Third Annual

Next Generation Dx Summit

Moving Assays to the Clinic

Final Agenda

August 23-25, 2011
The Ritz Carlton • Washington D.C.

Register by July 29 and Save up to $200!

August 23-24

- Enabling Point-of-Care Diagnostics
- Emerging Molecular Markers of Cancer
- Translating Proteomics into the Clinical Lab

New Program Just Added!

- Mass Spectrometry in Clinical Diagnostics

August 24-25

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

Plenary Discussion:

Changing Regulation of LDTs

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

Multi-Stakeholder Plenary Panel:

Future of Reimbursement for Molecular Diagnostics

Moderator: Thomas A. Gustafson, Ph.D., Arnold & Porter LLP

Panelists:
Ann-Marie Lynch, Advanced Medical Technology Association (AdvaMed)

David Mongillo, M.P.H., M.S.M., American Clinical Laboratory Association

Marc Hartstein, Centers for Medicare and Medicaid Services (tentative)

NextGenerationDx.com

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Event-at-a-Glance

Monday	Pre-Conference Short Courses*		
Tuesday Morning	Enabling Point-of-Care Diagnostics	Emerging Molecular Markers of Cancer	Translating Proteomics into the Clinical Lab
Tuesday Afternoon	Enabling Point-of-Care Diagnostics	Emerging Molecular Markers of Cancer	Translating Proteomics into the Clinical Lab
Wednesday Morning	Enabling Point-of-Care Diagnostics	Emerging Molecular Markers of Cancer	Translating Proteomics into the Clinical Lab
	Plenary Keynote Session		
Wednesday Afternoon	Molecular Diagnostics for Infectious Disease	Companion Diagnostics	Commercialization of Molecular Diagnostics
	Dinner Short Courses*		
Thursday Morning	Molecular Diagnostics for Infectious Disease	Companion Diagnostics	Commercialization of Molecular Diagnostics
Thursday Afternoon	Molecular Diagnostics for Infectious Disease	Companion Diagnostics	Commercialization of Molecular Diagnostics

**Separate Registration Required*

SPONSORSHIP & EXHIBIT INFORMATION

Sponsorships

Brand your company as a thought leader by participating as a Sponsor. Presenting your scientific solutions and services directly to our top-tier delegates can significantly impact their purchasing decisions and help you achieve your marketing and business development objectives.

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Exhibiting allows your company to differentiate your products, services or technology from competitors, and demonstrate your commitment to the science. It is also a perfect platform to launch a new product, collect feedback, network, and generate new leads.

FOR MORE INFORMATION, PLEASE CONTACT:

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HOTEL & TRAVEL INFORMATION

Conference Venue and Hotel:
The Ritz-Carlton, Washington, DC
1150 22nd Street, NW
Washington, DC 20037
Tel: 202-835-0500
Fax: 202-835-1588

Room Rate: $235 s/d
Reservation Cutoff: July 18, 2011
Please make your reservation online or call the hotel directly to reserve your sleeping accommodations. 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:

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- Call 1-800-433-1790 use Conference code 4281BF
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Special discount rentals have been established with Hertz for this conference. Please use one of the following methods:

- Call HERTZ, 800-654-3131 use our Hertz Convention Number (CV): 04KL0002
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Short Courses*

MONDAY, AUGUST 22
MORNING SHORT COURSES 9:00 AM – 12:00 PM

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

- Understand the basic physical principles and scaling laws governing miniaturization
- Identify the suitable material for a given microfluidic application
- Understand the basic technologies available for the microfabrication of glass, silicon and polymer materials and follow the device manufacturing process from design to the finished microfluidic device
- 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

Instructor: *Holger Becker, Ph.D., CSO, microfluidic ChipShop*

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

- Why study design is critical
- 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

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

SC3 Latest Advances in Molecular Pathology, Part I (Basic)

This course is designed to educate practicing pathologists on the applications of the latest molecular diagnostics technologies. The course will be created as a collaboration between Cambridge Healthtech Institute and the College of American Pathologists.

It will include three lectures:

- Basic Principles of PCR: A Primer
- DNA Sequencing and Current Applications
- Chromosomal Microarray Diagnostic Testing: The Basics

Instructors:

Gail H. Vance, M.D., Professor, Department of Medical and Molecular Genetics, IU School of Medicine

Andrea Ferreira-Gonzalez, Ph.D., Chair, Molecular Diagnostics, Virginia Commonwealth University

Jennifer Laudadio, M.D., Assistant Professor, Pathology, Wake Forest Baptist Medical Center

MONDAY, AUGUST 22
AFTERNOON SHORT COURSES – 2:00 – 5:00 PM

SC4 Applications of Detection Theory in Diagnostics

- Define false positives, false negatives and dichotomous test
- Define sensitivity, specificity, limit-of-detection, and response time
- Understand and analyze a dose-response curve
- Construct and analyze a Receiver Operating Characteristic (ROC) curve from raw data
- Define Positive Predictive Value (PPV) and Negative Predictive Value (NPV)
- Interpret detector performance trade-offs using a ROC curve

Instructor: *John C. Carrano, Ph.D., President, Carrano Consulting, LLC*

SC5 Automation Solutions for Molecular Diagnostics

Nucleic acid-based technologies have been widely and successfully used in clinical diagnostics. Despite available commercial instruments and reagent systems, diagnostic laboratories are still challenged to find compatible, cost-effective, and integrated solutions to automate molecular testing. This course aims to introduce automation and informatics tools useful in pre-analytical, analytical, and post-analytical phases of molecular diagnostic testing.

Instructor: *Weimin Sun, Ph.D., Senior Scientific Director, Molecular Genetics Department, Quest Diagnostics Nichols Institute*

SC6 Serve, Collaborate, Disintermediate: Business Strategies for Companion Diagnostics

- Pharma Stratified Medicine Economics: Why bother and what a bother.
- Three main Companion Diagnostic models: Serve, Collaborate or Disintermediate
- Implementation challenges: Reference lab case study
- Co-Development challenges: Good rhythm needed
- Optimizing the biomarker cut-off value to optimize therapeutic value

Instructor: *Mark Trusheim, President, Co-Bio Consulting, LLC; Executive in Residence & Visiting Scientist, MIT; former Special Government Employee, Office of the Commissioner, FDA*

SC7 Latest Advances in Molecular Pathology, Part II (Advanced)

This course is designed to educate practicing pathologists on the applications of the latest molecular diagnostics technologies. The course will be created as a collaboration between Cambridge Healthtech Institute and the College of American Pathologists.

