Fourth Annual

Next Generation Dx Summit

Moving Assays to the Clinic

August 21-23, 2012

Hyatt Regency on Capitol Hill
Washington, DC

AUGUST 21-22

- Enabling Point-of-Care Diagnostics
- Emerging Molecular Markers of Cancer
- Mass Spectrometry in Diagnostics of Infectious Disease
- Regulatory Compliance in Drug-Diagnostic Co-Development

AUGUST 22-23

- Molecular Diagnostics for Infectious Disease
- Companion Diagnostics
- Commercialization of Molecular Diagnostics

AUGUST 19

PHARMA-BIO PARTNERING —FORUMS—

- Emerging Diagnostic Partnering and Investment Forum

The Next Generation Dx Summit brings together all of the major players in the evolving areas of diagnostics

KEYNOTE DISCUSSION:

Regulation of LDTs and RUOs

Franklin R. Cockerill, III, M.D., Mayo Medical Laboratories and Mayo Collaborative Services, Inc.

Alberto Gutierrez, Ph.D., Office of in vitro Diagnostic Device Evaluation and Safety, Food & Drug Administration

KEYNOTE SESSION:

Position of IVDs on Regulatory Issues

Alan Mertz, American Clinical Laboratory Association (ACLA)

Diagnostic Manufacturers: Key Regulatory Issues

Andrew C. Fish, Executive Director, AdvaMedDx

Event-at-a-Glance

Sunday	PHARMA-BIO PARTNERING FORUMS	**Emerging Diagnostic Partnering and Investment Forum***		
Monday	**Pre-Conference Short Courses***			
Tuesday AM	**Enabling Point-of-Care Diagnostics**	**Emerging Molecular Markers of Cancer**	**Regulatory Compliance in Drug-Diagnostic Co-Development**	
Tuesday PM	**Enabling Point-of-Care Diagnostics**	**Emerging Molecular Markers of Cancer**	**Regulatory Compliance in Drug-Diagnostic Co-Development**	**Mass Spectrometry in Diagnostics of Infectious Disease**
Wednesday AM	**Enabling Point-of-Care Diagnostics**	**Emerging Molecular Markers of Cancer**	**Regulatory Compliance in Drug-Diagnostic Co-Development**	**Mass Spectrometry in Diagnostics of Infectious Disease**
	Plenary Keynote Session			
Wednesday PM	**Molecular Diagnostics for Infectious Disease**	**Companion Diagnostics**	**Commercialization of Molecular Diagnostics**	**Mass Spectrometry in Diagnostics of Infectious Disease**
	Dinner Short Courses*			
Thursday AM	**Molecular Diagnostics for Infectious Disease**	**Companion Diagnostics**	**Commercialization of Molecular Diagnostics**	
Thursday PM	**Molecular Diagnostics for Infectious Disease**	**Companion Diagnostics**	**Commercialization of Molecular Diagnostics**	

** Separate Registration Required*

About the Summit

Technological advances in next generation diagnostics are driving growth and innovation in healthcare. Rapid and precise diagnosis is essential for personalized medicine and will change the way value is assessed and compensated in the healthcare system. This meeting offers a comprehensive view of the changing landscape of diagnostics and brings together the key players in the field.

The **Next Generation Dx Summit** is designed to bring together all of the major players in the evolving areas of diagnostics. This year, we have assembled an impressive faculty of speakers from industry, government, and leading academic institutions. This meeting will showcase improvements in technology research and development with an emphasis on applications in the clinic and commercialization. Plan to hear what the industry leaders are saying about future market opportunities and network with your peers this August 21-23 in Washington, DC.

"The meeting was excellent, one of the best I have attended, and the standard of talks matched to the schedule across the board."

Vice President, Diagnostics, GlaxoSmithKline

"The Next Generation Dx Summit is the Conference to attend if you seek not only to learn about cutting edge diagnostics but to meet the people who develop and implement them."

R&D Consultant, Randox Laboratories

CORPORATE SPONSORS

Short Courses*

Morning Short Courses
Monday, August 20 | 9:00 am-12:00 pm

SC1 Micro- and Nanofluidics in Diagnostics and Life Sciences: Technologies, Applications and Markets

Holger Becker, Ph.D., CSO, microfluidic ChipShop GmbH

- Understand the basic physical principles and scaling laws governing miniaturization
- Identify the suitable material for a given microfluidic application
- Obtain an overview on the basic technologies available for the microfabrication of glass, silicon and polymer materials
- Understand the development strategies for integrated microfluidic devices
- Learn application examples of microfluidic devices in a wide range of disciplines
- Understand the current state of the markets and obstacles in the commercialization process

SC2 Smarter Studies: Boosting Your Omics and Biomarker Projects through an Efficient and Rigorous Study Design

Juergen von Frese, Ph.D., Managing Director, Data Analysis Solutions DA-SOL GmbH

- Why study design is decisive for success
- Common pitfalls and how to avoid them
- Planning your study from start to finish
- Getting the optimum out of your budget
- Ensuring validity
- Regulatory aspects

SC3 Differentiating Lateral Flow Products from the Competition Based on Performance and Design

Sponsored by DCN Diagnostic Consulting Network

Brendan O'Farrell, Ph.D., President, Diagnostic Consulting Network

John Zeis, President, Symbient Product Development

- Understand the issues in the generation of high sensitivity, highly reproducible lateral flow assays as well as key ways to control variability
- Learn about choices in labels and the advantages and disadvantages of each
- Learn about reagent selection criteria and methods for optimizing rapid assay performance
- Understand the options in reader design and learn about the key manufacturers and products available as well as options in the design of multiplexed assays
- Understand the design elements that go into a user friendly, single step lateral flow assay system
- Learn the process for the design and development of intuitive point-of-care devices
- Understand typical timelines, costs and outputs of OEM device and assay development programs for complete rapid assay systems
- See the unveiling of a new technology for the generation of intuitive, easy to read results in lateral flow assays

SC4 Latest Advances in Molecular Pathology

Jack H. Lichy, M.D., Ph.D., Chief, Pathology & Laboratory Medicine, VA Medical Center, Washington, D.C.

Karen E. Weck, M.D., Professor and Director of the Molecular Genetics Laboratory, University of North Carolina School of Medicine

Jennifer J.D. Morrissette, Ph.D., Adjunct Assistant Professor, Pathology and Laboratory Medicine, University of Pennsylvania School of Medicine; Clinical Director, Center for Personalized Diagnostics, Hospital of the University of Pennsylvania

Afternoon Short Courses
Monday, August 20 | 2:00-5:00 pm

SC5 Applications of Detection Theory in Diagnostics

John C. Carrano, Ph.D., President, Carrano Consulting, LLC

- The Dichotomous Test
- Analysis and definition of FP, FN, CP, CN as well as sensitivity, specificity, and LOD
- Construction of the Receiver Operating Characteristic
- ROC Curve Trends and Interpretation
- Negative and positive predictive values
- Detection theory and measurements
- Applications of ROC curves in sensing and diagnostics
- Mathematical principle of cost-benefit analysis and application to product choice
- Principles of decision tree analysis as well as construction, interpretation and practical applications
- The "spider" chart and systems level analysis

SC6 Next Generation Sequencing in Molecular Pathology: Challenges and Applications

Shashikant Kulkarni, Ph.D., Head, Clinical Genomics & Medical Director, Cytogenomics and Molecular Pathology, Pathology, Pediatrics and Genetics, Washington University School of Medicine

Jamie Platt, Ph.D., Scientific Director, Advanced Sequiencing, Quest Diagnostics Nichols Institute

SC7 Introducing Mass Spectrometry into a Clinical Laboratory

Michael E. Hodsdon, M.D., Ph.D., Associate Professor of Laboratory Medicine and Pharmacology, Yale University

David R. Peaper, M.D., Ph.D., Department of Laboratory Medicine, Yale University

- Modular view of chromatographic methods and modern mass spectrometer
- Practical aspects of introducing mass spectrometry into a clinical laboratory
- Development and validation of mass spectrometric methods
- Maintaining regulatory compliance (e.g. CAP) with your mass spectrometer

SC8 Cardiovascular Biomarkers: Clinical Impact and Crossover Applications

Allan S. Jaffe, M.D., Chair, Division of Core Clinical Laboratory Services, Department of Laboratory Medicine and Pathology, Mayo Clinic

Peter Kuhn, Ph.D., Associate Processor, Cell Biology, The Scripps Research Institute

Anand Rohatgi, M.D., MSCS, FACC, Assistant Professor, Preventive Cardiology, UT Southwestern Medical Center

Additional Instructors to be Announced

- The relation between cancer and cardiovascular disease
- Initiatives in cardiology that aid in cancer research
- Improved diagnostic information with the use of high sensitivity cardiac troponin
- Moving more effective markers to the clinic

Dinner Short Courses
Wednesday, August 22 | 6:30-8:30 pm

SC9 The Future of Point-of-Care Diagnostics

Keith F. Batchelder, M.D., CEO, Genomic Healthcare Strategies

Peter S. Miller, COO, Genomic Healthcare Strategies

- What factors come together to cause major changes in POC markets?
- How will old POC business models change?
- What's going to happen to the big box diagnostic companies?
- Where will the new markets be?
- What strategies make sense for Dx and POC companies?
- How will partnering evolve?

SC10 Deal Making in Companion Diagnostics: *CDx Deals Today and Tomorrow*

Jorge Leon, Ph.D., President, Leomics Associates, Inc.

Additional instructors to be Announced

- Deals between pharma and diagnostics in discovery, development and commercialization
  - o Needs from pharma
  - o Deliverables from diagnostics and the desired outcomes
  - o Average costs and financial structures
- Ingredients necessary to create the ideal type of pharma/diagnostics deals in order to increase the value for the diagnostic partners and to maximize the outcomes for the pharma partners.

** Separate Registration Required*

PHARMA-BIO PARTNERING —FORUMS—

Cambridge Healthtech Institute's Inaugural

Emerging Diagnostic Partnering and Investment Forum*

The pace of innovation continues to accelerate within the field of molecular diagnostics, making the right strategic partnerships critical to the development of promising new technologies and applications. CHI's **Emerging Diagnostic Partnering & Investment Forum** will bring together exciting early stage companies with decision makers representing pharma, larger biotechs, and VCs, providing an efficient opportunity to learn about emerging technologies and engage in networking, partnering and investment exploration discussions.

SUNDAY, AUGUST 19

PRESENTING COMPANIES:

Adarza has developed a proprietary technology and product platform for biological detection that enables higher levels of differentiating analytical and workflow performance. Arrayed Imaging Reflectometry offers a unique combination of sensitivity and highly multiplex detection on inexpensive microarray substrates.

AquaBioChip's technology integrates genomic information, isothermal amplification, simple optics for real time monitoring, microfluidics, and consumer electronics in a simplified package that works for many applications (genetic diagnostics related to clinical, food, water, and plant pathogens) under field conditions.

Aviana is developing a unique biosensor which is entirely electronic, translating a specific biological action directly into an electronic signal without the need for any other intervening technologies like optical or magnetic systems, which, in most systems, are needed to amplify and create bulky and complex systems.

Biocartis is engaged in the development of novel diagnostics platforms for low to highly multiplexed detection of molecular-based biomarkers. We are focused on the delivery of versatile and compact platforms that will make the testing of molecular diagnostics easier to perform in a wider range of healthcare settings.

Daktari has developed novel microfluidic control systems that enable separation of target analytes without sample preparation. Users introduce a drop of blood, and the handheld instrument completes the assay. A novel electrochemical sensing method greatly simplifies target detection, eliminating the need for optics or optical reagents.

CTC characterization provides a real-time tumor biopsy that could be used to guide treatment decisions. The Epic CTC platform has been designed to find enough CTCs in enough patients and in a format that will facilitate downstream characterization.

Genomic Expression is using intelligent target-filtering technology integrated with sequencing short reads on a small chip. Since all possible sequences are decoded, no assumptions need to be made about which ones will be informative, meaning biomarker discovery can proceed in a hypothesis-free fashion and even samples of unknown sequence can be analyzed.

InstantLabs is focused on making PCR available at the point-of-need and point-of-care, offering quicker time to results with an easy to use and affordable device. Our first test will be for the detection of MRSA, allowing hospitals to quickly identify patients that are infected before they enter the facility.

iCubate has developed the arm-PCR (amplicon rescued multiplex PCR), a fully integrated system that performs DNA/RNA extraction, amplification and detection, multiplexed, automated, and in a closed cassette. We integrated arm-PCR and PPI (polymerase preference index) algorithm into a software that is free to developers.

IVDiagnostics is focused on molecular diagnostics for blood borne diseases, with an initial field of interest is metastatic cancer. The IVDx system utilizes *in vivo* technology. We can scan one liter of a patient's blood without taking blood. Our molecular diagnostic platform uses aptamers applied to captured CTCs.

