at birth, most often based on the child's external anatomy.
- HL7 Version 2 and 3 need to be harmonized.
- See LOINC projects in the Interoperability Proving Ground.
- For more information about observations and observation values, see Appendix III of an informational resource developed by the Health IT Standards Committee.

### Applicable Value Set(s) and Starter Sets

- LOINC code: 76685-9 Sex assigned at birth
- Administrative Gender (HL7 V3) 2.16.840.1.113883.1.11.1
- ONC's 2015 certification requirements reference the following value set for birth sex that use a combination of HL7 V3 Version 3 (V3) Standard value set for Administrative Gender and Null Flavor:
  - M ("Male")
  - F ("Female")
  - U ("Unknown") (HL7 V3 Null Flavor code)
- Other HL7 V3 Null Flavor codes, while not specifically required, may also be useful:
  - OTH ("Other")
  - AOK ("AOK")
  - UNK ("Unknown")

### ACLA Comment:

This continues to be an ongoing challenge to laboratories and potentially impacts patient safety. Laboratories need the patient’s biological / chromosomal sex data to be distinct and separate from a patient’s “gender identity[1]” as certain reference ranges are dependent on the patient’s biological or chromosomal sex information. We recommend ONC evaluate the various state laws as some states are permitting residents to legally change their birth sex and/or enter a value other than Male or Female. With these changes being allowed on birth certificates, we recommend ONC consider changing this section from Representing Patient’s Sex (at birth) to something like Patient’s Biological / Chromosomal Sex. We are aware that HL7’s Gender Harmony project has published an Informative document[2] defining “Sex for Clinical Use” (SFCU) but we do not believe this concept is semantically equivalent to the patient’s biological or chromosomal sex.

Additionally, the representation of the patient’s biological or chromosomal sex should be similar across all various industries including Laboratory, Clinician, Pharmacy, etc.

This may require additional LOINC codes.

While the adoption level may be accurate for capturing this data since it is an EHR certification requirement, as a large commercial laboratory, we can assert we are not seeing this data reported from EHR systems, and laboratories may not be ready to accept Sex assigned at Birth as a patient demographic data element because they are currently supporting only HL7 V2 “Administrative Sex”.

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[1] From USCDI V2 published July 2021 Gender Identity defined as “A person’s internal sense of being a man, woman, both, or neither.

[2] HL7 Standards Product Brief - HL7 Informative Document: Gender Harmony - Modeling Sex and Gender Representation, Release 1 | HL7 International
Section II: Content/Structure Standards and Implementation Specifications

Support the Transmission of a Laboratory's Directory of Services to Provider's Health IT or EHR System

https://www.healthit.gov/isa/support-transmission-a-laboratorys-directory-services-providers-health-it-or-ehr-system

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<tbody>
<tr>
<td>Emerging Implementation Specification</td>
<td>HL7 PHR Order Catalog Implementation Guide/Laboratory Services 0.1.0 - STU Release 1 Hyperform to bellow</td>
<td>Bolstered Draft</td>
<td>Pilot</td>
<td></td>
<td></td>
<td>Free</td>
<td>No</td>
</tr>
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</table>

**2021-09-13 screen print**

**ACLA Comment:**

We support these comments submitted by HL7:

![ISA eDOS comments for 2022](https://www.healthit.gov/isa/support-transmission-a-laboratorys-directory-services-providers-health-it-or-ehr-system)

Additionally, we suggest that when you add Release 3.1 that you delete the older Release 3. Release 3.1 supports COVID-19 reporting requirements for DHHS and CDC.

Add:

Delete:
ACLA Comment

The 2nd column ‘header’ is “Applicable Security Patterns for Consideration” but the comments are not related to security; Suggest you retitle; these seem like general comments.

It is our understanding HL7 FHIR Implementation Guides are licensed, but there is not fee. Please confirm with HL7 and, if appropriate, remove the $ and replace with free in Cost column for the HL7® FHIR® Implementation Guide - LOINC/IVD Mapping (LIVD) R1 (STU).
ACLA Comment:
The quality of the data in the laboratory order from the provider may impact the laboratory result time to response and content, as we learned during the COVID-19 pandemic.

We suggest that ONC sponsor an HL7 project to develop US Core FHIR IG for laboratory order. Currently it’s a “Future Candidate”.

From HL7 FHIR:
Future Candidate Requirements Under Consideration
ServiceRequest - The CDS hooks community, and other implementers are gathering requirements for the ServiceRequest Resource.
Receive Electronic Laboratory Test Results

ACLA Comment:

- Please update the hyperlink in the “Federally required” column so implementers can understand the federal requirement. Most Federally Required hyperlinks are to a Federal Register posting. The NCPDP “Federally Required” hyperlink is to a NCPDP web page which does not explain the federal requirement.
- Implementers, including ACLA members, do not have access to the (National Council for Prescription Drug Programs) NCPDP link provided in the response. You must pay $750 to become a NCPDP member to download a standard. We do not have access to this standard and we do not understand why this NCPDP standard is included in content representing laboratory domain since NCPDP typically deals with medications.

Re: HL7® Implementation Guide for C-CDA Release 2.1: Consolidated CDA for Clinical Notes and C-CDA on FHIR R4

- Please separate the two C-CDA references so they are listed separately on two distinct rows. This entry refers to two distinct implementation guides, one that is Clinical Document Architecture (CDA) based and one that is Fast Healthcare Interoperability Resources (FHIR) based.
  1. The proper title is: HL7 CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 - US Realm
     o Remove $ in ‘Cost’ column; HL7 standards are available with no fee license.
  2. The proper title is: C-CDA on FHIR Implementation Guide (IG)
     o The hyperlink for C-CDA on FHIR is: http://hl7.org/fhir/us/ccda/history.html This lists multiple versions; the latest version published in 2018 is a STU (standard for trial use)
     o Please change the Standards Maturity from ‘Final’ to ‘Balloted Draft’ (because it is a STU).
     o Remove $ in ‘Cost’ column; HL7 standards are available with no fee license.
- Please add US Core DiagnosticReport Profile for Laboratory Results Reporting as an “Emerging Standard”
ACLA Comment:

EHRs should report required information with eCR (electronic case reporting) so ancillary information that does not pertain to laboratories does not have to be added to the ELR.
ACLA Comment:
Please add hyperlinks in the “Federally Required” column when Federally Required is ‘Yes’

Please revise both hyperlinks for Logica (https://covid-19-ig.logicahealth.org/index.html) to reference the official HL7 Logica webpage: http://hl7.org/standards/hsp-marketplace/index.html. The current ISA LOGICA hyperlink is to a non-HL7 website; HL7 projects must be hosted on an HL7 website per HL7 policy.

The SANER specification was published by HL7. Please update the hyperlink to the published version at: HL7 FHIR® Implementation Guide: Situational Awareness for Novel Epidemic Response (SANER) STU 1. The current hyperlink is to HL7 FHIR’s ‘build’ environment which is preparatory to balloting and publication. (build.fhir.org/ig/HL7/fhir-saner/)

Please update:

- CARES Act Section 18115 require laboratories to report results of SARS-CoV2 or COVID-19 testing to the Secretary of HHS in the form and manner outlined in this memo "COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115 June 4, 2020" and updated January 8, 2021

Please add reference to additional HHS artifacts which ultimately reference HL7, LOINC, and SNOMED standards:
  - This document (last column) references HL7 Field and HL7 V2 Guidance: https://confluence.hl7.org/display/OO/ProposedHHS+ELR+Submission+Guidance+using+HL7+v2+Messages