It will include five lectures:

- Clinical Applications of Pharmacogenomics in Molecular Diagnostic Cancer Testing
- Next-Generation Sequencing in Molecular Pathology
- Digital Pathology
- Direct to Consumer Genetic Tests: How to stay ahead of patients in this current trend
- Coding and Reimbursement for Molecular Testing: New Developments and Interesting Times Ahead

Instructors:

Karen Weck, M.D., Professor of Pathology & Laboratory Medicine and Genetics, Director, Molecular Genetics, Associate Director, Institute for Pharmacogenomics and Individualized Therapy, University of North Carolina at Chapel Hill

Wayne Grody, M.D., Ph.D., Professor, Departments of Pathology & Laboratory Medicine, Pediatrics, and Human Genetics at the UCLA School of Medicine

David Wilbur, Director, Clinical Imaging, Massachusetts General Hospital , Professor of Pathology, Harvard Medical School

Nazneen Aziz, Ph.D., Director of Molecular Medicine in the College of American Pathologists

Jeffrey A. Kant M.D. Ph.D., Director, Division of Molecular Diagnostics, University of Pittsburgh Medical Center Health System

WEDNESDAY, AUGUST 24
DINNER SHORT COURSES – 6:30 – 8:30 PM

SC8 The Future of Point-of-Care Diagnostics

- 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?

Instructors: *Keith F. Batchelder, M.D., CEO, Genomic Healthcare Strategies*

Peter S. Miller, COO, Genomic Healthcare Strategies

SC9 Mass Spec Methods for the Clinical Lab

MALDI-TOF mass spectrometry is a rapid, inexpensive identification method that detects biomarker spectra characteristics for individual species of organisms with an accuracy equivalent to gene sequencing. The introduction of mass spectrometry methods into clinical microbiology laboratories brings many possibilities for new clinical laboratory interventions in support of patient care. This course will describe and review mass spectrometry methods with current and potential application to diagnostic clinical microbiology laboratories.

Instructor: *Thomas Briese, Ph.D., Associate Professor of Clinical Epidemiology, Mailman School of Public Health, Columbia University*

**Separate Registration Required*

Fifth Annual

ENABLING POINT-OF-CARE DIAGNOSTICS

Discovering Key Factors for Success

TUESDAY, AUGUST 23

7:30 am Registration and Morning Coffee

OPENING SESSION: OVERVIEW OF POINT-OF-CARE DIAGNOSTICS

8:30 Chairperson's Opening Remarks
Penny Wilson, Ph.D., Lead Specialist, Detection and Identification of Infectious Agents, Technology Strategy Board

8:40 KEYNOTE PRESENTATION

Clinical Impact of Having Rapid Data from POCT
Daniel J. Wattendorf, M.D., Lt. Col., USAF, MC, Program Manager, Defense Sciences Office, Defense Advanced Research Projects Agency (DARPA)
This presentation will explore development of novel molecular-based platforms that can be applied to diagnosis and assessment of human health in low resource settings and at the point of care. Methods that allow direct testing of complex biospecimens with minimal size, weight, power, and storage at room temperature as an end-to-end integrated capability and formats that allow individuals to collect biospecimens in a simple, stable, universal format for subsequent analyses will be addressed for the low resource setting. Additionally, technical solutions suitable to overcome regulatory challenges and potential strategies for rapid design, production, and distribution of new assays onto point of care platforms will be addressed.

9:10 KEYNOTE PRESENTATION

How Quantitative Point-of-Care Tests are Going to Drive Molecular Diagnostics Forward and Enable Personalized Medicine
Kent Lewandrowski, M.D., FCAP, Associate Chief of Pathology, Director of Clinical Services, Associate Professor, Harvard Medical School, Massachusetts General Hospital

9:40 Point-of-Care Diagnostic Technologies: Today and Tomorrow
Thomas Li, Ph.D., FACB, FAAAAI, Senior Director, Technology Management, CTO, Roche Diagnostics, Pleasanton
This presentation will give an overview of current Point-of-Care Diagnostics Technologies. The future applications of innovative new technologies for Point-of-Care testing will also be covered.

10:10 Networking Coffee Break

DIAGNOSTIC APPLICATIONS IN THE CLINIC

10:55 Chairperson's Remarks
Shuqi Chen, Ph.D., CEO, IQuum, Inc.

11:00 Advances in Point-of-Care Diagnostics: HIV and TB Case Detection in Clinical Trials
Marco Schito, Ph.D., (Contractor) Senior Laboratory Program Manager, HJF-VRP Team Leader, Vaccine Clinical Research Branch, Division of AIDS, NIAID, NIH, DHHS
The development of safe and effective therapeutic, vaccine or other prevention methods to fight AIDS and tuberculosis remains of paramount importance. Clinical trials are typically conducted in populations with a high incidence of disease and have limited resources available for laboratory monitoring. Although point-of-care molecular diagnostics can enable early identification of infected individuals, there are challenges to meet the clinical and regulatory requirements. This presentation will outline the clinical needs, highlight the pipeline, identify issues and provide future perspectives.

11:30 POC HIV Virologic Assays for Early Infant Diagnosis and Monitoring
Susan A. Fiscus, Ph.D., Professor, Microbiology & Immunology, University of North Carolina, Chapel Hill
The latest point-of-care assays for diagnosing HIV infection in infants and monitoring responses to anti-retrovirals will be described in the context of their critical value in resource limited settings.

12:00 pm Development and Evaluation of POC CD4 Tests for HIV/AIDS Care in Resource-Poor Settings
Steven D. Reid, Ph.D., The CD4 Initiative, The Institute of Global Health Innovation, Imperial College London
Antiretroviral therapy is life-saving in HIV/AIDS. This treatment is not started immediately but rather when the number of CD4 T cells in the blood fall below a given threshold. Many resource-poor countries lack the infrastructure to support the technologies which count CD4 T cells and so the CD4 Initiative was created to develop new, point-of-care tests for CD4 suitable for low-income settings. This presentation will cover the development of such tests, their evaluation and how to measure their impact in the treatment of HIV/AIDS.