MBio Diagnostics is developing a platform for comprehensive diagnosis at the point of care by integrating panels of measurements in an easy-to-use system, for decentralized testing, from health clinics to the home. Initial products are infectious disease panels with attractive global markets. An elegantly simple biosensor enables highly sensitive multiplex rapid testing, with low cost to manufacture.

MZ Diagnostics' first product addresses the lack of a reliable rapid test to identify antimicrobial resistance among disease causing bacteria. We have developed a novel rapid phenotypic assay using mass spectrometry (MS) to detect the production of bacterial enzymes that inactivate carbapenems conferring antimicrobial resistance.

SpeeDx develops gene detection technology for faster, simpler, and cheaper diagnosis of disease to positively impact humanity world-wide. Our key technologies including MNAzymes, DNAzymes and EzyAmp provide the basis for a suite of highly specific and cost-effective methods for analysis of biological materials.

Xagenic is a venture-backed startup company founded in 2010 to commercialize a chip-based platform for molecular analysis with unprecedented sensitivity, speed and simplicity. Xagenic's technology is highly versatile and has been validated against a variety of cell and sample types.

FEATURED PANEL DISCUSSION:

Leveraging Strategic Alliances and Partnerships to Bring Diagnostics to the Market

Moderated by Katherine Tynan, Ph.D., Business Development & Strategic Consulting for Diagnostics Companies, Tynan Consulting LLC

View the complete agenda and detailed presentation information on our website:

www.nextgenerationdx.com/Dx-Partnering

** Separate Registration Required*

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Penny Wilson, Ph.D., *Innovation Platform Leader, Stratified Medicine Technology Strategy Board*

AUGUST 21-22

Sixth Annual

ENABLING POINT-OF-CARE DIAGNOSTICS

Evidence for Making an Impact

Recommended Pre-Conference Short Courses*

- Differentiating Lateral Flow Products
- Applications of Detection Theory in Diagnostics

*Separate registration required, please see page 3 for details

TUESDAY, AUGUST 21

7:30 am Registration and Morning Coffee

» KEYNOTE SESSION: MAKING THE CASE FOR POINT-OF-CARE TESTING

8:30 Chairperson's Opening Remarks

Penny Wilson, Ph.D., Innovation Platform Leader, Stratified Medicine Technology Strategy Board

8:40 Revolutionary Point-of-Care (POC) Diagnostic Technologies to Improve the Prevention, Control and Treatment of Infectious Diseases

Michel G.Bergeron, O.Q., M.D., FRCPC, Director and Founder, Centre de Recherche en Infectiologie de l'Université Laval

In 2012, it still takes ≥2 days to identify most microbes responsible for infectious diseases. This lack of rapid diagnostics has led to empirical therapy, the overuse of antibiotics, and a dangerous increase in antibiotic resistance, hospital-acquired infections (HAI), and in deaths. Combining genomics, microfluidics, miniaturized optics, and microcentripetal forces, we have developed a simple "lab-on-a-chip" device on a compact disc (CD) platform that reads DNA of microbes and which allows the diagnosis of up to 8 infections simultaneously at POC in real time.

9:10 HIV Viral Load Testing from Centralized Laboratories to POC Options

Lesley Scott, Ph.D., Professor, Molecular Medicine and Hematology, University of Witwatersrand

9:40 POC: The Search for the Holy Grail Continues

Harry Glorikian, Founder and Managing Partner, Scientia Advisors LLC

There is significant room for improvement in POC diagnostics. The sensitivity of lateral flow strips is unsatisfactory and immunoassays are insufficient for critical care/emergency situations. Developing markets may expedite approval, but this would be limited to specific geographies and conditions. The Holy Grail remains elusive: Rapid antigen level TaT + MDx accuracy, multiplexing capabilities, integration to laboratory information management systems (LIMS), reasonable cost, and easy-to-use.

10:10 Coffee Break

Evidence Required for Approval

10:55 Chairperson's Remarks

Sheldon Campbell, M.D. Ph.D. F.C.A.P., Department of Laboratory Medicine, Yale University School of Medicine

11:00 Infectious Disease Tests and Point-of-Care, an FDA Perspective

Francisco Martinez-Murillo, Ph.D., Staff Fellow, FDA CDRH

This talk will cover current FDA approaches to regulating rapid tests and testing algorithms based on rapid tests, particularly for detection of infectious disease when applied to point-of-care settings.

11:30 Evaluating Evidence for Diagnostic Tests: How Can We Improve Bench to Bedside Process?

Penny Wilson, Ph.D., Innovation Platform Leader, Stratified Medicine Technology Strategy Board

12:00 pm Use of Rapid Care Diagnostic Tests and Point-of-Care Diagnostics by Pharmacists

Michael E. Klepser, Pharm.D., FCCP, Professor of Pharmacy, Ferris State University

Pharmacists are uniquely positioned to identify patients early in the course of disease. The role of these tests and our experiences will be addressed.

Sponsored by DCN DIAGNOSTIC CONSULTING NETWORK

12:30 Differentiating Your Lateral Flow Assay; High Sensitivity, Fluorescent Reader Based Assays with Enhanced Functionality

Brendan O'Farrell, Ph.D., President, Diagnostic Consulting Network, Inc.

Attendees will learn about the key features of quantitative, sensitive, fluorescent lateral flow assays and be introduced to a novel method for the generation of highly functional signals in lateral flow, including parallel lines, arrays, letters, numbers or symbols, yielding intuitive, easily interpreted signals, simplified multiplexing, and improved quantification.

12:45 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

2:00 Session Break

Rapid Testing and the New HIV Testing Algorithm

2:15 Chairperson's Remarks

Christine C. Ginocchio, Ph.D., M. T. (ASCP), Hofstra University North Shore-LIJ School of Medicine

2:20 Overview and Impact of POC Testing

Bernard Branson, M.D., Medical Epidemiologist, Division of HIV/AIDS Prevention, Centers for Disease Control & Prevention

POC testing for HIV now plays a substantial role in identifying new HIV infections and facilitating linkage to care. However, with increasing recognition of importance of acute HIV infection in the onward transmission of HIV, CDC has proposed a new diagnostic HIV testing algorithm designed to improve detection of the acute HIV infection, reduce indeterminate test results, and facilitate the correct classification of HIV-2. This new algorithm currently depends on conventional laboratory tests, which might jeopardize some of the benefits associated with point-of-care testing such as improved access for hard to reach populations and reduced turnaround time, which increases receipt of test results. This overview will describe the rationale for the new testing algorithm and the challenges that demand new techniques for POC HIV technology.

2:40 Why Alere Determine HIV-1/2 Ag/Ab Combo First? Advantages of the Alere Determine HIV-1/2 Ag/Ab Combo Rapid Test as Compared to Ab Only Tests for Screening of HIV Infection at the Point-of-Care

Tomer Keren, Ph.D., Project Leader, R&D, Orgenics Ltd., a subsidiary of Alere, Inc.

Combined HIV antigen and antibody tests (4th generation) provides earlier detection of HIV infection than that afforded by antibody-only tests (3rd generation), yet are limited to central labs. The Alere Determine® HIV 1/2 Ag/Ab Combo is a novel point of care test bringing 4th generation capabilities to healthcare settings were 3rd generation HIV rapid tests algorithms are the mainstay.

3:00 Geenius™ HIV 1/2 Supplemental Assay: A New Unitary and Innovative Assay for Both Confirmation and Differentiation of HIV-1 and HIV-2 Antibodies in Less Than 30 Minutes

Christopher Bentsen, M.S., RAC, Regulatory Affairs Manager, Bio-Rad Laboratories

The Geenius™ HIV 1/2 Supplemental Assay is a single-use immunochromatographic test for the confirmation and differentiation of individual antibodies to HIV-1 (Group M & O) and HIV-2 in finger stick whole blood, venous whole blood, serum, and plasma samples. It employs HIV-1 and HIV-2 recombinant and/or peptide based antigens bound to a membrane and utilizes colloidal gold to develop a purple line for 6 HIV antigens and a control. The assay uses an innovative GeeniusTM Reader and associated Geenius software for result interpretation and reporting. Bar coding of patient samples and Geenius cartridges allow for full traceability of the system.

3:20 A New Test for the Determination of HIV 1/2 Viral Load at the Point-of-Care

Eugen Ermantraut, Managing Director, Alere Technologies GmbH

Quantitative determination of viral load using nucleic acid amplification techniques is considered to be the most accurate prognostic marker for HIV infection. Point-of-Care (POC) Viral Load test availability is expected to have a significant positive effect on treatment efficacy and health outcome of HIV patients. At the POC, and in particular in a pediatric context, large samples of plasma are difficult to obtain, whereas small amounts of whole blood collected by finger stick or heel prick sampling techniques are readily available. We have developed a fully integrated POC HIV -1/2 Viral Load test that operates using a battery powered instrument, which requires no operator handling starting from whole blood and have characterized its performance. The test targets un-spliced RNA of HIV-1 and HIV-2. All process steps including sample application, lysis, RNA capture, reverse transcription, target amplification and multiplexed real time detection on an integrated probe array have been accommodated on the disposable test cartridge. Commercially available reference material and the WHO standards were used to calibrate the test and to determine the lower limit of detection, linearity and dynamic range. Specificity and sensitivity of the test have been determined using blood samples from donors with confirmed HIV-infection and from confirmed HIV negative volunteers. As a reference, plasma viral load was measured on the COBAS Ampliprep/COBAS Taqman system. The test provides a quantitative viral load for HIV-1 and HIV-2 in less than one hour for a sample of 25µL of whole blood.

3:40 Refreshment Break in the Exhibit Hall with Poster Viewing

Novel POC Devices

4:05 Chairperson's Remarks

Matthew Lorence, Ph.D., M.B.A., Senior Vice President, Marketing, Sales, and Business Development, TessArae, LLC

4:10 Access to Point-Of-Care HIV Diagnostics in Developing Countries

Randy Allen, Ph.D., Manager, Corporate Relations, Clinton Health Access Initiative (CHAI)

There is a need for cost-effective Point-of-Care (POC) diagnostics, especially in rural settings to improve access and reduce loss of follow-up of patients. POC products are already in the marketplace with others under development. Effective POC scale-up will depend on many factors and will vary significantly across countries.

4:40 Inexpensive Portable Molecular Diagnostic Instruments

Axel Scherer, Ph.D., Neches Professor of Electrical Engineering, Applied Physics and Physics, California Institute of Technology

We have developed and characterized inexpensive PCR instruments and interfaced these with automated sample preparation and read-out systems. Pathogen identification without intervention from skilled operators relies heavily on automation and we discuss the trade-off space of sample type, reagent shelf-life and cost.

5:10 Wine and Cheese Pairing Welcome Reception in the Exhibit Hall with Poster Viewing

6:10 Close of Day

WEDNESDAY, AUGUST 22

7:30 am Problem Solving Breakout Discussions with Continental Breakfast

Sources of Error in POC Devices

8:30 PANEL DISCUSSION: Sources of Error in POC Devices: Where Do Things Go Wrong in the Real World?

Moderator: James H. Nichols, Ph.D., DABCC, FACB, Professor of Pathology, Tufts University School of Medicine; Medical Director, Clinical Chemistry, Baystate Health

Panelists: Sheldon Campbell, M.D., Ph.D., F.C.A.P., Department of Laboratory Medicine, Yale University School of Medicine; Pathology and Laboratory Medicine, VA Connecticut

Christine C. Ginocchio, Ph.D., M. T. (ASCP), Chief, Division of Infectious Disease Diagnostics, Department of Pathology and Laboratory Medicine, Professor, Hofstra University North Shore-LIJ School of Medicine

9:30 Sponsored Presentation *(Opportunity Available)*

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

Health Economics

10:25 Chairperson's Remarks

Shuqi Chen, Ph.D., CEO, IQuum, Inc.

10:30 Health Economics of Point-of-Care Diagnostics – What is the Price of POC Tests?

Ala Szczepura, D.Phil., Professor of Health Services Research, Division of Health Sciences, Warwick Medical School

This talk will consider economic issues associated with new point-of-care tests. It will use POC tests for infection detection as an example e.g. sepsis, tuberculosis, sexually transmitted infections and antimicrobial resistance. These four clinical/disease areas have recently been prioritised by the UK Department of Health and they form a major investment in innovation commissioned by the Technology Strategy Board.

