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

The Future of LDT Oversight

Wednesday, April 22, 2015
11:00am PST - 12:00pm PST

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.

Speakers:
James Nichols, PhD, Director, Clinical Chemistry, Vanderbilt University School of Medicine, Nashville, TN
Peter Kazon, JD, Senior Counsel, Alston & Bird, Washington, DC

Abstract:
In October 2014, the FDA published draft guidance outlining how the agency plans to regulate laboratory developed tests (LDTs) using a risk-based approach that, if implemented, would have significant implications for clinical laboratories. Since the release of the draft guidance, numerous stakeholders—ranging from clinicians and hospitals to commercial laboratories and disease-specific advocacy groups—have expressed concerns about the agency's proposed approach to LDT regulation, and have recommended substantial changes. Some have even hinted at potential legal action and possible congressional involvement.

What do these recent developments mean for the future of LDT oversight? Join us for this 60-minute webinar and get the most up-to-date information on the LDT regulatory policy issues of concern to the health care community. You will also learn about the legal and political forces that may shape the outcome of this debate.

Objectives:
The clinical laboratory community has a lot riding on the outcome of the current debate over how to regulate LDTs. Keep up-to-date with current thinking about what the future may hold for LDTS. Join AACC for this informative webinar and know:

- Laboratorians and other stakeholders' top concerns with the current LDT proposed guidance
- How major stakeholders such as the AMA, the American Hospital Association and others are responding to the draft guidance
- What congressional activities are being considered related to the LDT draft guidance
- What, given current information, clinical labs can expect to happen in the future related to oversight of LDTs

Policy expert Peter Kazon and AACC Government Relations Committee Chair Dr. James Nichols will also answer participant questions during a live Q&A at the end of the webinar

Target Audience:
Laboratory administrators, directors, managers, compliance officers and IVD industry professionals interested in the regulation of laboratory-developed tests.

Attendees are eligible for 1 CEU of Accent credit.