12:30 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

1:30 Session Break

NEAR PATIENT DISEASE MANAGEMENT

2:00 Chairperson's Remarks
Yolanda A. Cillo, M.D., M.B.A., Medical Director, Abbott Point of Care

2:10 Application of SAMBA – A Point-of-Care Nucleic Acid-Based Platform for Infectious Disease Diagnosis
Helen Lee, Ph.D., Director, Diagnostics Development Unit, University of Cambridge, UK; President & CEO, Diagnostics for the Real World, Ltd.
The technology and results for several infectious disease markers on a point-of-care nucleic acid based system called SAMBA (Simple AMplification Based Assay) will be presented. The chemistry is based on a simple and sensitive visual detection, stable in high temperature and thus circumvents the need of expensive instrumentation or cold-chain transport and storage, making SAMBA highly suitable for settings such as emergency rooms, physician's office or clinics in developing countries.

2:40 Biomarkers for the Rapid Management of Sepsis
Jennifer Williams, M.S.N., R.N., ACNS-BC, Clinical Nurse Specialist, Emergency Services, Barnes-Jewish Hospital
Use of point of care testing to evaluate key clinical conditions such as sepsis will be discussed. While POCT can be used to assess many different types of clinical conditions, sepsis is among the most dangerous problems the bedside clinician, who must quickly evaluate the patient in order to protect them from danger. Proper use of biomarkers can aid the clinician in providing effective, life saving therapies.

3:10 Networking Refreshment Break with Exhibits and Poster Viewing

4:00 Patient Self-Testing for Anti-Coagulation— Is It Here to Stay?
Conan Li, M.B.A., Ph.D., President & CEO, Health Freedom Network, Inc.
Three million Americans take the blood thinner Warfarin for a heart condition or thrombotic disorder. These patients must measure their blood coagulation every month, often for life. However, they are increasingly shifting from testing at a clinic or hospital to self-testing. Discussed will be the analytical, clinical, and economic factors that impact this shift.

4:30 Point-of-Care Diagnostics for the Developing World: The Example of HIV
Christine Rousseau, Ph.D., Program Officer, Global Health- Infectious Diseases Development, Bill & Melinda Gates Foundation
This talk will focus on the challenges in developing and delivering point-of-care diagnostics for the developing world, using HIV diagnostics as examples. The speaker will also discuss partnerships with philanthropic and public-sector organizations that can remove the risks associated with technology development and reaching the market.

5:00 Opening Reception in the Exhibit Hall with Exhibits and Poster Viewing

6:00 Close of Day

WEDNESDAY, AUGUST 24

7:30 am Breakout Sessions

Concurrent Problem Solving Breakout Sessions are interactive, topic-specific discussions hosted by a moderator. These sessions are open to all attendees, sponsors, exhibitors, and speakers and provide a forum for discussing key issues and meeting potential partners. Please pick a topic of your choice and join in.

INNOVATIONS IN POINT-OF-CARE

8:25 Chairperson's Remarks

James Nichols, Ph.D., DABCC, FACB, Medical Director, Clinical Chemistry, Pathology, Baystate Health

8:30 Integrated Innovation in Point-of-Care Diagnostics for Developing Countries

Rebecca Lackman, Ph.D., Program Officer, Grand Challenges Canada at the McLaughlin-Rotman Centre for Global Health

This talk will highlight the partnership between Grand Challenges Canada and the Bill & Melinda Gates Foundation on our joint initiative to develop greater access to point-of-care diagnostics in developing countries. The rationale for and vision of the joint program, what we set out to achieve and our approach, and the impact we hope to deliver will be addressed.

8:50 Non-Instrumented Nucleic Acid Amplification (NINA): Instrument-Free Molecular Malaria Diagnostics for Low-Resource Settings

Paul LaBarre, Ph.D., Technical Officer, PATH

We have achieved the first complete, non-instrumented nucleic acid amplification test (NAAT) using a calcium oxide heat source thermally linked to an engineered phase change material. These two components alone maintain a thermal profile suitable for the loop-mediated isothermal amplification assay. These developments will enable point-of-care diagnostics using accurate NAATs which until now have required a well-equipped laboratory. The aim of this research is to provide pathogen detection with NAAT-level sensitivity in low-resource settings where assays such as immunochromatographic strip tests are successfully used but where there is no access to the infrastructure and logistics required to operate and maintain instrument-based diagnostics.

9:10 A Zinc Finger Protein Array for the Visual Detection of Specific DNA Sequences for Diagnostic Applications

David J. Segal, Ph.D., Associate Professor, Genome Center and Department of Biochemistry and Molecular Medicine, University of California, Davis

We are developing a microfluidic point-of-care device to detect pathogens based on their genetic sequence. Instead of PCR, we are using our sequence-enabled reassembly (SEER) technology, based on engineered DNA-binding proteins, for isothermal colorimetric detection. The method can distinguish 50 fmol of target DNA from non-target DNA within 5 min.

9:30 Diagnostic MicroFluidics Assays: Lab Benchtop to Lab-on-Card

Sponsored by

Steve Jackinsky, MS, Director, Diagnostics, Wi

Microfluidic devices can be designed to closely match benchtop assays. In the development process are decision-making steps which have dramatic affects on the final launch of a diagnostic product. The general process of transferring an assay to a lab-on-card microfluidic will be presented. Selected topics will be presented to offer guidance on common development hurdles and methods to manage risk as the assay transforms into a Lab-on-Card diagnostic.

10:00 Networking Coffee Break with Exhibits and Poster Viewing

10:30 A Risk Management Approach to Enhancing POCT Quality

James Nichols, Ph.D., DABCC, FACB, Medical Director, Clinical Chemistry, Pathology, Baystate Health

POCT provides faster test results with the potential for improved patient care, but concerns about quality and regulatory challenges have limited its implementation. New CLSI guidelines under development take a logical approach to reducing the chance of error with POCT and other laboratory devices through use of risk management principles. The CLSI guidelines are based on industrial ISO guidelines interpreted for the clinical laboratory to allow staff to prioritize hazards and incorporate quality control processes (both manufacturer controls engineered into a device as well as laboratory implemented processes) to reduce risk. This presentation will discuss common sources of POCT error and how the CLSI guidelines can help laboratories develop a quality control plan based on risk management principles to reduce and manage POCT errors.

11:00 Health Economic Value Propositions for Point-of-Care Diagnostics

Cynthia Doucet, M.S., M.S.C.I., Director, Health Economics & Outcomes Research, Abbott Diagnostics

Payers, providers and health systems must make ongoing decisions about how to allocate limited resources. In addition to demonstrating clinical utility, diagnostics companies are increasingly asked to provide Health Economics & Outcomes Research (HEOR) data to support those decisions. This presentation will explore HEOR value messages in the context of point-of-care devices and tests.