11:00 POCT in the Hospital Setting: New Technologies, Clinical Utility, and Financial Considerations

Gyorgy Abel, M.D., Ph.D., Director, Molecular Diagnostics/Immunology/ Clinical Chemistry, Department of Laboratory Medicine, Lahey Clinic Medical Center

POCT is generally more expensive and more difficult to manage than tests on high-throughput central lab platforms. POCT can offer shorter turnaround times and convenience, and might impact outcomes. Implementing POCT programs requires careful analysis, including comparison of the quality of the results, potential errors in sample handling and reporting of the results, the additional physician, nurse, and medical technologist time, information technology, maintenance, quality control, regulatory requirements, and costs. The talk reviews the economy of POCT in the context of recent technological advancements and the changing healthcare environment, and offers real life examples of clinical chemistry and molecular diagnostics applications.

11:30 Transition to Plenary Session

» 11:50 PLENARY KEYNOTE DISCUSSION

Regulation of LDTs and RUOs

Alberto Gutierrez, Ph.D., Deputy Director, Office of in vitro Diagnostic Device Evaluation and Safety, Food & Drug Administration

Moderated by: Franklin R. Cockerill, III, M.D., Ann and Leo Markin Professor of Microbiology & Medicine; Chair, Department of Laboratory Medicine and Pathology, Mayo Clinic College of Medicine; President and CEO, Mayo Medical Laboratories and Mayo Collaborative Services, Inc.

12:45 pm Enjoy Lunch on Your Own

» PLENARY KEYNOTE

1:45 Views of the Laboratory Industry on Regulatory Issues

Alan Mertz, President, American Clinical Laboratory Association (ACLA)

2:10 Views of Diagnostics Manufacturers on Regulatory Issues

Andrew C. Fish, Executive Director, AdvaMedDx

2:30 Close of Enabling Point-of-Care Diagnostics

AUGUST 21-22

Fifth Annual

EMERGING MOLECULAR MARKERS OF CANCER

Evaluating for Clinical Use

Recommended Pre-Conference Short Courses*

- Micro- and Nanofluidics in Diagnostics and Life Sciences: Technologies, Applications and Markets
- Cardiovascular Biomarkers: Clinical Impact and Crossover Applications

**Separate registration required, please see page 3 for details*

TUESDAY, AUGUST 21

7:30 am Registration and Morning Coffee

Sequencing for Biomarker Analysis and Discovery

8:30 Chairperson's Opening Remarks

Lyle Arnold, Ph.D., CSO & Senior Vice President, R&D, Biocept

8:40 From Assay to Answers to Action: Clinical Implementation of High-Throughput Sequencing for Improved Cancer Care

Olivier Harismendy, Ph.D., Asst. Adj. Professor, Pediatrics, Division of Genome Information Sciences, Moores UCSD Cancer Ctr and UC San Diego Clinical and Translational Research Inst, Univ of California, San Diego

9:10 Circulating Tumor Cells and Plasma as Sample Types for Biomarker Analysis

Lyle Arnold, Ph.D., CSO & Senior Vice President, R&D, Biocept

The rapid advances in next generation sequencing are providing a much greater depth of discovery and analysis for accelerating the path to personalized medicine. The intersection of alternative sample types together with sequencing technologies provides further opportunities to help manage patient care. We have further enabled the use of sequencing with blood based "liquid biopsy" sample types by selectively enriching biomarkers of interest using an assay we call SelectorTM. This allows analysis, using sequencing, of very rare alleles of medical interest. Single nucleotide mutations as low as 0.002% become detectable in a complex genomic background.

9:40 Advanced Molecular Diagnostics Based on Ultrasensitive RNA in situ Hybridization

Sponsored by ACD ADVANCED CELL DIAGNOSTICS, INC

Yuling Luo, Ph.D., Founder, President & CEO, Advanced Cell Diagnostics, Inc.

RNA biomarkers are traditionally analyzed by "grind-and-bind" assays such as RT-PCR, which loses critical cellular context for clinical interpretation. Recent advances in in situ RNA analysis capable of detecting single RNA molecules in routine clinical specimens may finally enable more advanced RNA-based diagnostics.

9:55 High Sensitivity Detection of Cancer-Associated Mutations in FFPE and FNA Biopsies Using Different PCR Enrichment and NGS Methods

Sponsored by AsuraGen

Elizabeth Mambo, Ph.D., Senior Scientist, Technology Development, Asuragen Inc.

NGS platforms have become an indispensible tool for characterizing genetic abnormalities in cancer. To address needs for mutation detection in challenging tumor samples, we developed multiple PCR-based target enrichment methods compatible with distinct next generation sequencing platforms. These PCR methods support the full range of clinical research applications, from broad cancer gene screening to targeted mutation assessments or confirmation. Asuragen's SuraSeq 7500 panel represents >7500 distinct mutations across 52 cancer genes and interrogates over 120,000 unique bases from DNA inputs as low as 250 ng. SuraSeq 200 and 500 panels are ideal for high throughput, focused sequencing of commonly mutated regions from as little as 10 ng DNA. Emerging commercial panels, such as the Ion AmpliSeq™ Cancer Panel, provide additional options for balancing input and content breadth with throughput and turnaround time. Data generated from over 170 FFPE and FNA specimens and utilizing these different enrichment methods and NGS platforms will be presented.

10:25 Coffee Break

11:00 Talk Title to be Announced

Steven Shak, M.D., Chief Medical Officer, Genomic Health

11:30 Clinical Application of Next Generation Sequencing for Actionable Mutations in Cancer

Marilyn M. Li, M.D., Professor, Department of Molecular and Human Genetics, Baylor College of Medicine

Mutation detection in cancer has been a challenge due to the mosaic nature of tumor tissues and the genomic heterogeneity of tumor clones. Targeted NGS permits deep sequencing of hundreds of mutations concurrently. The technology allows the detection of multiple clinically actionable mutations at the same time with high sensitivity and specificity. The low input DNA, short turn around time, and low cost of targeted NGS provide huge potential of clinical utility, including diagnostic and therapeutic applications.

12:00 Clinical Applications of Cancer Genomics

John McPherson, Ph.D., Director, Genome Technologies, Ontario Institute for Cancer Research

Next-generation sequencing (NGS) enables deep sequencing of tumour biopsies to reveal the landscape of somatic mutations. Many detected mutations can help guide therapeutic decisions but the functional consequence of others remain to be elucidated. As data are accumulated in conjunction with functional studies and patient outcome new biomarkers can potentially be revealed.

12:30 Towards a Human Clinical Grade Genome - EdgeBio and The Archon Genomics X PRIZE Presented by Medco

Sponsored by EdgeBio

Justin Johnson, Director, Bioinformatics, EdgeBio

The Archon Genomics X PRIZE presented by Express Scripts created a "Validation Protocol" that is helping to define for the first time what it means to have a complete and accurate "medical grade" whole human genome sequence. This presentation will describe the Validation protocol in detail.

12:45 Randox Biochip Array Technology: A Revolutionary Step in Multiplex Oncogene Mutation Screening

Sponsored by RANDOX

Robert Wilson, Lead, Molecular Pathology, Northern Health & Social Care Trust

Randox have developed award-winning Biochip Array Technology (BAT) for rapid proteomic, and most recently, genomic diagnostics across a range of human diseases. Utilizing multiplex PCR, spatially tethered specific probes and chemiluminescence detection methods, our innovative array simultaneously identifies 20 mutations across KRAS, BRAF and PIK3CA oncogenes within 3 hours.

1:00 Luncheon Presentation NextGen Technology Solutions for Patient Selection and Monitoring

Sponsored by MolecularMD Oncology Biomarker Diagnostics

Jin Li, Ph.D., Research Director, Advanced Diagnostics, MolecularMD Corp.

In the era of personalized medicine, new methodologies enable development of increasingly sensitive clinical assays that provide more comprehensive tumor characterization using minimal tissue or blood samples. Case studies will be presented highlighting NGS and digital PCR as platform solutions for selecting patients for targeted therapies, monitoring therapeutic responses, and detecting emergent drug resistance.

Pancreas, Renal, Lung, and HPV Related Head and Neck Cancer Biomarkers

2:00 Chairperson's Remarks

George Netto, M.D., Associate Professor of Pathology, Urology and Oncology, Johns Hopkins University School of Medicine

2:05 The Role of Molecular Markers in the Diagnosis of Non-Small Cell Lung Cancer

Peter B. Illei, M.D., Assistant Professor of Pathology, Johns Hopkins University School of Medicine; Director, Immunopathology Laboratory, The Johns Hopkins Hospital, Baltimore, Maryland

Histology and the presence of driver mutations are predictive of response to systemic therapy. Immunohistochemistry is important for accurately classifying tumors, while molecular studies can identify common driver mutations (i.e.: EGFR mutation, EML4-ALK translocation, k-ras mutation, B-Raf mutation, Her2 mutation) that can be targeted. These analyses should be performed in all adenocarcinomas and other non-squamous non-small cell lung carcinomas.

2:35 Advances in the Development of Clinical Tests Using MALDI ToF Mass Spectrometry

Sponsored by biodesix

Heinrich Röder, D.Phil., CTO, Biodesix

The Biodesix mass spectrometry test discovery platform, ProTS, measures protein/peptide expression data reproducibly in a high throughput fashion. This platform has been successfully employed in the development of a commercially available, multivariate test, VeriStrat, developed to help physicians guide treatment in solid epithelial tumors, including NSCLC and SCCHN.

2:50 Human Papillomavirus and Carcinomas of the Head and Neck

Justin A. Bishop, M.D., Assistant Professor of Pathology, Johns Hopkins Bayview Medical Center

This talk will discuss the role of human papillomavirus (HPV) in head and neck cancers. I will briefly touch upon mechanisms of oncogenesis, histopathologic findings, and implications for diagnosis and management.

3:20 Incorporating Next-Gen Sequencing into the Clinical Environment

Sponsored by Predictive Biosciences

Anthony P. Shuber, CTO, Predictive Biosciences

We have recently developed a non-invasive assay that uses Next Gen sequencing to detect single mutant molecules of FGFR3 in urine that are indicative of bladder cancer. The superior analytical sensitivity of this assay results in mutation detection in urine that is >90% concordant with that found in tissue. This NGS approach can be applied to other cancer markers and bodily fluids to improve clinical performance and ultimately, patient management.

3:35 Refreshment Break in the Exhibit Hall with Poster Viewing

4:10 Molecular Genetics of Pancreatic Neoplasms: Insights from High-Throughput Sequencing

Laura Wood, M.D., Ph.D., Pathology, Johns Hopkins University School of Medicine

Neoplasms of the pancreas cover a wide clinical spectrum, from benign tumors to the deadliest cancers. Recent large-scale sequencing analyses provided great insights into the unique biology of pancreatic neoplasms, deepening our understanding of tumorigenesis in the pancreas. Moreover, these studies identified several promising targets for the development of novel diagnostics and therapeutics, highlighting the ability of genomic analyses to pinpoint clinically-actionable alterations.

4:40 Renal Cell Carcinoma: Current and Emerging Therapies and Biomarkers

Hans Hammer, M.D., Ph.D., Assistant Professor, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University

The treatment paradigm for kidney cancer has changed dramatically over the last decade. Current and emerging therapies and potential biomarkers will be reviewed.

5:10 Wine and Cheese Pairing Welcome Reception in the Exhibit Hall with Poster Viewing

6:10 Close of Day

WEDNESDAY, AUGUST 22

7:30 am Problem Solving Breakout Discussions with Continental Breakfast

Cancer Stem Cell Markers: Proving Their Existence and Understanding Tumor Cell Heterogeneity

8:25 Chairperson's Opening Remarks

8:30 Cancer Stem Cells: To Believe or Not to Believe

Sunil Badve, Ph.D., Associate Professor, Clarian Pathology Laboratory, Indiana University School of Medicine

9:00 Translating the Cancer Stem Cell Hypothesis from the Lab to the Clinic

William Matsui, M.D., Associate Professor of Oncology, Division of Hematologic Malignancies, The Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University (tentative)

9:30 Sponsored Presentation *(Opportunity Available)*

9:45 Sponsored Presentation *(Opportunity Available)*

10:00 Coffee Break in Exhibit Hall with Poster Viewing

10:30 Emerging Cancer Stem Cell Biomarkers Based on the "9th Hallmark of Cancer"

James Sherley, M.D., Ph.D., Senior Scientist, Programs in Regenerative Biology and Cancer Biology; Director, Adult Stem Cell Technology Center, Boston Biomedical Research Institute

Carcinogenesis has been attributed to eight cellular alterations highlighted as the "Hallmarks of Cancer." This representation overlooks a "9th Hallmark of Cancer," the absolute requirement for originating tissue stem cells to shift from asymmetric self-renewal kinetics to increased symmetric self-renewal kinetics to achieve the cell production rates necessary to form clinically significant tumors. Biomarkers for asymmetric self-renewal are now emerging. Beyond identifying tissue stem cells, these novel biomarkers also have potential to be highly effective for detecting cancer stem cells.

