Sponsored Webinar San Diego Section, AACC
Free to Members and their Guest

The New Guidance on LDTs: A Q&A with the FDA

Wednesday, September 10, 2014
11:00am PDT - 12:00pm PDT

Location:

USCD Center for Advanced Laboratory Medicine
UC San Diego, 10300 Campus Point Drive, San Diego, CA 92121
Conference Room C, on the SE side of the building; first parking lot on the right as you enter the complex.

The Expert:

Alberto Gutierrez, PhD, Director, Office of In Vitro Diagnostic Devices, FDA, Silver Spring, MD

Abstract:

Food and Drug Administration (FDA) recently notified Congress that it will issue its long-awaited draft guidance on Laboratory Developed Tests this fall. In its letter to the key congressional committees, the Agency outlined, in detail, its plans for regulating LDTs. The FDA proposes to adopt a risk-based approach that will have wide-ranging implications for all laboratories developing and utilizing LDTs. Low-risk LDTs will be subject to registration, listing and medical device reporting requirements, while high- and moderate-risk LDTs will need to meet more extensive requirements, including seeking premarket approval or clearance.

Join us for a 60-minute webinar with the Director of the FDA's Office of In Vitro Diagnostic Devices to learn what the agency's regulatory intentions are and what they will mean for your lab and its ability to perform LDTs.

Participate and learn:

- How this plan will affect molecular testing and other cutting edge tests
- What data labs will need to provide for new and existing LDTs
- What constitutes a modification to an LDT and agency requirements
- The data needed for registering and listing an LDT
- What is considered an adverse event and the laboratory's responsibilities for reporting it
- What LDTs will be subject to lesser oversight
- The various phase-in periods for compliance
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Clinical laboratories need answers to these and other questions to understand how this guidance could affect them and their ability to serve their patients. This is one program you cannot afford to miss!

Target Audience:

Laboratory administrators, directors, managers, compliance officers and IVD industry professionals.

Attendees are eligible for 1 CEU of Accent credit.