11:30 Move to Plenary Session

PLENARY KEYNOTE SESSION

KEYNOTE DISCUSSION:

11:50 Changing Regulation of LDTs

Moderator: *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.*

Featured Guest: *Alberto Gutierrez, Ph.D., Deputy Director, Office of In Vitro Diagnostic Device Evaluation and Safety, Food & Drug Administration*

Audience will be asked to submit questions in advance for the discussion.

MULTI-STAKEHOLDER PANEL:

12:30 Future of Reimbursement for Molecular Diagnostics

Moderator: *Thomas A. Gustafson, Ph.D., Senior Policy Advisor, Arnold & Porter LLP*

- Status of CPT coding and fee schedules (clinical lab vs. physician fee)
- Impact of new CPT coding for reimbursement of tests
- What do changes in regulation portend for suppliers and reimbursement?

Panelists: *Ann-Marie Lynch, Executive Vice President, Payment and Health Care Delivery Policy, AdvaMed*

David Mongillo, M.P.H., M.S.M., Vice President, Policy and Medical Affairs, American Clinical Laboratory Association

1:20 - 2:20 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

2:20 Close of Conference

Fourth Annual

EMERGING MOLECULAR MARKERS OF CANCER

Evaluating for Clinical Use

TUESDAY, AUGUST 23

7:30 am Registration and Morning Coffee

DEEP SEQUENCING

8:30 Chairperson's Opening Remarks
Lyle Arnold, Ph.D., President & Founder, Aegea Biotechnologies; Member, Board of Directors, Asuragen, Inc.

8:40 Development of Cancer Diagnostics at Genomic Health
Joffre Baker, Ph.D., CSO, Genomic Health, Inc., Genomic Health, Inc.
Components of the strategy include product focus on difficult clinical decisions, high level of clinical validation, and a commitment to stay at the cutting edge of genomic technology.

9:10 Clinician's Dilemma: Challenges and Practical Aspects of Sequencing
Ramesh K. Ramanathan, M.D., Medical Director, TGen Clinical Research Service, Scottsdale Health Care and Clinical Professor of Medicine, University of Arizona, College of Medicine
The practical aspects of incorporating sequencing information for the treatment of patients with advanced cancer will be discussed.

9:40 Development of Personalized Tumor Biomarkers Using Massively Parallel Sequencing
Rebecca Leary, Ph.D., Postdoctoral Fellow, Oncology, Ludwig Center for Cancer Genetics and Therapeutics, Johns Hopkins Kimmel Cancer Center
Personalized Analysis of Rearranged Ends (PARE) is a novel approach to identify tumor-specific rearrangements on a per-patient basis and create personalized biomarkers for detection of circulating tumor DNA. The PARE approach may be used to monitor tumor levels after therapy and determine cancer recurrence.

10:10 Networking Coffee Break

CANCER BIOMARKERS

10:55 Chairperson's Remarks
Peter Blume-Jensen, Ph.D., CSO, Metamark Genetics

11:00 Disease Biology-Based, Post-Genomic Approaches for Prognostic and Efficacy-Predictive Biomarkers for Cancer
Peter Blume-Jensen, Ph.D., CSO, Metamark Genetics
The significant advances in cancer genetics in recent years have been met with only limited successes in progress in cancer treatment and care. To a great extent this is due to the challenges in identifying which specific genetic mutations are 'drivers' of the cancer phenotype. Metamark is taking a functional, mechanistic approach to identify the proteins and signaling pathways that are causally involved in the aggressive, metastatic cancer phenotype. Many of these 'driver' proteins are potential novel drug targets. Our scientific approach enables development of powerful prognostic and efficacy-predictive, protein-based, quantitative biomarkers.

11:30 Talk Title to be Announced
Speaker to be Announced

12:00 pm Uptake of Molecular Biomarkers as Standard Care in Oncology
Joan McClure, Senior Vice President, Clinical Information and Publications, National Comprehensive Cancer Network
Use of new molecular biomarkers to guide treatment decision making in cancer has become the standard of care for a subset of validated testing modalities in the United States. Acceptance in the oncology community, as demonstrated by inclusion in the NCCN Clinical Practice Guidelines, has implications for coverage of the cost of testing because tests which have achieved the required level of evidence of clinical utility required by Guidelines Panels are more likely to be reimbursed. Analysis of the types and quality of data required to support recommendation in NCCN Guidelines for routine use of new molecular tests used for diagnosis, treatment selection, response evaluation, or prognosis will be described. This talk will also provide a historical context describing the incorporation of guidelines recommendations for molecular testing into clinical practice from 2000-2011. Descriptive data regarding the concordance of practice with these recommendations in a group of academic medical centers over this period demonstrates uptake of emerging molecular tests as part of routine patient care.

12:30 The Use of the Exosomes as Non-Invasive Diagnostics for Disease Management via Transcriptional Profile Analysis
Sponsored by exosome diagnostics
Leileata M. Russo, Ph.D., Director, Research, Exosome Diagnostics, Inc.
Microvesicles, including exosomes, are small lipid bilayer vesicles released from all cells into bodily fluids. We have developed techniques to extract high quality RNA from microvesicles derived from fresh and frozen biobanked biofluids (blood and urine) taken from patients with a myriad of diseases ranging from cancer (prostate, glioblastoma) to metabolic diseases. Analysis of the RNA via transcriptional signatures, SNP analysis, and translocation analysis allows for the non-invasive diagnosis and treatment of disease.

1:00 A High Multiplex Open Platform Approach to Fusion Gene Test Development
Sponsored by PrimeraDx The Multiplex PCR Company
Lilly Kong, DVM, CSO, PrimeraDx
The molecular detection of Myeloproliferative Disorders has traditionally focused on BCR-ABL fusion gene variants. The discovery of an activating mutation in JAK2 has opened the door to additional testing and treatment guidance. A High Multiplex qPCR solution allows simultaneous detection of key BCR-ABL fusion gene variants and the JAK2 mutations.

1:30 Session Break

CANCER BIOMARKERS

2:00 Chairperson's Remarks
Gary V. Borzillo, Ph.D., Director, Translational Oncology, Pfizer, Inc.

2:10 Emerging Molecular and Immunohistochemical Markers of Detection and Prognostication in Prostate Cancer
George Netto, M.D., Associate Professor of Pathology, Urology and Oncology, Johns Hopkins University School of Medicine
Molecular diagnostics applications are now an integral part of the management algorithms of several solid tumors. In stark contrast, the current clinical management of urologic malignancies is lagging behind. Clinically robust molecular tests that can identify prostate cancer patients that are more likely to respond to a given targeted agent or those in need of a more aggressive treatment based on well-validated molecular prognosticators are still lacking. Several promising biomarkers for detection, prognosis, and targeted therapeutics are now under evaluation. Candidate biomarkers that may soon make their transition to clinical assays in urologic oncology patients are discussed.