11:00 Tracking Stem Cell Overpopulation during Colon Cancer Development

Bruce Boman, M.D., Thomas Jefferson University Hospital

Recent developments in the identification and isolation of colon cancer stem cells (SC) using SC markers will be discussed. The hypothesis is that the mechanism that links abnormalities at the gene level and abnormalities at the tissue level is stem cell overpopulation. The concept that symmetric cancer stem cell division is a key mechanism that drives tumor growth, and that development of a new generation of therapeutics that target colon cancer SC holds promise for patients with advanced colorectal cancers will also be addressed.

11:30 Transition to Plenary Session

» 11:50 PLENARY KEYNOTE DISCUSSION

Regulation of LDTs and RUOs

Alberto Gutierrez, Ph.D., Deputy Director, Office of in vitro Diagnostic Device Evaluation and Safety, Food & Drug Administration

Moderated by: Franklin R. Cockerill, III, M.D., Ann and Leo Markin Professor of Microbiology & Medicine; Chair, Department of Laboratory Medicine and Pathology, Mayo Clinic College of Medicine; President and CEO, Mayo Medical Laboratories and Mayo Collaborative Services, Inc.

12:45 pm Enjoy Lunch on Your Own

» PLENARY KEYNOTE

1:45 Views of the Laboratory Industry on Regulatory Issues

Alan Mertz, President, American Clinical Laboratory Association (ACLA)

2:10 Views of Diagnostics Manufacturers on Regulatory Issues

Andrew C. Fish, Executive Director, AdvaMedDx

2:30 Close of Emerging Molecular Markers of Cancer Conference

AUGUST 21-22

Second Annual

MASS SPECTROMETRY IN DIAGNOSTICS OF INFECTIOUS DISEASE AND CLINICAL MICROBIOLOGY

Recommended Pre-Conference Short Courses*

Introducing Mass Spectrometry into a Clinical Laboratory

**Separate registration required, please see page 3 for details*

TUESDAY, AUGUST 21

1:00 pm Registration

Applying Mass Spec-Based Methods to Infectious Disease

2:15 Chairperson's Remarks

Robin Patel, M.D., Chair, Division of Clinical Microbiology, Consultant, Divisions of Clinical Microbiology and Infectious Diseases, Professor of Microbiology and Medicine, College of Medicine, Mayo Clinic

2:20 Progress and Approaches in Developing Mass Spectrometry-Based Proteomic Assays to Distinguish Clinical Strains of Methicillin-Sensitive and Methicillin-Resistant *Staphylococcus aureus*

Richard R. Drake, Ph.D., Professor and Director, MUSC Proteomics Center, Medical University of South Carolina

The use of MALDI-TOF mass spectrometry to identify bacteria at the genus and species level is becoming standard in many clinical microbiology laboratories. Extending these methods and development of other mass spectrometry-based diagnostics for identification of strain differences within a species, particularly for clinical isolates, remains a challenge. Our group has been focusing on assay development to distinguish methicillin-sensitive (MSSA) and methicillin-resistant (MRSA) *Staphylococcus aureus* strains; two primary approaches will be described.

2:50 Rapid Detection of Beta-Lactamase Activity in Clinical Specimens by Electrospray LC/MS/MS

Michael E. Hodsdon, M.D., Ph.D., Associate Professor of Laboratory Medicine and Pharmacology, Yale University School of Medicine

Carbapenemase-expressing bacteria are associated with resistance to most modern antibiotics. Rapid diagnosis is critical to live-saving clinical care and to prevent the spread of outbreaks. We present a rapid, liquid chromatography-coupled, electrospray ionization mass spectrometric assay that detects carbapenemase activity within hours from complex biologic matrices. We are validating this method on both bacterial isolates and primary clinical specimens.

3:20 Sponsored Presentation *(Opportunity Available)*

3:35 Refreshment Break in the Exhibit Hall with Poster Viewing

4:10 Digging Deeper: Improving Results through Detailed Analysis of MALDI-TOF Data

Mark Fisher, Ph.D., Assistant Professor of Pathology, The University of Utah, ARUP Institute for Clinical and Experimental Pathology

MALDI-TOF is rapidly becoming an accepted identification method. Current platforms accurately identify a broad range of organisms, but yield ambiguous results for some clinically relevant pathogens. Detailed analysis of the data at both the scoring and spectral levels can allow for better resolution and more reliable results.

4:40 Next Generation Molecular Diagnostics: MALDI-TOF versus PCR/ESI-MS

Robert Bonomo, M.D., Associate Professor of Medicine, Division of Infectious Disease and HIV Medicine, Case Western Reserve University

The field of molecular diagnostics is rapidly changing and new platforms are introduced regularly. At present clinicians must decide the advantages and disadvantages of choosing between technologies that identify pathogens alone from technologies that reveal the resistance determinants present in bacteria. Each approach assists with decisions to initiate therapy. A comparison of technologies that use mass spectrometry (MALDI TOF and PCR/ESI-MS) will be examined.

5:10 Wine and Cheese Pairing Welcome Reception in the Exhibit Hall with Poster Viewing

6:10 Close of Day

WEDNESDAY, AUGUST 22

7:30 am Problem Solving Breakout Discussions with Continental Breakfast

Applying Mass Spec-Based Methods to Infectious Disease (cont'd)

8:25 Chairperson's Opening Remarks

Richard R. Drake, Ph.D., Professor and Director, MUSC Proteomics Center, Medical University of South Carolina

8:30 Matrix-Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry in the Clinical Microbiology Laboratory in 2012

Robin Patel, M.D., Chair, Division of Clinical Microbiology, Consultant, Divisions of Clinical Microbiology and Infectious Diseases, Professor of Microbiology and Medicine, College of Medicine, Mayo Clinic

Matrix-assisted laser desorption ionization time of flight mass spectrometry allows identification of a wide range of types of bacterial and fungal colonies growing on plates within minutes, without the need for traditional time-consuming and expensive identification tools. This technology is rapidly gaining use in clinical microbiology laboratories worldwide. This presentation will overview the position of matrix-assisted laser desorption ionization time of flight mass spectrometry in clinical microbiology laboratories in 2012, addressing strengths and weaknesses.

9:00 MALDI-TOF in the Mycobacteriology Laboratory and Direct Susceptibility Testing from Blood Cultures: Are They Now Reality?

Nathan A. Ledeboer, Ph.D., Assistant Professor of Pathology, Medical College of Wisconsin

We evaluated the performance of a new Biotyper MALDI-TOF extraction method and library for identification of Mycobacterium spp compared to HPLC. Using a modified reference spectral library created with silica bead extraction resulted in a final identification rate of 94.6%. Further, detection of ampicillin and ertapenem resistance was measured in Enterobacteriaceae using MALDI and initial data indicates high sensitivity.

9:30 Sponsored Presentation *(Opportunity Available)*

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

10:30 Diagnosis of Periprosthetic Joint Infection

Javad Parvizi, M.D., FRCS, Vice Chairman, Research; Director, Clinical Research, Rothman Institute

There are many challenges in diagnosis of PJI, most important of which relates to the lack of an absolute diagnostic test. A workgroup convened by the AAOS proposed an evidence based algorithmic approach. Our center and many others have identified molecular markers that can be utilized for more accurate diagnosis. I will discuss some of the molecular strategies that can be used.

10:55 MALDI-TOF for Routine Identification of Bacteria and Fungi in the NIH Clinical Center Microbiology Laboratory

Daniel P. Fedorko, Ph.D., Microbiologist, NIH/CC/DLM/Microbiology Service

The use of MALDI-TOF to identify anaerobic bacteria isolated from clinical specimens means the clinical microbiology laboratory no longer has to perform presumptive identifications using rapid tests or tests that require growth of suspect anaerobes. Identification of both aerobes and anaerobes growing from primary culture plates of an anaerobic culture can be rapidly and accurately identified by MALDI-TOF.

11:20 Development of a Comprehensive Database and Straightforward Extraction Procedure for Mold Identification Using MALDI-TOF MS

Anna F. Lau, Ph.D., Clinical Microbiology Fellow, Microbiology Service, Department of Laboratory Medicine, Clinical Center, National Institutes of Health

Mold identification is laborious and complex with some newly-described species inseparable morphologically from others. We designed a simple, adaptable protocol mold extraction procedure, and developed a comprehensive, expandable database for accurate identification of 207 clinically relevant molds (hyaline, aseptate, dematiaceous, dermatophyte, dimorphic) by MALDI-TOF MS from solid media. Correct identification was obtainable for genetically different but morphologically indistinguishable species.

11:45 Transition to Plenary Session

» 11:50 PLENARY KEYNOTE DISCUSSION

Regulation of LDTs and RUOs

Alberto Gutierrez, Ph.D., Deputy Director, Office of in vitro Diagnostic Device Evaluation and Safety, Food & Drug Administration

Moderated by: Franklin R. Cockerill, III, M.D., Ann and Leo Markin Professor of Microbiology & Medicine; Chair, Department of Laboratory Medicine and Pathology, Mayo Clinic College of Medicine; President and CEO, Mayo Medical Laboratories and Mayo Collaborative Services, Inc.

12:45 pm Enjoy Lunch on Your Own

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2:10 Views of Diagnostics Manufacturers on Regulatory Issues

Andrew C. Fish, Executive Director, AdvaMedDx

2:30 Refreshment Break in the Exhibit Hall with Poster Viewing

3:15 Chairperson's Opening Remarks

Nathan A. Ledeboer, Ph.D., Assistant Professor of Pathology, Medical College of Wisconsin

3:20 SPOTLIGHT PRESENTATION: Innovative Technologies from Mass Spec to Multiplex Technologies

Christine C. Ginocchio, Ph.D., M.T. (ASCP), Chief, Division of Infectious Disease Diagnostics, Department of Pathology and Laboratory Medicine Professor, Hofstra University North Shore-LIJ School of Medicine North Shore-LIJ Health System Laboratories

Identification of infectious agent(s) is essential to provide an accurate diagnosis, appropriately manage patient care, and in certain cases reduce the risk of transmission within the community and health care settings. This lecture will provide an overview of technologies including unit test systems designed for point-of-care diagnostics, arrays, droplet digital PCR, and mass spectroscopy analysis. Unmet diagnostic needs, regulatory challenges and future considerations will be discussed.

Mass Spectrometry in Clinical Microbiology

3:50 Advancing Diagnostics...Saving Lives: How Rapid Diagnostic Microbiology Can Make a Difference

Donna M. Wolk, M.H.A., Ph.D., D.(ABMM), Division Chief, Clinical and Molecular Microbiology; Associate Professor, Pathology and Medicine, Arizona Health Science Center and University Medical Center

Over the last decade, the Medical Diagnostic Laboratory Sciences community gained access to the proliferation of new and rapid diagnostic technology, largely based in the fields of genomics and proteomics. With access to emerging technology comes the responsibility for prudent stewardship of healthcare resources, supported by the application of evidence-based interventions that encompass the contemporary practice of Laboratory Medicine. This session will review the applications of mass spectrometry in clinical microbiology and describe its implementation in an academic medical center.

Sponsored by Luminex

4:20 Improved Diagnosis of Gastroenteritis using the xTAG Gastrointestinal Pathogen Panel Multiplexed Molecular Assay

Richard Janeczko, Ph.D., Vice President, Emerging Markets & Technologies, Luminex Corporation

Gastroenteritis (GI) is one of the most common infections in both hospital and community patients. Management of these patients imposes strains on healthcare resources, carries a significant economic burden and is compounded by the possibility of multiple aetiologies, both infectious and non-infectious. The results from a prospective study comparing xTAG GPP to standard protocols will be presented.

4:35 Sponsored Presentation *(Opportunities Available)*

4:50 PCR-ESI-TOF-MS-Based Diagnostics Provide Unprecedented Sensitivity, Specificity, and Inclusivity in the Detection and Characterization of Infectious Diseases

Garth D. Ehrlich, Ph.D., Executive Director, Center for Genomic Sciences, Allegheny-Singer Research Institute

We have used the Ibis technology in multiple comparative studies with culture to evaluate the bacteriology of numerous infectious and inflammatory conditions including: total joint failures; osteoarthritis, bony non-union, ACL-repair failure, chronic non-healing wounds, vaginal and uterine microbiomes and infections, urinary and male genital tract infections, and surgical site infections.

5:20 Digging Deeper: Improving Results through Detailed Analysis of MALDI-TOF Data

Mark Fisher, Ph.D., Assistant Professor of Pathology, The University of Utah, ARUP Institute for Clinical and Experimental Pathology

MALDI-TOF is rapidly becoming an accepted identification method in the clinical microbiology laboratory. Current platforms accurately identify a broad range of organisms, but yield ambiguous results for some clinically relevant pathogens. Detailed analysis of the data at both the scoring and spectral levels can allow for better resolution and more reliable results.

