



AdvaMedDx  
Vital Insights | Transforming Care

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Submitted via email to [MGagnon@cdc.gov](mailto:MGagnon@cdc.gov)

**Re: Inquiry on Posting of Manufacturer Logical Observation Identifiers Name and Codes (LOINC) Codes on [loinc.org](http://loinc.org)**

Dear Ms. Gagnon:

On behalf of AdvaMedDx, a Division of the Advanced Medical Technology Association (AdvaMed), we thank you for your leadership in efforts to support laboratory health information and promote overall best practices for accurate and proper use of LOINC codes. The use of uniformly formatted laboratory test results will play a critical role in supporting interoperability and helping improve overall patient care.

AdvaMedDx member companies produce advanced, *in vitro* diagnostic tests that facilitate evidence-based medicine, improve quality of patient care, enable early detection of disease and reduce overall health care costs. Functioning as an association within AdvaMed, AdvaMedDx is the only multi-faceted, policy organization that deals exclusively with issues facing *in vitro* diagnostic companies both in the United States and abroad. Our members work to provide the latest diagnostic innovations to aid clinical laboratories and promote the public health.

Thank you for your outreach on the potential posting by manufacturers of LOINC codes generated by the Regenstrief Institute. We believe that consistent, harmonized terminology will be important to successful implementation of electronic laboratory reporting. However, further dialogue is necessary on how to best realize the adoption of standardized results reporting. We have witnessed considerable confusion amongst laboratories and manufacturers alike as to the correct selection of LOINC codes, and meaningful ways should be explored to improve consistent and accurate use.

While manufacturers take great care to support timely, accurate information when requests are made for support from customers to assist in correct selection of codes, manufacturers neither create nor manage LOINC coding assignments. LOINC codes are created and managed by Regenstrief Institute. Furthermore, laboratories are responsible to assure selection of each appropriate code based on the component, specimen type, method, and scale. LOINC codes are not associated with specific products. Thus, having a manufacturer post LOINC codes in a database would not ensure accurate reporting nor take into account the necessary specificity in test use. Furthermore, manufacturers would be placed in the inappropriate position of promoting any and all possible uses for their FDA-approved or cleared products in a third-party database.

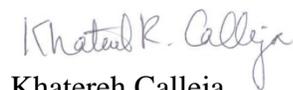
Due to the differing use of tests by laboratorians and the desire for specificity in LOINC coding, one test can have multiple associated LOINC codes. Laboratorians and manufacturers undertake significant efforts to understand the codes and keep abreast of continuous changes to the codes to support accurate use of these codes; however, LOINC coding can be challenging and require a significant time and resource commitment.

While LOINC codes provide a great deal of flexibility, they can be readily affected by inconsistency or inaccuracy as a result of variable reporting. Considerable human review is needed to choose the correct code. Thus, a simple listing online of LOINC codes will not assure the selection of accurate codes, which are third-party owned and often laboratory-specific. In fact, manufacturers are concerned that such information may increase inaccuracy in reporting due to the necessary desired specificity in LOINC coding as the specific use by laboratories will impact the correct LOINC code selection.

While manufacturers are unable to generate this content for posting online, we would welcome dialogue on how to best support efforts to enhance patient care and support accurate and efficient exchange of test results. It may be useful to consider whether additional avenues might be explored for best harmonizing nomenclature (e.g., SNOMED CT) and assuring accurate and efficient exchange of health information.

We would encourage discussion of meaningful ways to support ease in reporting by laboratorians while ensuring accurate, compliant reporting. We are happy to answer any questions and/or discuss our comments further with you. Please feel free to contact me at 202-434-7267 or [kcalleja@advamed.org](mailto:kcalleja@advamed.org).

Sincerely,



Khatereh Calleja  
Senior Vice President  
Technology and Regulatory Affairs