

# Division of Laboratory Systems

## The Use of Clinical Standards to Improve Laboratory Quality

Introduction

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# CLIA Does Not Address the Use of Standards

- **§ 493.1230 Condition: General laboratory systems.**
  - Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in [§§ 493.1231](#) through [493.1236](#), unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. *The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems as specified in [§ 493.1239](#) for each specialty and subspecialty of testing performed.*
- **§ 493.1253 Standard: Establishment and verification of performance specifications.**
  - (b2) ***Establishment of performance specifications.*** Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, *establish for each test system the performance specifications for the following performance characteristics, as applicable...*

# Presentation

## **CDC's Clinical Standardization Programs: Ensuring the Accuracy and Reliability of Chronic Disease Biomarker Tests**

**Hubert Vesper, PhD**

Director, Clinical Standardization Programs  
Division of Laboratory Sciences  
Centers for Disease Control and Prevention

# Presentation

## **Clinical and Laboratory Standards Institute (CLSI): Consensus Standards to Support Operational Excellence and Regulatory Compliance**

**Barb Jones, PhD**

Chief Executive Officer  
Clinical and Laboratory Standards Institute

## Questions to CLIAC

- 1) Clinical standardization programs (CSPs) improve the accuracy and reliability of laboratory tests for key chronic disease biomarkers. How can the CLIA program agencies promote participation in CSPs by laboratories and test manufacturers to improve analytical performance?
- 2) Currently, the FDA provides a [list](#) of Recognized Consensus Standards related to medical devices. What are other ways that the CLIA program agencies and professional organizations can promote the use of standardization programs and standards?





For more information, contact CDC  
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