5:50 Close of Mass Spectrometry Conference

AUGUST 21-22

Inaugural

REGULATORY COMPLIANCE IN DRUG-DIAGNOSTIC CO-DEVELOPMENT

TUESDAY, AUGUST 21

7:30 am Registration and Morning Coffee

Case Studies of Recent Combined Drug and Diagnostic Approvals

8:30 Chairperson's Opening Remarks

Erling Thor Donnelly, Ph.D., R.A.C., Director, Worldwide Regulatory Strategy, Pfizer, Inc.

8:40 XALKORI & ALK FISH Test Approval: Pharmaceutical Perspective

Erling Thor Donnelly, Ph.D., R.A.C., Director, Worldwide Regulatory Strategy, Pfizer, Inc.

The simultaneous submission and approval of Pfizer's XALKORI (crizotinib) and Abbott Molecular's ALK break-apart FISH companion diagnostic in 2011 presented unique clinical development and regulatory challenges, requiring novel approaches as well as close collaboration between Pfizer, Abbott, CDER, and CDRH. XALKORI was approved only five years after entering clinical trials on the strength of its clinical data in ALK-positive NSCLC patients and unique regulatory strategy.

9:10 XALKORI & ALK FISH Test Approval: Diagnostics Perspective

Pamela L. Swatkowski, Director, Regulatory Affairs, Abbott Molecular, Inc.

The simultaneous submission and approval of Pfizer's XALKORI (crizotinib) and Abbott Molecular's ALK break-apart FISH companion diagnostic in 2011 presented unique clinical development and regulatory challenges, requiring novel approaches as well as close collaboration between Pfizer, Abbott, CDER, and CDRH. The Abbott Molecular ALK Break Apart FISH test development timeline was accelerated from three years to two years and FDA approval was achieved in just five months.

9:40 Paving the Way for Contemporaneous Diagnostic Co-Development and Health Authority Review: The Zelboraf Story

Linda Burdette, Ph.D., Director, Drug Regulatory Affairs, F. Hoffmann-La Roche, Inc.

Co-development of the BRAF-targeted therapy, ZELBORAF™ (vemurafenib) with its companion diagnostic, the cobas® 4800 BRAF V600 Mutation Test highlights aspects of the regulatory pathway described in FDA's 2011 draft guidance, *In Vitro* Companion Diagnostic Devices, and the resulting accelerated process for contemporaneous approval of a drug and companion diagnostic test. The ZELBORAF story also demonstrates the need for an integrated global regulatory strategy for marketing approval in a targeted population.

10:10 Coffee Break

11:00 Paving the Way for Contemporaneous Diagnostic Co-Development and Health Authority Review: The Cobas 4800 Braf Mutation Test Story

Lesley Farrington, Senior Manager, Regulatory Affairs, Roche Molecular System

An overview of the regulatory interactions and lessons learned on the road to contemporaneous review and approval of the companion diagnostic, cobas® 4800 BRAF V600 Mutation Test, with the selective BRAF inhibitor, ZELBORAFTM (vemurafenib) for the treatment of unresectable or metastatic melanoma with the BRAF V600E mutation. The accelerated Dx/Rx approval also demonstrates the ability to accelerate diagnostic development and registration timelines in coordination with drug development programs, while maintaining compliance and quality.

11:30 PANEL DISCUSSION: What's Past is Prologue: A Regulatory Perspective on Contemporaneous Diagnostic Co-Development

Moderator: Janet Jenkins-Showalter, Senior Director, Regulatory Group, Intelligence and Policy, US Pharamceutical Development Regulatory, Genentech - A Member of the Roche Group

A Panel of Experts will discuss:

- Lessons learned from contemporaneous diagnostic co-development successes
- The current and future regulatory environment
- How the most recent "poster-child" success stories, along with the regulatory environment and interested stakeholders, will shape the future of personalized medicine.

Panelists:

Erling Thor Donnelly, Ph.D., R.A.C., Director, Worldwide Regulatory Strategy, Pfizer, Inc.

Pamela L. Swatkowski, Director, Regulatory Affairs, Abbott Molecular, Inc.

Linda Burdette, Ph.D., Director, Drug Regulatory Affairs, F. Hoffmann- La Roche, Inc.

Lesley Farrington, Senior Manager, Regulatory Affairs, Roche Molecular System

Jeff Allen, Ph.D., Executive Director, Friends of Cancer Research

12:30 Enjoy Lunch on Your Own

Working With Regulators

1:45 Chairperson's Remarks

Maham Ansari, M.S., Senior Associate, Regulatory Affairs. US Strategic Regulatory Services, OptumInsight

1:50 FDA Draft Guidances: Overview, Key Messages and Impact

Debra Rasmussen, RAC, MBA, Senior Director, Regulatory Affairs, Johnson & Johnson

2:20 Demystifying Bridging Studies

Marina V. Kondratovich, Ph.D., Associate Director for Clinical Studies, Personalized Medicine, OIVD, CDRH, U.S. Food and Drug Administration

In a "bridging study", clinical samples tested initially with a clinical trial assay (CTA) are re-tested with a market ready assay (MRA) to support approval/clearance of the MRA. We discuss why high levels are required for positive and negative agreement of MRA with CTA and various challenges with such studies (e.g., unavailable samples, missing re-test results, impact of discordance between the two assays on drug efficacy).

2:50 Q&A with Speakers

LABORATORIES' PERSPECTIVE

3:20 FDA Approved Laboratory IVD Assays as Companion Diagnostics: A New Paradigm?

C. Donald Kafader II, Director, Regulatory Affairs, Esoterix Clinical Trials Services, a Division of LabCorp

IVD manufacturers have little incentive to seek and obtain FDA approval for some assays unless there is a substantial potential market for them to sell into. An alternative exists where centralized testing can support the need for a companion diagnostic assay. Laboratories are seeking FDA approvals for assays run only within their facilities. This new paradigm brings new concerns to the diagnostic laboratory and to the FDA.

3:35 Refreshment Break in the Exhibit Hall with Poster Viewing

4:10 Laboratory Developed Tests and Their Place in the Genomic Medicine Era: A CLIA Laboratory Perspective on Companion Dagnostics

Elaine Lyon, Ph.D., Medical Director, Genetics Division; Co-Medical Director, Pharmacogenomics; Co-Director, Clinical Molecular Genetics Fellowship Program, ARUP Laboratories

Clinical laboratories may develop and validate their own methods following CLIA regulatory requirements as laboratory-developed tests (LDT). They may also validate FDA-cleared products for an off-label use (such as additional sample types) as LDTs. This presentation will discuss factors CLIA-certified laboratories consider in deciding to use an FDA-cleared IVD, an off-label use or an in-lab developed assay. The role of LDTs and clinical validations is put into an historical, as well as a near-future genomic medicine, perspective

4:40 CLIA, CAP, GCLP and the FDA: Clinically Certified Lab Processes Enable New Approaches to Therapeutic Compound and Companion Diagnostic Development.

Tera Eerkes, Ph.D., CSO, iGenix, Inc.

High-throughput genotyping, massively parallel sequencing (NGS) and other high-complexity techniques have made it possible to design clinical trials to maximize compound efficacy, minimize toxicity, and pre-segregate patient populations. However, there is a dearth of specific guidance on how these new data and techniques should be incorporated and utilized for FDA submissions. This talk will explore joining these revolutionary techniques and data with existing "best-in-class" regulatory certification processes, as well as future regulatory guides, to maximize successful FDA application potential.

5:10 Wine and Cheese Pairing Welcome Reception in the Exhibit Hall with Poster Viewing

6:10 Close of Day

WEDNESDAY, AUGUST 22

7:30 am Problem Solving Breakout Discussions with Continental Breakfast

New Paradigms in Regulatory Approaches

8:25 Chairperson's Opening Remarks

Debra Rasmussen, RAC, MBA, Senior Director, Regulatory Affairs, Johnson & Johnson

8:30 Whole Genome Sequencing as Companion Diagnostic: Regulatory Considerations

Melina Cimler, Vice President, Quality & Regulatory Affairs, Illumina, Inc.

9:00 Looking into the Global Regulatory Future of Companion Diagnostics and Personalized Medicine

Maham Ansari, M.S., Senior Associate, Regulatory Affairs. US Strategic Regulatory Services, OptumInsight

The global regulatory landscape for companion diagnostics (CDx) is changing very fast making it extremely challenging for industry to keep up with the increasing demands of the regulators. This presentation will examine the changing regulatory framework for CDx in complex and key jurisdictions like Japan, China, Canada, US, and EU and provide tips on what is required to obtain successful market approval for these niche products in these countries. An overview of global design & development requirements will also be provided.

9:30 EU Regulatory Environment Around Companion Diagnostics

Bruno Flamion, M.D., Ph.D., Professor of Physiology and Pharmacology, University of Namur, Belgium, and Chairman, Scientific Advice Working Party, The European Medicines Agency (EMEA)

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

10:30 Companion Diagnostics and Personalized Medicine: The FDA Perspective

Alberto Gutierrez, Ph.D., Office of in vitro Diagnostic Device Evaluation and Safety, Food & Drug Administration

11:15 Transition to Plenary Session

» 11:50 PLENARY KEYNOTE DISCUSSION

Regulation of LDTs and RUOs

Alberto Gutierrez, Ph.D., Deputy Director, Office of in vitro Diagnostic Device Evaluation and Safety, Food & Drug Administration

Moderated by: Franklin R. Cockerill, III, M.D., Ann and Leo Markin Professor of Microbiology & Medicine; Chair, Department of Laboratory Medicine and Pathology, Mayo Clinic College of Medicine; President and CEO, Mayo Medical Laboratories and Mayo Collaborative Services, Inc.

12:45 pm Enjoy Lunch on Your Own

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Alan Mertz, President, American Clinical Laboratory Association (ACLA)

2:10 Views of Diagnostics Manufacturers on Regulatory Issues

Andrew C. Fish, Executive Director, AdvaMedDx

2:30 Close of Regulatory Compliance in Drug-Diagnostic Co-Development Conference

Hotel & Travel Information

Conference Hotel:

The Hyatt Regency on Capitol Hill, Washington, DC
400 New Jersey Avenue
Washington, DC 20001
Tel: 202-737-1234

Room Rate: $195 s/d
Reservation Cutoff: July 20, 2012

Please visit our conference website to make your reservation online or call the Hotel directly to reserve your sleeping room accommodations. You will need to identify yourself as a Cambridge Healthtech Institute conference attendee to receive the discounted room rate. **Reservations made after the cut-off date or after the group room block has been filled (whichever comes first) will be accepted on a space- and rate-availability basis. Rooms are limited, so please book early.**

Flight Discounts:

American Airlines
Special discounts have been established with American Airlines for this conference:

- Call 1-800-433-1790 and use Conference Code 9482BG
- Go online at www.aa/group.com enter Conference code 9482BG in promotion discount box
- Contact our designated travel agent, Wendy Levine at 1-877-559-5549 or wendy.levine@protravelinc.com

Car Rental Discounts:

Special discount rentals have been established with Hertz for this conference.

- Call HERTZ, 800-654-3131 use our Hertz Convention Number (CV): 04KL0003
- Go online www.hertz.com use our Hertz Convention Number (CV): 04KL0003

AUGUST 22-23

Fourth Annual

MOLECULAR DIAGNOSTICS FOR INFECTIOUS DISEASE

Recommended Pre-Conference Short Course*

Introducing Mass Spectrometry into a Clinical Laboratory

**Separate registration required, please see page 3 for details*

WEDNESDAY, AUGUST 22

11:00 am Registration

» 11:50 PLENARY KEYNOTE DISCUSSION

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Nathan A. Ledeboer, Medical College of Wisconsin

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Christine C. Ginocchio, Ph.D., M.T. (ASCP), Chief, Division of Infectious Disease Diagnostics, Department of Pathology and Laboratory Medicine; Professor, Hofstra University North Shore-LIJ School of Medicine North Shore-LIJ Health System Laboratories

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Mass Spectrometry in Clinical Microbiology

3:50 Advancing Diagnostics...Saving Lives: How Rapid Diagnostic Microbiology Can Make a Difference

Donna M. Wolk, M.H.A., Ph.D., D.(ABMM), Division Chief, Clinical and Molecular Microbiology; Associate Professor, Pathology and Medicine, Arizona Health Science Center and University Medical Center

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Richard Janeczko, Ph.D., Vice President, Emerging Markets & Technologies, Luminex Corporation

Gastroenteritis (GI) is one of the most common infections in both hospital and community patients. Management of these patients imposes strains on healthcare resources, carries a significant economic burden and is compounded by the possibility of multiple aetiologies, both infectious and non-infectious. The results from a prospective study comparing xTAG GPP to standard protocols will be presented.