2:40 Patient Selection Biomarkers for Drugs Targeting PI3K and KRAS Signaling
Gary V. Borzillo, Ph.D., Director, Translational Oncology, Pfizer, Inc.
PI3K and KRAS signaling elements have been recognized as drug discovery targets for two decades. However, considerable hurdles were encountered in the development of effective inhibitors, and challenges still remain in using these agents to help patients. My talk will introduce the PI3K and KRAS pathways and provide a general overview of the emerging therapies. I will then share some ideas on which cancer patients might particularly benefit from the use of PI3K and/or KRAS-directed therapies.

3:10 Networking Refreshment Break with Exhibits and Poster Viewing

4:00 Cancer Diagnosis Based on Analysis of the Plasma Soluble HLA Peptidome
Arie Admon, Faculty of Biology, Technion - Israel Institute of Technology, Israel
The normally cell-surface human leukocyte antigens are released in large amounts to the circulation by many types of cancer cells. Thus, immunoaffinity purification of these soluble HLA molecules followed by mass spectrometry identification their bound peptides, forms the basis for a new simple and universal immuno-MS paradigm for diagnosis of cancer.

4:30 Faster, Better Diagnosis for Unknown Primary Cancer
Richard Osborne, M.D., FRCP, Consultant in Medical Oncology, Dorset Cancer Centre, Poole Hospital

Cancer of Unknown Primary (CUP) is a common but neglected clinical problem. Conventional clinical approaches to diagnosis and treatment often fail to deliver meaningful results, and are costly and inefficient. Gene expression based profiling is emerging as a useful tool to expedite diagnosis and improve treatment outcomes. There are however still large barriers to the use of such new approaches and lack of understanding of the nature of CUP lies at the core of this failure.

5:00 Opening Reception in the Exhibit Hall with Exhibits and Poster Viewing

6:00 Close of Day

WEDNESDAY, AUGUST 24

7:30 am Breakout Sessions

Concurrent Problem Solving Breakout Sessions are interactive, topic-specific discussions hosted by a moderator. These sessions are open to all attendees, sponsors, exhibitors, and speakers and provide a forum for discussing key issues and meeting potential partners. Please pick a topic of your choice and join in.

CIRCULATING BIOMARKERS- LIQUID BIOPSY

8:25 Chairperson's Remarks
Joseph M. Carroll, Ph.D., Associate Director, Biomedical Diagnostics Institute,Dublin City University (DCU)

8:30 The Role of Platelets in Circulating Tumor Cell Diagnostics
Joseph M. Carroll, Ph.D., Associate Director, Biomedical Diagnostics Institute, Dublin City University (DCU)

This presentation will give an overview of the Biomedical Diagnostics Institute (BDI) and its CTC diagnostic platform. The mission of the BDI is to create and advance diagnostic platforms through an innovative academic-industrial consortium. Industrial partners include OrthoClinical Diagnostics, Alere and Becton Dickinson.

9:00 Biomarkers of Cancer Malignancy for Clinical, Molecular Diagnosis
Marek Malecki, M.D., Ph.D., Associate Professor of Genetics, Genomics, and Gene Therapy; Director of Biotechnology Program, Western University of Health Sciences

Circulating tumor cells disseminate from the primary neoplasm via blood and lymph to the patients distant organs to form metastases. Therefore, they create a diagnostic opportunity and a therapeutic challenge. We genetically engineered the single chain variable fragments (scFv) targeting molecules on CTC – molecular biomarkers and developed quantitative antibody labeling amplification protocol followed by antibody microarrays. We also engineered probes suitable for multiplex qPCR, nucleic acid arrays, and sequencing. We applied these technologies towards molecular characterization of metastasizing cancer.

Sponsored by VERIDEX LLC

9:30 Investigation of Circulating Endothelial Cells as Potential Predictive Biomarkers in Acute Coronary Syndromes
Samir Damani, M.D., PharmD, Scripps Translational Science Institute

Veridex and Scripps are collaborating to explore the use of circulating endothelial cells in coronary artery disease. Coronary artery disease and its downstream complications remain the leading cause of death worldwide. While stable coronary artery disease (CAD) is readily diagnosed through functional stress testing and coronary angiography, acute cardiovascular events such as myocardial infarction remain highly unpredictable. Accordingly, there is a significant need for a non-invasive biomarker such as a protein, nucleic acid, or cellular based assay that can identify those individuals who are at the greatest risk for sudden arterial disruptive events before they are clinically manifested. Data demonstrate that circulating endothelial cells may hold promise to fill this void. Further investigations will need to be conducted to explore the utility aspects.

10:00 Networking Coffee Break with Exhibits and Poster Viewing

10:30 Targeting Circulating Tumor Cells in Blood Using Selectin Adhesion and Natural Halloysite Nanotubes
Michael King, Ph.D., Associate Professor, Biomedical Engineering, Cornell University

Our laboratory has developed new methods for the isolation of intact, viable cancer cells from patient blood, based on the physiological adhesion of selectin proteins in microscale flow devices. More recently, we have found that thin monolayer coatings of colloidal nanoparticles, or naturally-forming halloysite nanotubes, can greatly improve the efficiency of cell capture under flow. In related work, we have developed novel procedures for the delivery of siRNA, taxane drugs, and receptor-mediated apoptosis signal to circulating tumor cells.

Sponsored by Asuragen

11:00 Targeted Deep Sequencing of Clinical FFPE and FNA Tumor Specimens Using two Differentiated Next Generation Platforms
Elizabeth Mambo, Ph.D., Senior Scientist, Asuragen, Inc.

Next generation sequencing (NGS) technologies hold enormous promise to advance personalized cancer treatment. We developed PCR-based target enrichment methods for amplifying up to 1000 cancer gene regions in FFPE specimens, a sample type not yet assessed by NGS. As few as 1-2% mutations were detected using the Illumina GAIIx. Variants were confirmed by other orthogonal methods. FNA tumor samples could also be successfully profiled using these methods.

11:30 Move to Plenary Session

PLENARY KEYNOTE SESSION

KEYNOTE DISCUSSION:

11:50 Changing Regulation of LDTs
Moderator: *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.*
Featured Guest: *Alberto Gutierrez, Ph.D., Deputy Director, Office of In Vitro Diagnostic Device Evaluation and Safety, Food & Drug Administration*
Audience will be asked to submit questions in advance for the discussion.

