

Diagnostics Briefing

Diagnostics Briefing explores the growing role of diagnostics within the healthcare industry. Participants learn about a range of diagnostic tests and their indications, as well as the basic science behind their development. Specific terminology such as sensitivity, specificity, false positives, false negatives and ROC curves are fully explained. The day culminates in a detailed overview of the US reimbursement and approval process for diagnostic devices.

Diagnostics Role in Medicine Today 9:00–10:00

Diagnosis of Disease- Do you have it?
Following a Disease- What's your prognosis?
Following a Treatment- Are you cured?
Carrier- Will you pass it on to your child?

Statistical Features of Diagnostics 10:00–10:50

Sensitivity and Specificity
Positive and Negative Predictive Values
ROC Curves
Current Statistical Approaches to Diagnostics
Issues with Screening Tests

Break 10:50–11:00

Risk of Diagnostic Tests 11:00–11:30

False Positive and False Negative
Invasive Procedures

Types of Diagnostics 11:30–12:30

Blood Tests- Biomarkers
Physiologic Tests- Blood Pressure, EKG
Anatomic Tests- Xray, CAT Scan, MRI, Nuclear Markers

Lunch 12:30-1:30

How Diagnostic Tests Work 1:30–2:30

Blood or Tissue, Microscope, Stains
Rapid Multiplexed Analyzers
Sandwich Immunoassay
PCR
SNP Chips, DNA Sequencing Machines

Break 2:30–2:40

Diagnostic Development and Approval 2:40–3:30

Need for "Gold Standard"
Clinical Tests
FDA Approval Pathway
Device Issues
510-K and PMA
"Home Brew", CLIA Labs

How Diagnostic Tests Are Reimbursed 3:30-4:00

CMS
CPT Codes

Current Issues 4:00–4:15

Companion Diagnostics
IVDMIA
Consumer Genomics

Q&A/Review 4:15–4:30

Contact: Stacey Franklin, CEO franklin@biotechprimerinc.com tel. 443.798.2385