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4:50 PCR-ESI-TOF-MS-Based Diagnostics Provide Unprecedented Sensitivity, Specificity, and Inclusivity in the Detection and Characterization of Infectious Diseases

Garth D. Ehrlich, Ph.D., Executive Director, Center for Genomic Sciences, Allegheny-Singer Research Institute

We have used the Ibis technology in multiple comparative studies with culture to evaluate the bacteriology of numerous infectious and inflammatory conditions including: total joint failures; osteoarthritis, bony non-union, ACL-repair failure, chronic non-healing wounds, vaginal and uterine microbiomes and infections, urinary and male genital tract infections, and surgical site infections.

5:20 Imaging the Effect of the Microbiome on Gut Metabolism with Mass Spectrometry with Real-Time Analysis of Bacterial Metabolic Output

Christopher Rath, Ph.D., Scientist, Dorrestein Laboratory, University of California, San Diego

Changes in gut microbiome populations have been correlated with disease status. We applied imaging mass spectrometry to localize metabolites in gnotobiotic mouse models of the human gut microbiome. Inflammation-associated molecules with altered spatial distributions include: amino-acids, bile-acids, polysaccharides, and lipids. Identifications were validated by semi-quantitative LCMS/GCMS. Findings were then correlated to human fecal samples, pure bacterial cultures, and transcriptomics analysis.

5:50 Close of Day

6:30- 8:30 pm Dinner Short Courses*

**Separate registration required, please see page 3 for details*

THURSDAY, AUGUST 23

7:30 am Problem Solving Breakout Discussions with Continental Breakfast

Multiplex Diagnosis of Infectious Disease

8:25 Chairperson's Opening Remarks

Charles Chiu, University of California San Francisco School of Medicine

8:30 Multiplex Nucleic Acid Tests for Respiratory Pathogens: Technology, Applications and Clinical Relevance

Frederick S. Nolte, Ph.D., D(ABMM), F(AAM), Professor, Pathology and Laboratory Medicine; Vice Chair, Laboratory Medicine; Director, Clinical Laboratories, Medical University of South Carolina

Respiratory viruses are responsible for significant morbidity and mortality especially in children, the elderly and immunecompromised individuals. The emerging technologies for multiplex nucleic acid-based tests for the detection of respiratory viruses will be reviewed. The use of these technologies in clinical laboratories to provide comprehensive diagnostic tests for these pathogens and their clinical impact will be discussed.

9:00 Using Next-Generation Sequencing and Microarrays for Multiplexed Testing in the Clinical Microbiology Lab

Charles Chiu, M.D., Ph.D., Assistant Professor, Departments of Laboratory Medicine and Medicine, Infectious Diseases, University of California San Francisco School of Medicine

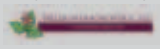
Pan-pathogen microarrays such as the UCSF ViroChip and unbiased deep sequencing have proven effective for broad-based identification of pathogens in clinical specimens. Significant challenges remain, however, in adapting these technologies for routine use in clinical and public health settings.

9:30 Molecular Diagnostic Platforms for Detecting Drug Resistance in Fungal Pathogens

David S. Perlin, Ph.D., Executive Director and Professor, Public Health Research Institute & UMDNJ Regional Biocontainment Laboratory, International Center for Public Health, UMDNJ-New Jersey Medical School

Early detection of fungi in clinical specimens with rapid evaluation of drug susceptibility has the potential to improve survival of patients with invasive mycoses. A variety of robust real-time RNA- or DNA-amplification and detection platforms are available that provide simultaneous species identification and high fidelity allelic discrimination of resistance markers.

Sponsored by



10:00 Companion Diagnostic using Multiparameter Flow Cytometry for Nucleoside Transporter hENT1 in Acute Myeloid Leukemia

Bruce H. Davis, M.D., President & Founder, Trillium Diagnostics, LLC

The human Equilibrative Nucleoside Transporter 1 (hENT1) transports nucleoside analogs such as cytarabine (ara-C) and gemcitabine into the cells. We developed a flow cytometric assay for hENT1 to identify patients that might benefit from ara-C alternatives, such as ElacytarabineTM due to low hENT1 expression to serve as a companion diagnostic. We report our experience with the flow cytometric assay for hENT1 in blood (PB) and bone marrow (BM) specimens using a ratiometric method. The studies demonstrate variable hENT1 expression in leukocytes and nearly a ten-fold range of hENT1 expression among AML blasts. This diagnostic assay for hENT1 expression could be integrated into clinical practice and help personalize medicine by rapidly identifying alternative AML therapies when hENT1 expression is decreased.

10:15 Coffee Break in the Exhibit Hall with Poster Viewing

From Multiplex to Deep Sequencing in ID

10:45 FEATURED PRESENTATION: Applying NGS Sequencing to Diagnostic Virology

Gregory A. Storch, M.D., Ruth L. Siteman Professor of Pediatrics, Professor of Medicine and of Molecular Microbiology; Director, Pediatric Infectious Diseases and Pediatric Laboratory Medicine; Medical Director, Clinical Laboratories, St. Louis Children's Hospital

High throughput sequencing offers the appeal of an open approach to viral detection that can reveal the presence of a broader range of pathogens than viral isolation, antigen detection or amplification-based technologies. The challenges of using high throughput sequencing in a diagnostic virology lab, and data from an on-going study comparing sequencing to an extensive panel of PCR assays will be presented.

11:15 Principles and Recommendations for the Implementation of NGS into Diagnostic Labs

Amy Gargis, ORISE Fellow, Centers for Disease Control and Prevention

Current professional and regulatory standards that address the quality of NGS are minimal at this time. This presentation will describe the outcomes from a national workgroup that developed principles and guidance for NGS that considered test validation, quality control procedures, proficiency testing, and reference materials.

11:45 Sequencing Methods in Diagnostic Laboratory Medicine

Andrea Ferreira-Gonzalez, Ph.D., Professor of Pathology & Director, Molecular Diagnostics Laboratory, VCUHS

12:15 pm PANEL DISCUSSION: Multiplex Testing Platforms & Technologies for the Clinical Laboratory

Moderator: *Charles Chiu, University of California San Francisco School of Medicine*

Sponsored spotlight presentions from technology & platform providers supporting multiplex testing. (Opportunities Available)

12:45 Luncheon Presentations *(Sponsorship Opportunities Available)* or Lunch on Your Own

1:45 Session Break

Hcv and Hpv – Clinical Diagnostics

2:00 Chairperson's Remarks

Christine C. Ginocchio, Hofstra University North Shore-LIJ School of Medicine North Shore-LIJ Health System Laboratories

2:05 FEATURED PRESENTATION: Monitoring HCV RNA in the Era of Potent Anti-Viral Therapy

Mitchell L. Shiffman, M.D., Liver Institute of Virginia, Bon Secours Virginia Health System

Chronic HCV is the most common cause of chronic liver disease, cirrhosis and liver cancer in the USA. In 2011 the first 2 direct acting anti-viral agents for HCV were approved by the US FDA. Over 20 protease and/or polymerase inhibitors are now under development. The treatment of chronic HCV requires highly sensitive assays to measure HCV RNA and knowledge of how to utilize the results of these assays to assess response and guide HCV treatment.

2:35 What's New in Viral Hepatitis and HIV Testing?

Joseph D. Yao, M.D., Division of Clinical Microbiology, Department of Laboratory Medicine and Pathology, Mayo Clinic & Mayo Medical Laboratories

This talk will cover: Hepatitis A - serologic and molecular test updates; Hepatitis B - quantitative HBsAg serologic and HBV molecular testing; Hepatitis C - impact of DAA on HCV RNA quantification and HCV resistance testing; and Hepatitis E - serologic and molecular testing.

3:05 Hepatitis C Virus Genotyping to Detect Drug Resistance to Direct Acting Antiviral Agents: From the Bench to the Clinic

Michael J. Kozal, M.D., Professor of Medicine , Division of Infectious Diseases, Yale School of Medicine; Director, Yale HIV Clinical Trials Program; Chief, Section of Infectious Diseases, VA CT Healthcare System

Combinations of direct acting antivirals (DAAs) have cured some HCV-infected patients without the use of pegylated interferon and ribavirin. However, amino acid changes in the NS3, NS5A and NS5B genes can lead to high-level drug resistance and are strongly associated with treatment failure with DAAs. This talk will review current methods and new emerging technologies used to detect DAA drug resistance and how these new assays may be employed in the clinic.

3:35 Novel Sample Storage and Transport by ViveST for Downstream HCV Viral Load and Genotypic Testing

Daniel R. McClernon, CSO, bioMONTR Laboratory, a division of McClernon LLC.

Infectious disease monitoring often requires collection sites to ship patient samples to reference testing laboratories. These samples require careful temperature control and special packaging. We will describe performance of ViveST, a novel dried ambient transportation matrix, to frozen plasma for use with commercially available HCV viral load and genotypic assays.

4:05 SPOTLIGHT PRESENTATION: Cytomegalovirus in Transplant Testing: Challenges and the Promise of Standardization

Randall T. Hayden, M.D. , Director, Clinical and Molecular Microbiology , Member, Department of Pathology, St. Jude Children's Research Hospital

Cytomegalovirus (CMV) viral load testing, most commonly by real-time PCR has become a mainstay of post-transplant care. However, the interpretation of such testing is fraught with challenges, largely due to suboptimal assay precision and the lack of standardized quantitative controls. An overview of the role of CMV testing will be presented, along with issues related to result variability and standardization.

4:35 Close of Infectious Disease Conference

Third Annual

COMPANION DIAGNOSTICS

Recommended Pre-Conference Short Courses*
- Latest Advances in Molecular Pathology
- Deal Making in Companion Diagnostics
- Next Generation Sequencing in Molecular Pathology

**Separate registration required, please see page 3 for details*

WEDNESDAY, AUGUST 22

11:00 am Registration

» 11:50 PLENARY KEYNOTE DISCUSSION

Regulation of LDTs and RUOs
Alberto Gutierrez, Ph.D., Deputy Director, Office of in vitro Diagnostic Device Evaluation and Safety, Food & Drug Administration

Moderated by: Franklin R. Cockerill, III, M.D., Ann and Leo Markin Professor of Microbiology & Medicine; Chair, Department of Laboratory Medicine and Pathology, Mayo Clinic College of Medicine; President and CEO, Mayo Medical Laboratories and Mayo Collaborative Services, Inc.

12:45 pm Enjoy Lunch on Your Own

» PLENARY KEYNOTE

1:45 Views of the Laboratory Industry on Regulatory Issues
Alan Mertz, President, American Clinical Laboratory Association (ACLA)

2:10 Views of Diagnostics Manufacturers on Regulatory Issues
Andrew C. Fish, Executive Director, AdvaMedDx

2:30 Refreshment Break in the Exhibit Hall with Poster Viewing

Technology in the Service of Companion Diagnostics

3:15 Chairperson's Opening Remarks

3:20 What Will it Take to Realize the True Potential of Companion Dx?
Michael Nohaile, Ph.D., Global Head, Novartis Molecular Diagnostics
Generally speaking, today's diagnostics are simple profiles of single markers. While there has been tremendous hype around the recent advances in Next Generation Sequencing Technology (NGS), by itself, NGS is just another platform. To truly revolutionize companion dx and the way medicine is practiced, we need to address a host of clinical, scientific, technical, political and societal barriers. In his talk, Dr. Nohaile will discuss the critical steps in this process.

3:50 Companion Diagnostics of the Future: LDTs and Complex Gene Signatures Using Next Generation Sequencing
Premal Shah, Ph.D., Director, Business Development, Genomic Health, Inc.
As technology evolves in the genomics space to incorporate Next Generation Sequencing, it is very conceivable that the companion diagnostics of the future will be complex gene signatures. As an extension, these diagnostics could very well be laboratory developed tests (LDTs) and not traditional kits or point-of-care solutions. There is a need for all stakeholders in these spaces to understand the upside and value in these kinds of tests and paradigm shifts to enable higher level of patient care.

4:20 Fully Automated Platform for Companion Diagnostics
Sponsored by Rheonix
Richard A. Montagna, Ph.D., Senior Vice President, Scientific Affairs, RHEONIX, Inc.
The Rheonix CARD® system is able to automatically process a wide range of clinical specimens for companion diagnostic applications. Such samples as buccal swabs, whole blood, fresh tissue and FFPE samples can be placed into the system which will automatically lyse cells, extract and purify DNA, multiplex PCR amplify targets of interest and then detect the resulting amplicons on an integrated DNA microarray. Examples of using the CARD technology to detect the presence of SNPs associated with warfarin sensitivity, Plavix sensitivity and KRAS markers will be provided.

