[DRAFT] Comments for the ONC Interoperability Standards Advisory

ISA Table of Contents entries:

Representing Laboratory Tests

Add under limitations

- Additional information beyond the test/observation code (such as LOINC) and result value is required for correct handling and interpretation of test results. This additional information includes the result harmonization status, the reference range, and result units. See “Representing Laboratory Values/Results” for discussion of this information.

Representing Laboratory Values/Results

Delete current limitations content
Add under limitations

- Correct handling and interpretation of laboratory test values requires information about the test instance, including the result value, the units, the reference range, and the harmonization status of the test.
- Units for numeric results may be represented using UCUM, see “Representing Units of Measure.”
- Non-numeric results may be represented using LOINC answer lists, SNOMED CT codes, or standard scales or grading schemes.
- Reference ranges or expected values are represented as single or dual values in the same form and with the same units as results.
- Harmonization status indicates calibration equivalencies of tests and is required to verify clinical interoperability of results. Tests that are harmonized may be interpreted and trended together, and may use the same calculations, decision support rules, and machine learning models. Tests that are not harmonized should be interpreted and processed individually, not in aggregate with other tests. Standard harmonization procedures for tests with and without reference methods and materials are described in ISO 17511:2020 and 21151:2020, respectively, but corresponding data elements in results communication standards have not yet been defined.
- Future uses of laboratory test results may include “real world evidence” collection for final regulatory approval and performance monitoring of specific commercial products. These tasks will require results to include device IDs, test kit IDs, kit versions, reagent lots, and calibrator lots. The messaging structure to carry this information is available in the IHE LAW and LTW profiles, but in the current version is supported only for QC specimens within the order filling system and is not reported back to the order placing system.

Receive Electronic Laboratory Test Results

Add

- Laboratory test results may require additional information beyond the result value for correct handling and interpretation, including units, reference range, harmonization status of the test, and identifiers for device, test kit, kit version, reagent lot, and calibrator lot. Not all of these elements are included in current messaging standards for the full result reporting path. See “Representing Laboratory Values/Results.”

Exchanging InVitro Diagnostics (IVD) Test Orders & Results

Add under limitations, above LAW

- Laboratory test results may require additional information beyond the result value for correct handling and interpretation, including units, reference range, harmonization status of the test, and identifiers for device, test kit, kit version, reagent lot, and calibrator lot. Not all of these elements are included in current messaging standards for the full result reporting path.
- Current versions of the IHE LAW and LTW profiles support communication of lot information only within an order filling system and only for QC specimens. Reporting test harmonization status is not supported in current versions of communication standards. See additional discussion in “Representing Laboratory Values/Results.”