MULTI-STAKEHOLDER PANEL:

12:30 Future of Reimbursement for Molecular Diagnostics
Moderator: *Thomas A. Gustafson, Ph.D., Senior Policy Advisor, Arnold & Porter LLP*

- Status of CPT coding and fee schedules (clinical lab vs. physician fee)
- Impact of new CPT coding for reimbursement of tests
- What do changes in regulation portend for suppliers and reimbursement?

Panelists: *Ann-Marie Lynch, Executive Vice President, Payment and Health Care Delivery Policy, AdvaMed*
David Mongillo, M.P.H., M.S.M., Vice President, Policy and Medical Affairs, American Clinical Laboratory Association
Elaine K. Jeter, M.D., Medical Director, Palmetto gba

1:20 - 2:20 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

2:20 Close of Conference

ATTENDEE QUOTES FROM THE 2010 Next Generation Dx Summit

"You and your team did a splendid job on your coverage of single cell detection diagnostics. The comments that I heard from several attendees were all very positive about the meeting."

Professor of Radiology and Physics, and Director, University of Missouri Cancer Nanotechnology Platform; University of Missouri

"Good conference to learn new platform technologies for diagnostics."

Professor, Biotechnology, AIMST University, Malaysia

"The scope of the meeting was impressive, giving a good overview of commercial systems available as well as new technology options that meet the target features of POCS: fast, easy, cost-effective, accurate."

Chief Scientific Officer, TREK Systems

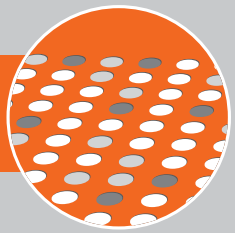
"The meeting provided insight into the thinking of diverse stakeholders with unique scientific perspectives. It allowed participants an opportunity to network and to learn what their colleagues in the field are thinking."

Associate Director, Technology Evaluation Center, Blue Cross and Blue Shield Association

AUGUST 23-24

Inaugural

TRANSLATING PROTEOMICS AND METABOLOMICS INTO THE CLINICAL LABORATORY



TUESDAY, AUGUST 23

7:30 am Registration and Morning Coffee

OVERCOMING GENERAL CHALLENGES

8:30 Chairperson's Opening Remarks
Daniel W. Chan, Ph.D., Professor and Director, Center for Biomarker Discovery and Translation, and Clinical Chemistry Division, Johns Hopkins University

8:40 KEYNOTE PRESENTATION

Translating Proteomics and Metabolomics into the Clinical Labortatory: The Future is Now
Daniel W. Chan, Ph.D., Professor and Director, Center for Biomarker Discovery and Translation, and Clinical Chemistry Division, Johns Hopkins University

Despite the success of discovering many disease associated biomarkers, very few biomarkers have been translated into clinical diagnostics. To be successful in the translation, we need to develop a roadmap and identify several key steps that are critical in this process. These steps include defining a specific clinical "intended use" for unmet clinical needs, generating sufficient evidence in preliminary validation studies to support the investment for a large-scale validation study, developing assays with analytical performance suitable for the clinical laboratory and conducting clinical trials to demonstrate clinical utilities in order to obtain regulatory approval and gain acceptance by the clinical community. Specific examples will be shown to demonstrate the opportunities and challenges for the development of clinical proteomic diagnostics. The successful translation of these biomarkers into clinical practice will require close collaboration between researcher, industry, regulatory agency and clinician

9:10 Regulatory Perspective on Translating Proteomic Biomarkers to Clinical Diagnostics
Jinong Li, Ph.D., DABCC, Regulatory Scientist, FDA/CDRH/OIVD/DCTD
Kellie B. Kelm, Ph.D., Regulatory Scientist, FDA/CDRH/OIVD/DCTD

Issues associated with the translation of complex proteomic biomarkers from discovery to clinical diagnostics have been widely discussed among academic researchers, government agencies, as well as assay and instrumentation manufacturers. Here, we provide an overview of the regulatory framework and type of information that is typically required in order to evaluate ***in vitro*** diagnostic tests regulated by the Office of ***In Vitro*** Diagnostic Device Evaluation and Safety (OIVD) at the US Food and Drug Administration (FDA), with the focus on some of the issues specific to protein-based complex tests.

10:10 Networking Coffee Break

11:00 Criteria for Medical Necessity for Protein and Metabolite-Based Multiplex Assays
Gilbert S. Omenn, M.D., Ph.D., Director, Center for Computational Medicine & Bioinformatics Professor of Internal Medicine, Human Genetics and Public Health, University of Michigan

Major advances in proteomics and metabolomics are enhancing the sensitivity and reproducibility of these measurements with plasma and other clinical specimens. Differential diagnosis may require recognition of post-translational modifications, splice variants, and even sequence polymorphisms of proteins, as well as modeling of effects on interacting signaling pathways. Clinical laboratory criteria, including medical necessity for reimbursement, put a premium on positive-predictive value, narrow coefficient of variation, and results that make a difference in clinical decision-making for patients. The classifiers must be transparent, preferably with open code, to enhance reproducibility and confidence in moving toward personalized medicine.

MULTIPLEX IMMUNOASSAYS

11:30 Enabling Technologies for the Specific Immunoglobulin Analysis in the Diagnosis of Allergic and Autoimmune Diseases
Per Matsson, Ph.D., CTO, Phadia; Associate Professor, Uppsala University

The diagnostic industry is under great change and new emerging technologies allow the possibility to analyze more variables faster and more accurately. Specific Immunoglobulin analysis is today a routine for the diagnosis of allergic and autoimmune diseases. We can presently only analyze different antigens for S-IgE (allergy) or S-IgG (autoimmunity) through traditional sequential immuno-assay systems. The need for more and simultaneous information has encouraged us to search for new possibilities. Therefore, we have developed the possibility to simultaneously analyze >100 different antigens with a minute amount of patient sample. After reviewing a large number of assay technologies we now have the possibility to use multiplexed technologies both in the point-of-care setting, as well as the basis for new laboratory systems. These enabling technologies allow for the development of new information in immunology.

12:00 pm The PreDx® Diabetes Risk Score: A Prognostic Algorithm for Type 2 Diabetes Developed Using a High-Throughput, Quantitative Immunoassay Platform
Steven M. Watkins, Ph.D., CSO, Tethys Bioscience, Inc.

