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In Vitro Diagnostic Multivariate Index Assays - FDA Releases Revised Guidance Document

GET THE MOST TIMELY AND UP-TO-DATE INFORMATION ON THIS EMERGING TOPIC

When:

Tuesday, August 14, 2007

2:00 - 3:30 pm Eastern Time

Format:

90-minute audio conference

The Speakers:

Moderator and Overview:
Alan Mertz, President - ACLA

Presenter:

Courtney C. Harper, Ph.D.

Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health
U.S. FDA

Program Overview:

The Food and Drug Administration (FDA) released revised draft guidance on "In Vitro Diagnostic Multivariate Index Assays". The guidance is available for a 30 day public comment ending August 27, 2007. The initial IVDMA draft guidance was issued September 7, 2006 and met with considerable interest from the laboratory community and others. Stakeholders were concerned that the definition of IVDMIAs in the initial draft guidance document could encompass a wider range of tests than FDA had intended, they raised questions about the FDA regulatory mechanisms in general, such as how devices are classified and reviewed based on the risk of the intended use; how laboratory-developed IVDMIAs should be labeled; and how manufacturers can update and improve cleared or approved devices using existing mechanisms within the regulatory framework. There was a general concern that requiring FDA regulatory compliance for IVDMIAs has the potential to discourage the development of new tests for rare diseases and could stifle the innovation of new tests to the market.

This ACLA LABline program will provide expert insight into FDA's revised thinking on IVDMIAs. You will learn from a leading agency expert how FDA has revised the guidance document to address the issues raised and more.

This program is applicable to all clinical laboratories that utilize laboratory developed tests for patient care and will be of interest to manufacturers, law firms and others. This audio conference will communicate FDA's current thinking about the use of IVDMIAs as laboratory developed tests, and will discuss how labs can ensure they are in compliance with the new guidance.

Attend this Audio Conference and Learn:

- > **Explanation of what is and what is not an IVDMA.**
- > **Perspective on the regulatory status of an IVDMA.**
- > **Response to the concern that regulatory compliance for IVDMIAs will discourage tests for rare disease.**
- > **Insight into how labs that manufacture IVDMIAs will have to follow FDA Quality Systems Regulations.**

How It Works:

It's easy. Sign-up using the following registration form. The registration fee entitles each site to one phone line with as many participants at the site as interested. So please, share this information packed program with your colleagues.

Prior to the audio conference, we will provide you with instructions on how to sign-in and participate. Program materials will be made available in advance of the program to all registered participants.

5 Ways to Register:

- > **CALL**
202-637-9466
- > **FAX** this form to:
202-637-2050
- > **MAIL** this form to:
1250 H STREET, NW
SUITE 880
WASHINGTON, DC 20005
- > **EMAIL**
chawk@clinical-labs.org
- > **ONLINE**
www.clinical-labs.org

Audio Conference Registration

- Please sign me up for the ACLA LABline Audio Conference:
In Vitro Diagnostic Multivariate Index Assays

NAME _____	TITLE _____	
FIRM _____		
ADDRESS* (NO P.O. BOXES) _____		
CITY* _____	STATE* _____	ZIP* _____
PHONE* _____	FAX* _____	
EMAIL ADDRESS* _____		
SIGNATURE _____		
ACCOUNT NO. _____	EXPIRATION DATE _____	SECURITY CODE _____

- ACLA member – \$99
 Non-member – \$199

Charge \$_____ to my credit card. (Please sign at left.)

- VISA
 MasterCard
 AmEx

* By providing your mail, phone, fax and email address, you agree to receive communications from ACLA via mail, phone, fax, and email.