Standard provides labs with predefined LOINC codes for IVD tests

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February 2019—Logical Observation Identifiers Names and Codes, or LOINC, is a universal code system for identifying laboratory and clinical observations. LOINC provides unique numeric codes that identify the type of in vitro diagnostic test with defined attributes including component, property, time, system, scale, and method. LOINC codes are used within messaging standards such as Health Level-7 and facilitate the electronic exchange of test results between independent systems. Laboratories may be most familiar with LOINC as an essential component of meaningful use.

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The process of mapping local test codes to LOINC codes is complex and resource-intensive. The mapping process requires expert knowledge of the local tests performed and the hierarchical LOINC system. Few laboratories have the expert personnel to accomplish this task well, and this has resulted in variability among laboratories in the LOINC codes used for similar tests. These variations undermine the ability of organizations to leverage the benefits of unified data.

On June 15, 2018, the Food and Drug Administration published a document titled “Logical Observation Identifiers Names and Codes for In Vitro Diagnostic Tests: Guidance for Industry and Food and Drug Administration Staff.” This document encourages manufacturers to voluntarily include LOINC codes for IVD tests in their device labeling. The IVD Industry Connectivity Consortium, a global, nonprofit organization composed of clinical laboratories, laboratory IT vendors, and IVD instrument manufacturers, working in collaboration with the FDA, has developed an industry format for publication of LOINC codes for identification of vendor IVD results, known as LOINC to IVD (LIVD). LIVD matches vendor-defined IVD tests with an associated set of predefined LOINC codes. The human-readable format ensures that laboratory personnel select the appropriate LOINC codes for the IVD tests used by their laboratory. It also allows laboratory information systems to automatically map the correct IVD vendor test result to a LOINC code.

Adoption of LIVD is in the early stages and laboratories may be unaware that they can request through their sales representatives the set of LOINC codes associated with the test menu of a particular IVD manufacturer. The codes are provided as an Excel spreadsheet containing the analyte transmission code, specimen description, result description, and LOINC code. Currently the IVD tests are mapped only to LOINC codes.

In a related initiative, known as Systemic Harmonization and Interoperability Enhancement for Lab Data, or SHIELD, the FDA seeks to promote the application of semantic standards in structured data through such efforts as the publication of the Microbiology LOINC Mapping Manual that provides step-by-step instructions on how to map

LOINC codes for microbiology tests. The LIVD format developed by the connectivity consortium addresses the IVD test to LOINC mapping, and the consortium is working to establish a similar format for IVD value set mappings.

Dr. Luu is an associate professor of pathology, UT Southwestern Medical Center, a member of the CAP Informatics and CAP Standards committees, and the CAP's liaison to the LOINC effort. Dr. Heierman is a product software architect for Abbott and chief technology officer for the IVD Industry Connectivity Consortium. See the March issue of CAP TODAY for more information.