The PreDx Diabetes Risk score is a commercial prognostic test that provides patients with their absolute risk for type 2 diabetes within the next five years. The test was developed by a quantitative screen of protein concentrations in several large epidemiological cohorts that contained diabetes outcomes. A description of the test as well as a summary of the research technology and validation data will be provided in this talk.

12:30 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

1:30 Session Break

MASS SPECTROMETRY APPLICATIONS

1:55 Chairperson's Remarks
Cory Bystrom, Ph.D., Associate Scientific Director, Quest Diagnostics, Nichols Institute

2:00 Mass Spectrometry as an Enabling Technology in Diagnostics
Cory Bystrom, Ph.D., Associate Scientific Director, Quest Diagnostics, Nichols Institute

Diagnostic use of Liquid Chromatography-Mass Spectrometry has taken off over the last 5 years. The assays provide higher specificity, sensitivity and require smaller sample volumes - ideal for precious samples e.g. pediatrics. The instrumentation allows for multiplexed assays further providing sample savings. These factors have lead to professional bodies endorsing the use of this technology. The ability to automate assays on LC-MS/MS entices labs to adopt the methodology. Since LC-MS/MS is becoming prevalent it is important that users be aware of LC-MS/MS performnce compared to RIAs and ICMAs. This presentation will detail assays through development, validation and use. Examples will differentiate LC-MS/MS results from traditional assays

2:40 Quantifying Proteins by LC-MS/MS
Andrew N. Hoofnagle, M.D., Ph.D., Assistant Professor, Laboratory Medicine, Departments of Laboratory Medicine and Medicine, University of Washington

There have been significant advances in the quantification of proteins by liquid chromatography-tandem mass spectrometry. Targeted proteomics workflows have major advantages over traditional automated immunoassays in the clinical laboratory. In addition, they are more precise than shotgun proteomics approaches. Using standard isotope dilution methods, we have developed several assays that demonstrate the utility of targeted mass spectrometry for the quantification of proteins in human samples. We will discuss the development of these assays and their application to tumor marker detection in serum and to studying the mechanisms of lipoprotein metabolism.

3:10 Absolute Protein Quantification by MS *Sponsored by* promise ADVANCED PROTEOMICS
Virginie Brun, Ph.D., CSO & Cofounder, Promise Advanced Proteomics

Promise proposes an innovative technology (PSAQ™) based on the use of full-length stable isotope-labeled protein standards and mass spectrometry analysis. Compared to ELISA, this method allows better results in terms of precision, specificity and accuracy, for the dosage of proteins such as biomarkers in complex biological matrices.

3:25 Networking Refreshment Break with Exhibits and Poster Viewing

4:00 Evaluation of Cancer Biomarkers using Multiple Reaction Monitoring Cubed (MRM³)
Genevieve Choquet-Kastylevsky, M.D., Ph.D., Scientific Advisor, BioMarker Department, R&D, BioMerieux
Stable isotope dilution-selected reaction-monitoring mass spectrometry (SID-SRM-MS), or stable isotope dilution-multiple reaction-monitoring mass spectrometry (SID-MRM-MS), carried out in triple quadrupole instruments has emerged as a promising alternative to ELISA for validation of putative protein biomarkers discovered during proteomics projects.

4:30 Enhanced Detection of Low-Abundance Protein Modifications and Potential Biomarkers by Hexapeptide Libraries
Sricharan Bandhakavi, Ph.D., Sr. Scientist, New Technologies R&D, Life Science Group, Bio-Rad
Dynamic range compression (DRC) by hexapeptide libraries increases MS/MS-identification of lower-abundance proteins in biological samples. However, two questions impede fully realizing DRC's potential. First, does DRC enhance identification of protein post-translational modifications (PTMs)? Second, can DRC be incorporated into differential analyses? Using DRC, we doubled identified salivary glyco- and phospho-proteins by MS/MS. Secondly, DRC enabled identification of novel changes to lower-abundance salivary proteins from breast cancer patients. Thus, DRC offers value for enhancing protein/PTM-based biomarker detection studies.*ol*

5:00 Opening Reception in the Exhibit Hall with Exhibits and Poster Viewing

6:00 Close of Day

WEDNESDAY, AUGUST 24

7:30 am Breakout Sessions
Concurrent Problem Solving Breakout Sessions are interactive, topic-specific discussions hosted by a moderator. These sessions are open to all attendees, sponsors, exhibitors, and speakers and provide a forum for discussing key issues and meeting potential partners. Please pick a topic of your choice and join in.

CLINICAL APPLICATIONS FOR PROTEIN MICROARRAYS

8:25 Chairperson's Remarks
Brian Liu, Ph.D., Director, Translational Research in Urology, Brigham and Women's Hospital

8:30 Native Antigen Protein Microarrays for Cancer Immunomics
Brian Liu, Ph.D., Director, Translational Research in Urology, Brigham and Women's Hospital
With the advent of high-throughput, multiplexed technologies, researchers are now better equipped to search for and validate new, sensitive and specific disease biomarkers for use in clinical diagnostics and treatment. Key among these technologies is the development of the protein microarrays, which allows for the rapid screening of cell/tissue lysates and a variety of biofluid samples, including serum, plasma, and urine.

9:00 Functional Protein Pathway Activation Mapping of Human Cancer for Personalized Therapy
Emanuel F. Petricoin, Ph.D., Co-Director, Center for Applied Proteomics and Molecular Medicine, George Mason University
Recently, genomic analysis of human tumors has revealed that cancer is a protein pathway disease at the functional level. However, since genomic and transcript profiling likely cannot alone sufficiently predict protein pathway activation, and it is these protein signaling pathways that represent the targets for new molecular guided therapeutics, it is critical that we begin to define human cancer using the functional protein signaling activation architecture as a basis for taxonomony and guided, targeted therapy.

9:30 High Through-Put Proteomic Tools for Cancer Biomarker Discovery
Sponsored by OriGene
Donghui Ma, Ph.D., Director, Immunology, OriGene Technologies Inc.
The key feature for P4 medicine is to use biomarkers to detect and diagnose diseases at an early stage. OriGene, a gene centric biotech company, developed a series of proteomic research tools for cancer biomarker discovery. We will present our genome wide proteomics technologies (MS, arrays) in serum autoantibody detection or cancer biomarker survey from hundreds of cancer patients.

