



April 16, 2007

**To:** Companies Marketing IVD Products in the US

**Subject:** Special Educational Program  
U.S. Regulation & Reimbursement of *In Vitro* Diagnostic Products

**Location:** 2007 AACC Meeting & Clinical Lab Expo

**Date/Time:** Sunday, July 15, 2006 – 1:00 PM to 5:00 PM

This workshop is specifically directed to the needs of individuals with product development or product marketing responsibilities for the U.S. market. It is organized by the AACC and the Clinical Lab Expo, with the support of the DxMA—Diagnostics Marketing Association—to help industry executives to better understand the U.S. regulatory and reimbursement environment. The AACC welcomes the Diagnostics Marketing Association in the presentation of this program.

The following should attend this workshop:

- Chief executives of new IVD companies
- Export executives
- Regulatory specialists
- Marketing staff
- Product development personnel
- Product managers
- Anyone new to the IVD industry

The presenters of these sessions are recognized experts in the regulatory, reimbursement, and marketing aspects of the process of bringing IVD products to the US market.

The workshop begins with Approvals to Market, followed by a session on Coverage, Reimbursement and Coding. The final session will provide an overview, IVD Marketing: Regulatory Limitations and Restrictions.

The following pages are:

- The program
- Learning objectives for each session
- The registration form.

**Program and Registration form >>**

# Program

AACC Annual Meeting - Special Session  
July 15, 2007

## **U.S. REGULATION AND REIMBURSEMENT OF *IN VITRO* DIAGNOSTIC PRODUCTS**

1:00 - 1:05      Welcome  
Jerry Goldsmith, VP Marketing Programs, AACC  
John Sperzel, Axis-Shield, President, Diagnostics Marketing Association  
Hope S. Foster, JD, Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.

### **1:05 – 2:30      APPROVALS TO MARKET**

IVD Regulation by the FDA in the United States  
FDA Speaker - TBA  
Food and Drug Administration

Questions and Answers

#### Learning objectives for this session include:

- The manner in which the U.S. FDA regulates IVDs;
- The different classifications of IVD products and the requirements for each;
- How to decide which classification is appropriate for new products;
- Sources of additional information

### **2:30 - 3:00      COFFEE BREAK**

### **3:00 - 4:30      COVERAGE, REIMBURSEMENT AND CODING**

Decision-making in the U.S  
Joan Logue, Health Systems Concepts

Questions and Answers

#### Learning objectives for this session include:

- The factors affecting government and private payor coverage decisions;
- The government's Medicare fee schedules and their influence on private payment amounts;
- The limitations of the current coding system, criteria for new test codes and the ability to influence payment through coding

### **4:20 - 4:45      IVD MARKETING: REGULATORY LIMITATIONS AND RESTRICTIONS**

Hope S. Foster, JD, Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.

#### Learning objectives for this session include

- The manner in which the U.S. regulates the marketing of IVDs;
- A brief examination of the marketing practices that have attracted government scrutiny;
- Sources of additional information.

### **4:50 - 5:00      QUESTIONS, ANSWERS AND WRAP UP**

Jerry Goldsmith, VP, Marketing Programs, AACC  
Hope S. Foster, JD, Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.

Presented in cooperation with the  
**DxMA - The Diagnostics Marketing Association**



## Registration Form

### U.S. REGULATION AND REIMBURSEMENT OF *IN VITRO* DIAGNOSTIC PRODUCTS

July 15, 2007 – 1:00 PM to 5:00PM

Registrants will be advised of the location by June 15, 2007

Please complete one form for each registrant:

Workshop Fee (credit card charges will be made after June 1, 2007)

2007 Annual Meeting Exhibitor \$225     Non-exhibitor \$300

Visa         MasterCard         American Express

Credit card number \_\_\_\_\_

Expiration date (mm/yy) \_\_\_\_\_

Exact spelling of name on credit card \_\_\_\_\_

Company/Organization \_\_\_\_\_

Name of registrant (if different from name on credit card) \_\_\_\_\_

Title \_\_\_\_\_

Phone (Include Country Code) \_\_\_\_\_

Fax (Include Country Code) \_\_\_\_\_

Email \_\_\_\_\_

Country: \_\_\_\_\_

Registration confirmation will be sent to you by fax and email.

Please fax to Herb Burklund at +1 201-653-5705

Email inquiries: [herbb@schicago.com](mailto:herbb@schicago.com)