4:35 Single Molecule Arrays (SiMoA) for Ultrasensitive Protein Detection in Companion Diagnostics
Sponsored by Quanterix
David C. Duffy, Ph.D., Vice President, Research, Quanterix Corporation
SiMoA is a game-changing technology for the quantification of low concentrations of proteins in blood. This fully automated platform enables high throughput, multiplexed measurement of proteins at low cost. We will describe the potential for SiMoA to have a dramatic impact on the development of companion diagnostics for antibody therapeutics.

4:50 A New Paradigm for Advancing Personalized Medicine: The Contract Diagnostics Organization
Sponsored by ResearchDx
Philip D. Cotter, Ph.D., F.A.C.M.G., Co-Founder, ResearchDx, LLC

5:05 Using Protein Microarray Technology to Screen Ultra-Specific mAbs for Diagnostic Purpose
Sponsored by ORIGENE
Donghui Ma, Ph.D., Director, Immunology, OriGene Technologies, Inc.
Antibody with cross-reactivity can create unexpected side effects or false diagnostic reports if used for clinical purposes. By using high density protein microarray chip technology, we discovered that a number of well known diagnostic mAbs are not specific and we were able to generate the corresponding UltraMABs with extreme target specificty and ultra-performance.

5:20 Finding the Right Tool: Tailoring the Assay to the Clinical Need
Jamie Platt, Ph.D., Scientific Director, Advanced Sequencing, Quest Diagnostics Nichols Institute
There are several categories of genetic variants associated with disease, drug response, or cancer prognosis. These include point mutations, triplet repeat expansions, small insertions and deletions (in-dels), large deletions and duplications, chromosomal translocations, and copy number abnormalities. There is an extensive variety of platforms to detect the variations. The concept that any single test, even whole genome sequencing (WGS) will be able to detect all of these variants is naive. This talk will use examples of clinical and companion diagnostic scenarios which would mandate use of a particular technology to optimize sensitivity and specificity and minimize costs.

5:50 Predicting Tumor Response to Targeted Therapy using Multiplexed Tissue Protein Analysis
Sponsored by 20/20 GeneSystems
John Gillespie, M.D., Director, Medical Affairs, 20/20 GeneSystems, Inc.
Layered immunohistochemistry (L-IHC) permits the multiplex analysis of biomarkers in FFPE tissue sections. Analysis of biomarkers along the mTOR pathway using L-IHC was performed on breast and kidney cancer samples from patients treated with trastuzumab and temsirolimus, respectively. In both cases a small set of biomarkers correctly identified responders and non-responders with 90% or better accuracy. This is a substantial improvement over other tests currently used to predict response.

6:05 Close of Day

6:30- 8:30 pm Dinner Short Courses*
**Separate registration required, please see page 3 for details*

THURSDAY, AUGUST 23

7:30 am Problem Solving Breakout Discussions with Continental Breakfast

Pharma-IVD Partnerships: Striving for Fair and Effective Models

8:10 Chairperson's Opening Remarks

8:15 Co-Development of Zelboraf and the Cobas BRAF V600 Test, and Beyond

Walter Koch, Ph.D., Vice President & Head, Global Research, Roche Molecular Systems

8:45 How to Partner with Pharma and Enable Value Capture for Both Parties

Peter Collins, Ph.D., Vice President & Head, Diagnostics, GlaxoSmithKline Biologicals

This talk will discuss the critical differences between the world of drug development and diagnostic development. Understanding the cultural divide is crucial to agreeing a partnering model as opposed to fee for service. For diagnostics companies to gain fairer and more effective partnership models it is of key importance to understand how pharma views risk, investment and returns.

9:15 Diagnostic Partnerships in Biomarker Identification, Development, and Commercialization

Matthew J. Hawryluk, Ph.D., Director, Business Development , Foundation Medicine, Inc.

This presentation will discuss diagnostic partnership models of clinical development of novel diagnostic tests, from early stages to later and commercial stages. Our goal of these partnerships is to improve patient-centered and personalized cancer care by allowing for an improved understanding of the molecular basis of an individual's tumor.

Sponsored by GfK

9:45 Funding for Companion Diagnostics in the US Market: Stakeholders and Trends

Gavin Erickson, Principal Consultant, GfK Bridgehead

For many companion diagnostic manufacturers, the differing reimbursement pathways for pharmaceuticals and diagnostics makes establishing market access in the United States a significant challenge. From policies driven by CMS to working with private health insurers and consumers directly, GfK Bridgehead will bring perspective and clarity to obtaining reimbursement in the US, with comparisons to key European markets.

- US market access overview
- Comparisons between US and EU funding
- Impact of coding, payment and regulatory issues

10:15 Coffee Break in the Exhibit Hall with Poster Viewing

10:45 Towards Effective Drug-Diagnostic Co-Development and Commercialization – How Do We Get There?

Rainer Metzger, Ph.D., Vice President, Pharma Partnerships, Leica Biosytems

This presentation will discuss an array of important issues such as: Key considerations for the selection of the Rx & Dx partner of choice; Shaping the partnership to achieve mutual business benefit; Options and rights granted to the partner company; Governance structure models to effectively run collaborations; Key aspects in regulatory, marketing & commercialization; and Partnership and business models for CDx: Danaher, Leica and associated collaborators.

11:15 Evolving Effective Partnering Models for Rx/Dx Co-Development and Commercialization

Andrea Lauber, Ph.D., Global Head, Transactions for Clinical Biomarkers and Pharmacodiagnostics, Bristol-Myers Squibb

Strategies that guide Rx/Dx partnerships need to incorporate flexible business models to be effective in a continuously evolving landscape of Targeted Medicine. Moreover, aligning goals and objectives of pharmaceutical and diagnostic companies can be challenging as partners focus on separate, interrelated assets and developing different types of products for the market place. Considerations will be discussed that enable Rx/Dx partners to deliver as medical, regulatory, legal, financial and business considerations continue to evolve.

Sponsored by BOSTON HEALTHCARE

11:45 Challenges Posed to Dx Business Models by Companion Diagnostics and Personalized Medicine

Joseph V. Ferrara, President, Boston Healthcare

Personalized medicine offers the potential to improve well-established practices for physicians and patients, but the concept presents a direct challenge to other health care stakeholders essential to its realization — especially diagnostics companies. At the core of the challenge is the question "How will the emergence of a personalized medicine paradigm change these companies' innovation and commercialization approaches?" This presentation will examine sources of value for companion diagnostics and discuss how diagnostics companies can retool to capture it in the future.

12:15 pm PANEL DISCUSSION: Increasing Partnership Value for Diagnostics Partners

Sponsored by MYRIAD RBM

1:00 Luncheon Presentation I A Blood-Based Protein Biomarker Approach to Companion Diagnostic Development

Dominic Eisinger, Ph.D., Director, Strategic Development, Myriad RBM

- Choosing the right patients – disease segmentation in heterogeneous diseases
- Case study of a successful program: CDx diagnostic partnership with Pharma
- Myriad RBM partnership models: flexibility, shared risk, and strategic fit.

Sponsored by SLONE PARTNERS

1:30 Luncheon Presentation II Hire Right the First Time; Interview Techniques That Work

Tara Kochis, President, Slone Partners

Learn from recruiting experts, must ask interview questions, how to probe and understand a candidate's motivation and why this matters, why do people leave good jobs and how can knowing this help you retain your top talent.

Evidence Generation for Reimbursement Decisions

2:00 Chairperson's Remarks

2:05 Roadmap for Demonstrating Clinical Utility of Molecular Diagnostics: Experience with the 92-Gene Assay for Cancer Classification, Cancertype ID

Catherine A. Schnabel, Ph.D., Senior Director, Medical & Scientific Affairs, bioTheranostics, Inc.

In the era towards individualizing patient care, the changing landscape of molecular diagnostics presents many challenges to enabling clinical adoption and applicability of high complexity tests. This presentation will discuss the importance of accurate tumor classification in current paradigms of evidence-based patient management, overview perspectives and propose a framework for developing clinical utility through discussion of CancerTYPE ID, a 92-gene expression-based assay for molecular classification of tumors. In particular, evidentiary requirements of analytical validity, clinical validity, clinical utility and health effectiveness will be presented along with highlighting how the clinical value story is organized for various healthcare stakeholders.

2:35 A Payer's Perspective: Reimbursement of Companion Diagnostics

David A. Dworaczyk, Ph.D., COO, Meta Diagnostic

The discussion will examine the engagement of a broad spectrum of stakeholders, to generate, gather and interpret real world evidence to inform the development and implementation of payer policies and support the translation of molecular medicine products into practice. It will review how to gain meaningful diagnostic insights and provide clinical and economic benefits to patients, healthcare providers, and payers including real-world clinical research to generate evidentiary standards to inform coverage decisions, creation of actionable insights from actual spend & reimbursement trends, and implementation of personalized medicine interventions into practice, where appropriate, toward better managing outcomes and costs.

3:05 PANEL DISCUSSION

Moderator: Patrick F. Terry, Principal, Pricing & Market Access Practice, Scientia Advisors

Additional Panelists:

Elaine K. Jeter, M.D., Medical Director, Palmetto GBA

Sheila D. Walcoff, Esq., Founding Principal, Goldbug Strategies LLC and Counsel for the Coalition for 21st Century Medicine

4:00 Close of Companion Diagnostics Conference

AUGUST 22-23

Second Annual

COMMERCIALIZATION OF MOLECULAR DIAGNOSTICS

Roadmap for Success

Recommended Pre-Conference Short Course*

• Micro- and Nanofluidics in Diagnostics and Life Sciences: Technologies, Applications and Markets

**Separate registration required, please see page 3 for details*

WEDNESDAY, AUGUST 22

11:00 am Registration

» 11:50 PLENARY KEYNOTE DISCUSSION

Regulation of LDTs and RUOs

Alberto Gutierrez, Ph.D., Deputy Director, Office of in vitro Diagnostic Device Evaluation and Safety, Food & Drug Administration

Moderated by: Franklin R. Cockerill, III, M.D., Ann and Leo Markin Professor of Microbiology & Medicine; Chair, Department of Laboratory Medicine and Pathology, Mayo Clinic College of Medicine; President and CEO, Mayo Medical Laboratories and Mayo Collaborative Services, Inc.

12:45 pm Enjoy Lunch on Your Own

» PLENARY KEYNOTE

1:45 Views of the Laboratory Industry on Regulatory Issues

Alan Mertz, President, American Clinical Laboratory Association (ACLA)

2:10 Views of Diagnostics Manufacturers on Regulatory Issues

Andrew C. Fish, Executive Director, AdvaMedDx

2:30 Refreshment Break in the Exhibit Hall with Poster Viewing

Future of Pricing and Reimbursement in Diagnostics

3:00 Chairperson's Opening Remarks

Patrick F. Terry, Principal, Pricing & Market Access Practice, Scientia Advisors

Sponsored by Elbit Systems of America Medical - KMC Systems

3:05 Simulation Reduces Risk Earlier in IVD Instrument Development Programs

Walter Gilde, Manager, Business Development, KMC Systems, Inc.

IVD instrument development programs carry degrees of risks depending on marketing requirements, business value proposition and/or technology maturity. Early simulation has proven effective in exposing concealed requirements, design conflicts, and technical risks. Simulation models allow the resolution of these issues, and the ability to revise concepts and make informed tradeoffs before substantial development expenditures and capital commitments are made. This proven process provides a more robust business case analysis, optimizing parameters leading to cost effective instrument platforms and tests.

3:20 Launching Diagnostics into a Global Marketplace

Patrick F. Terry, Principal, Pricing & Market Access Practice, Scientia Advisors

This presentation will provide an overview of the necessary clinical, delivery model, business, and financial considerations for informed decisionmaking in entering new geographic markets.

3:50 Translating Good Science into Good Business: What Do You Need for Successful Commercialization in a Changing Environment?

Rina Wolf, Vice President, Commercialization Strategies, Consulting & Industry Affairs, Xifin

In this era of change, learn about recent updates on coding, coverage, reimbursement and pricing and discover how you can prepare yourself to respond. Through discussions of case studies, gain insights into what data and strategies are most effective to fully bring a test to market. This is the perfect session for our changing environment to find out what you will need to be successful in commercialization and techniques to translate your good science into good business.

Sponsored by McKESSON

4:20 Partnering with Payers to Shift to Value-Based Reimbursement

Douglas Moeller, M.D., Medical Director, McKesson Health Solutions

Several critical trends in the market are making it more difficult for Laboratories to get reimbursed for the advanced diagnostic tests they perform. For many labs, partnering with Health Plans may be the answer to not only improve reimbursement, but move towards an environment where they are reimbursed on value. Attendees will gain an understanding of those trends impacting the reimbursement of molecular and genetic tests and uncover the opportunities to partner with payers to move towards value-based reimbursement

Challenges of Stratified Medicine Commercialization

Sponsored by Sony DADC

4:50 Industrialization of Next-Generation Diagnostics

Ali Tinazli, Ph.D., Director, Business Development & Sales, Sony DADC

Smart Consumables with microfluidic or optical features are prerequisites for emerging applications in the biomedical markets. The increasing complexity of such new products requires new manufacturing technologies. Sony DADC is applying its excellence in customized mass manufacturing to these highly sophisticated consumables in its new OEM business.

