# FDA Approach to Semantic Interoperability Standards Describing *in vitro* Diagnostic (IVD) Tests

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# OIR Perspective on Harmonization of IVD Descriptive Coding (Semantic Interoperability)

- FDA recognizes the importance of semantic interoperability for IVD tests, which is essential to enabling multi-source laboratory data access and advancing health information technology.
  - The unambiguous and consistent representation of laboratory tests (and results) can drive the development of decision support tools and disease monitoring systems, provide 'real world evidence' of safety and effectiveness and far more.

# 2015 & 2016 CDC/FDA/NLM/ONC/CMS Public Workshop on Promoting Semantic Interoperability of Laboratory Data

***Harmonizing Codes for Public Health***


CDC

FDA

NIH

The Office of the National Coordinator for Health Information Technology

CMS

Geisinger

Regenstrief Institute
Better Care. Better Health.

Quest Diagnostics

LabCorp

Cerner

Abbott

OrchardSoftware

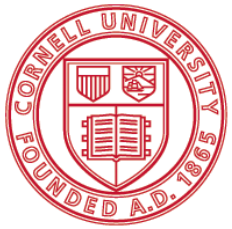
HL7 INTERNATIONAL

ACLA

American Clinical Laboratory Association

COLLEGE of AMERICAN PATHOLOGISTS

Harvest the Power

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# 2015 & 2016 Public Workshop Take-Home Messages for FDA

- FDA can support IVD semantic interoperability adoption efforts by being proactive.
- Currently, focus should be on adoption of Logical Observations, Names and Codes (LOINC®) while continuing develop/explore efforts to describe results from IVD tests.
- A 3rd party resource for codes (and coding) would aid in harmonization efforts.
- Regulatory clarity is important.

# Regulatory Question Responses

## 1. Will FDA 'mandate' LOINC coding for IVDs for industry?

- LOINC, or any similar coding system for *characterizing* IVDs is not required by FDA (note: this is separate from systems such as UDI for *identifying* devices).
- FDA encourages the use of consensus standards for the coding of IVD tests, and partially recognizes the use of LOINC under §514(c) of the Food Drug and Cosmetic Act for this purpose .
- Efforts by IVD manufacturers to disseminate LOINC coding for their devices is voluntary.
- No regulatory action is planned for IVD manufacturers distributing LOINC coding, assuming the coding information that is distributed by manufacturers is accurate and consistent with current device labeling.

# Regulatory Question Responses

## 2. Are LOINC codes considered part of device labeling?

- FDA has supported sponsors in including LOINC coding in labeling when FDA input was requested. (Inclusion in labeling may pose greater concerns to sponsors than FDA.)
- FDA supports using mechanisms other than package labeling to disseminate coding information, including referencing established standards and a 3rd party to disseminate information (e.g., Regenstrief, Orchard Software, etc.).
- FDA does not intend to perform premarket review of LOINC coding that is intended to be provided by the manufacturer to clinical laboratories or to other IVD test users.

# Regulatory Question Responses

**3. Can manufacturers provide coding for Indications For Use not described in current device product labeling?**

- Distribution of LOINC coding *by manufacturers* that suggests an unapproved/uncleared Indication for Use (i.e., off-label use) could result in the device being considered adulterated and/or misbranded.
- Note that laboratories and/or other users must fulfill their obligations, including (but not limited to) any statutes, regulations, and validation procedures that must be complied with when making the results from the off-label uses available to those requesting the test.

# Regulatory Question Responses

4. **Is a specific format recommended by FDA for distribution of LOINC codes?**
   - There is no specific FDA-recommended format for distribution of LOINC-codes.
   - FDA strongly encourages use of FDA-recognized consensus standards to communicate or disseminate LOINC coding.
     - A standard could be recognized for this purpose.

# Conclusion

- Adoption and implementation of semantic interoperability standards for IVDs is essential for enabling the development of 21st century healthcare solutions.
- FDA supports these efforts to assist in the adoption of unambiguous electronically transmissible codes *describing* IVD tests.


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