Sponsored by htg Molecular

5:05 Multiplex Molecular Assays from Discovery to the Clinic on FFPE Samples: Extraction-Free

Chris Roberts, Vice President, Medical Innovation, HTG Molecular

HTG's qNPA enables analysis of FFPE tissue samples in a simple workflow process. The ability to measure dozens to hundreds of genes in a single micro well, along with the flexibility to use old or degraded samples, permits the use of retrospective cohorts in discovery and validation, and is important in clinical practice. HTG has an extensive publication record and clinical labs use qNPA today.

5:20 What Defines Value Capture in Drug Diagnostic Co-Development

Peter Collins, Vice President, Personalized Medicine Diagnostics, GlaxoSmithKline

This talk will describe the fundamental components of Value Capture in an Rx/Dx setting. What is the value proposition to various stakeholders? What are the challenges involved in establishing value for drug, diagnostic and the combination? An assessment of the differences between commercializing a drug versus a typical diagnostic will be considered.

5:50 Addressing the Challenges of CDx Development and Commercialization: Perspectives from a Global IVD Leader

John F. Beeler, Ph.D., Director, Theranostics and Business Development, bioMerieux

The speaker will discuss bioMerieux's successful theranostic partnering strategy with pharmaceutical developers. bioMerieux has developed a real-world knowledge of win-win deal terms, co-development strategies and alliance management. The speaker will discuss theranostic development issues from the diagnostic developer perspective and will comment on the likely future evolution of commercializing companion diagnostics in this field.

6:30- 8:30 pm Dinner Short Courses*

The Future of Point-of-Care Diagnostics

**Separate registration required, please see page 3 for details*

THURSDAY, AUGUST 23

7:30 am Problem Solving Breakout Discussions with Continental Breakfast

Navigating the Challenges of Personalized Medicine in Europe

8:25 Chairperson's Opening Remarks

Alain Huriez, M.D., Chairman, Epemed: European Personalized Medicine Association

8:30 Navigating Market Access in Europe

Alain Huriez, M.D., Chairman, Epemed

9:00 PANEL DISCUSSION:

Bruno Flamion, M.D., Ph.D., Professor of Physiology and Pharmacology, University of Namur, Belgium, and Chairman, Scientific Advice Working Party, The European Medicines Agency (EMEA)

Irene Norstedt, Deputy Head, DG Research and Innovation, Health Research: Personalised Medicine, European Commission

Nick Crabb, Associate Director, Diagnostics Assessment Programme, Centre for Health Technology Evaluation, National Institute for Clinical Excellence (NICE)

Fabien Calvo, M.D., Ph.D., Deputy General Director, National Cancer Institute, France

10:00 Novel Clinical Trial Design in IVD Development

Sponsored by D-TARGET a Premier Research Company

Hua Gong, M.D., Ph.D., Executive Director, IVD, D-Target, a Premier Research Company

D-Target/PRG provides innovative clinical trial design to establish clinical utility and validity of IVD products. We will present our solutions to address some of those challenges by using novel clinical trial design. We hope our audience will gain good understanding of novel trial design methods, learn how to mitigate risks and maximize success in IVD clinical development.

10:15 Coffee Break in the Exhibit Hall with Poster Viewing

How do Early Stage Start-Ups Meet Expectations of VCs?

10:40 Chairperson's Remarks

Thomas F. Soriano, President & CEO, DOCRO, Inc.

10:45 Finding Real Customers in a Billion Dollar Market

Manfred Scholz, Ph.D., President, Scholz Consulting Partners LLC

Every business plan states a billion dollar market. It is true that no one should invest in small markets. No one (at least in the diagnostics industry) doubts market size, but investors question your ability to capture customers, and they should. We will take a look at the critical points in the fundraising and development of early ventures with real world case examples of failures and big FAILURES and very few successes. The brilliant team that can not manage. The professionally looking website that does not convince investors or customers. The greatest technology that gets shoe-horned into the wrong application. The design concept that gets lost when geeks start playing. The importance of stealth mode: How to hide from your customers? And finally how to focus on pleasing customers and attracting bidders for your business.

11:10 Spending Your Funding $$$ Wisely to Get an IVD on the Market (or "We have to do WHAT?")

Thomas F. Soriano, President & CEO, DOCRO, Inc.

This presentation will provide practical information about the hoops and hurdles an IVD company faces as they use their new money to commercialize an IVD test. One or more "crash and burn" scenarios will be used to illustrate "what not to do" while successes will be discussed as counterpoints. A summary of "lessons learned" will be provided. There will be a 10 minute Q&A period available at the end of the session. Audience members are encouraged to e-mail questions to the chairman in advance of the session if the questioner requests anonymity.

11:35 Q&A with Speakers

Commercialization Challenges for Next-Generation Sequencing

11:45 EXPERT PANEL

- What are the actual commercial opportunities?
- What are some of the obstacles?
- What is the best path forward?
- IT: data management challenges

Moderator:

Andrew Fish, J.D., Executive Director, AdvaMed Dx

Panelists:

Meeting Informatics Challenges in a Genomic World

M. Michael Barmada, Ph.D., Associate Professor of Human Genetics; Director, Center for Computational Genetics, GSPH; Associate Director, Center for Simulation and Modeling, University of Pittsburgh

Intellectual Property & Innovation Following Prometheus & Myriad

Gregory Carlin, Principal, McKeon, Meunier, Carlin & Curfman, LLC

12:45 Luncheon Presentations

Sponsored by PrimeraDx The Multiplex PCR Company

Innovative Partnering Strategies for Multiplex Companion Diagnostics

David Jackson, Ph.D., Vice President, Business Development, PrimeraDx

Development and Commercialization of multiplexed companion diagnostics requires specialized technologies, expertise and partnerships. Not only do drug developers require innovative solutions but so do diagnostic developers and the labs working on behalf of both. This talk will cover novel partnership strategies in the multiplexed companion diagnostics space including:

- Use of novel technologies with innovative partnerships
- Co-development and co-commercialization deal structures
- Aligning commercial interests of stake-holders

1:45 Session Break

Evidence Generation for Reimbursement Decisions

2:00 Chairperson's Remarks

2:05 Roadmap for Demonstrating Clinical Utility of Molecular Diagnostics: Experience with the 92-Gene Assay for Cancer Classification, Cancertype ID

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Additional Panelists:

Elaine K. Jeter, M.D., Medical Director, Palmetto GBA

Sheila D. Walcoff, Esq., Founding Principal, Goldbug Strategies LLC and Counsel for the Coalition for 21st Century Medicine

4:00 Close of Commercialization of Molecular Diagnostics Conference

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Opportunity includes a 30-minute podium presentation. Boxed lunches are delivered into the main session room, which guarantees audience attendance and participation. A limited number of presentations are available for sponsorship and they will sell out quickly. Sign on early to secure your talk!

Invitation-Only VIP Dinner/Hospitality Suite

Sponsors will hand-pick their top prospects from the conference pre-registration list for an evening of networking at the hotel or at a choice local venue. CHI will extend invitations and deliver prospects. Evening will be customized according to sponsor's objectives (i.e. purely social, focus group, reception style or plated dinner, plated dinner with specific conversation focus).

CHI Lead Generation

CHI can help you with lead generation throughout the year. Our internal database includes over 800,000 prospects in the life sciences. By leveraging the database and mining for your specific requirements, we can produce multiple custom projects which will deliver your prospective buyers:

- Web Symposia
- Podcasts
- White Papers
- Custom Market Research Surveys
- And More!

Exhibit Information

Exhibitors will enjoy facilitated networking opportunities with qualified decision makers at the Next Generation Diagnostics Summit, making it the perfect platform to launch a new product, collect feedback and generate new leads. Exhibit space sells out quickly, so reserve yours today!

Additional networking & promotional opportunities are available!

For additional information, please contact:

Joseph Vacca
Manager, Business Development
781-972-5431 | jvacca@healthtech.com

2011 Sponsors & Exhibitors

Advanced Cell Diagnostics
ArcticZymes
Asuragen
BD Diagnostics
Biosearch Technologies
Boston Healthcare Associates
Cureline, Inc.
Exosome Diagnostics
Hologic
KMC Systems
Luminex
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Pathogenica
PrimeraDx
Promise Advanced Proteomics
QIAGEN
Randox Labs
Renishaw Diagnostics
ResearchDx, LLC
Signal Genetics
SurModics
Theranostics Health
TwistDx Limited
Veridex
Wi, Inc.

Reserve your exhibit space by **May 18th & SAVE $300**

"The meeting was very worthwhile. Engaged audience, interesting presentations, well attended by decision makers and leaders in the industry. We enjoyed exciting discussions which gave us perspective on where our technology fits in the market."

– VP of Business Development, Exosome Diagnostics

Pricing and Registration Information

PARTNERING FORUM

(Includes access to Partnering Forum only)	Non-Attendee	Conference Attendee
Emerging Diagnostic Partnering and Investment Forum	$1395	$995

CONFERENCE PRICING

SUMMIT PRICING — BEST VALUE!

(Includes access to 2 conferences, excludes short courses)	Commercial	Academic, Government, Hospital-affiliated
Registrations after July 27, 2012, and on-site	$2395	$1045

SINGLE CONFERENCE

(Includes access to 1 conference, excludes short courses)		
Registrations after July 27, 2012, and on-site	$1775	$725

August 21-22	August 22-23
Enabling Point-of-Care Diagnostics	Molecular Diagnostics for Infectious Disease
Emerging Molecular Markers of Cancer	Companion Diagnostics
Mass Spectrometry in Diagnostics of Infectious Disease	Commercialization of Molecular Diagnostics
Regulatory Compliance in Drug-Diagnostic Co-Development	

SHORT COURSES

(Includes access to short courses only)	Commercial	Academic, Government, Hospital-affiliated
One short course	$695	$395
Two short courses	$995	$695
Three short courses	$1195	$795

Monday, August 20th – Morning	Monday, August 20th – Afternoon	Wednesday, August 22nd – Dinner
SC1 Micro- and Nanofluidics in Diagnostics and Life Sciences	**SC5** Applications of Detection Theory in Diagnostics	**SC9** The Future of Point-of-Care Diagnostics
SC2 Smarter Studies: Boosting Omics and Biomarker Projects through an Efficient and Rigorous Study Design	**SC6** Next Generation Sequencing as a Diagnostics Platform	**SC10** Deal Making in Companion Diagnostics
SC3 Differentiating Lateral Flow Products from the Competition Based on Performance and Design	**SC7** Introducing Mass Spectrometry into a Clinical Laboratory	
SC4 Latest Advances in Molecular Pathology	**SC8** Improving Cardiovascular Biomarkers: Clinical Impact and Crossover Applications	

CONFERENCE DISCOUNTS

Poster Submission-Discount ($50 Off)
Poster abstracts are due by July 20, 2012. Once your registration has been fully processed, we will send an email containing a unique link allowing you to submit your poster abstract. If you do not receive your link within 5 business days, please contact jring@healthtech.com. *CHI reserves the right to publish your poster title and abstract in various marketing materials and products.

REGISTER 3 - 4th IS FREE: Individuals must register for the same conference or conference combination and submit completed registration form together for discount to apply.

Additional discounts are available for multiple attendees from the same organization. For more information on group rates contact David Cunningham at +1-781-972-5472

ADDITIONAL REGISTRATION DETAILS

Each registration includes all conference sessions, posters and exhibits, food functions, and access to the conference proceedings link.

Handicapped Equal Access: In accordance with the ADA, Cambridge Healthtech Institute is pleased to arrange special accommodations for attendees with special needs. All requests for such assistance must be submitted in writing to CHI at least 30 days prior to the start of the meeting.

To view our Substitutions/ Cancellations Policy, go to http://www.healthtech.com/regdetails

Video and or audio recording of any kind is prohibited onsite at all CHI events.

If you are unable to attend but would like to purchase the Next Generation Dx Sumit CD for $750 (plus shipping), please visit NextGenerationDx.com. Massachusetts delivery will include sales tax.

How to Register: **NextGenerationDx.com**

reg@healthtech.com • P: 781.972.5400 or Toll-free in the U.S. 888.999.6288

Please use keycode **1280 F** when registering!

Please refer to the Registration Code below:

Cambridge Healthtech Institute
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