10:00 Networking Coffee Break with Exhibits and Poster Viewing

METABOLOMICS DEVELOPMENTS

10:30 The Metabolic Checkup: Clinical Screening from Newborns to Adults
Donald H. Chace, Ph.D., MSFS, FACB, Director, Pediatrix Analytical, Center for Research, Education and Quality, Pediatrix Medical Group
Several dozen metabolites that include amino acids, acylcarnitines can be analyzed by tandem MS from a single drop of blood from newborns. This metabolic profiling approach is a key clinical test for screening of more than 4 million infants per year in the United States with detection of hundreds of infants with inherited disorders of metabolism that includes the most commonly known disorder, PKU. This panel and its enhancement to include other metabolites or hormones such as succinylacentone and thryoxine can be applied to populations beyond term newborns to nutrition studies on low birthweight preterm infants, adults undergoing renal dialysis and postmortem screening. Broad panel metabolic screening using dried blood spots is keystone to expanding screening beyond newborns and an important tool for looking at metabolism or protein (enzyme) expression.

11:00 Urinary Metabolomics for Biomarker Discovery
Robert H. Weiss, M.D., Professor of Medicine, Division of Nephrology and Cancer Center, University of California, Davis
Metabolomics is the study of all small molecule metabolites produced by the body. Based on the fact that there is intimate communication between the kidney and the most readily available biofluid, urine, we have been studying the prospect of using urinary biomarkers for diagnosis of kidney and other diseases. Discovery studies in my laboratory have identified several pathway and metabolites in several kidney diseases which when validated have the potential to lead to novel biomarkers which could be used as screening test in high risk patients in the clinical setting.

11:30 Move to Plenary Session

PLENARY KEYNOTE SESSION

KEYNOTE DISCUSSION:

11:50 Changing Regulation of LDTs
Moderator: *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.*
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1:20 - 2:00 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

2:00 Close of Conference

Inaugural

MASS SPECTROMETRY IN CLINICAL DIAGNOSTICS

TUESDAY, AUGUST 23

7:30 am Registration and Morning Coffee

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Daniel W. Chan, Ph.D., Professor and Director, Center for Biomarker Discovery and Translation, and Clinical Chemistry Division, Johns Hopkins University

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MASS SPECTROMETRY APPLICATIONS

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Cory Bystrom, Ph.D. , Associate Scientific Director, Quest Diagnostics, Nichols Institute

2:00 Mass Spectrometry as an Enabling Technology in Diagnostics
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Andrew N. Hoofnagle, M.D., Ph.D., Assistant Professor, Laboratory Medicine, Departments of Laboratory Medicine and Medicine, University of Washington

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3:25 Networking Refreshment Break with Exhibits and Poster Viewing

4:00 Evaluation of Cancer Biomarkers using Multiple Reaction Monitoring Cubed (MRM³)

Jean-Philippe Charrier, bioMerieux, R&D biomarkers, Marcy L'étoile , France

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Sricharan Bandhakavi, Ph.D., Sr. Scientist, New Technologies R&D, Life Science Group, Bio-Rad

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5:00 Opening Reception in the Exhibit Hall with Exhibits and Poster Viewing

6:00 Close of Day

WEDNESDAY, AUGUST 24

Enjoy Your Morning!

PLENARY KEYNOTE SESSION

KEYNOTE DISCUSSION

11:50 Changing Regulation of LDTs

Moderator: *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.*

Featured Guest: *Alberto Gutierrez, Ph.D., Deputy Director, Office of In Vitro Diagnostic Device Evaluation and Safety, Food & Drug Administration*

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David Mongillo, M.P.H., M.S.M., Vice President, Policy and Medical Affairs, American Clinical Laboratory Association

1:20 - 2:20 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

2:20 - 2:30 Session Break

NOVEL TECHNOLOGIES FOR CLINICAL DIAGNOSTICS – AN OVERVIEW OF THE FIELD

2:30 pm Chairperson's Remarks

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.

2:35 The Rapidly Changing Era of Molecular Diagnostics: New Technologies and New Promises

Christine C. Ginocchio, Ph.D., MT(ASCP), Senior Director, Division of Infectious Disease Diagnostics, North Shore-LIJ Health System; Associate Professor, Department of Pathology and Laboratory Medicine and Department of Molecular Medicine, Hofstra University School of Medicine in collaboration with the North Shore-LIJ Health System

Global travel, the threat of new pandemics, and the spread of re-emerging infectious diseases highlight the need for comprehensive pathogen detection. Identification of the 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. To meet these challenges, innovative technologies have been developed that detect single pathogens, multiple syndromic related pathogens and genotypic drug resistance. This lecture will provide an overview of new technologies including cartridge based test systems for point of care diagnostics, chip and bead based arrays, next-gen sequencing platforms, and mass spectrometry analysis. Their current and future roles in clinical diagnostics will be discussed.

CLINICAL APPLICATIONS OF MASS SPEC IN INFECTIOUS DISEASE

3:05 Bacterial and Yeast Identification in the Clinical Microbiology Laboratory Using Matrix-Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry

Robin Patel, M.D.(CM), FRCP(C), (D)ABMM, FACP, Consultant, Divisions of Clinical, Microbiology and Infectious Diseases, Professor of Microbiology and Medicine, College of Medicine, Mayo Clinic

Traditional microbial identification in the clinical microbiology laboratory is accomplished by phenotypic analysis using manual, automated, and molecular approaches. Most require hours to days to final results. Matrix-assisted laser desorption ionization–time of flight (MALDI-TOF) mass spectrometry (MS) can rapidly identify and analyze signature bacterial and fungal proteins in colonies of these organisms, enabling identification of grown organisms within minutes. Mass spectrometers, software and microbial mass spectrum libraries have been compiled into automated systems resulting in user-friendly platforms for microbial identification using MALDI-TOF MS.

3:35 MALDI-MS and NGS for Diagnosis of Infectious Disease

Dag Harmsen, Ph.D., Professor, University Münster, Germany

Matrix-assisted laser desorption ionization-time of flight mass spectrometry (MALDI-TOF) has emerged as a rapid, cost-effective, and highly intra- and inter-laboratory reproducible method for bacterial species identification. Next generation sequencing (NGS) has fundamentally altered genomic research. New developments will bring NGS costs and performance down to an everyman's technology with extreme potential for ultra fast and accurate molecular bacterial typing as it provides the ultimate whole genome information. Currently, however, bioinformatics constraints restrict the application of NGS to a few highly experienced laboratories.

4:05 Networking Refreshment Break with Exhibit and Poster Viewing *Sponsored by* HOLOGIC MOLECULAR DIAGNOSTICS

4:45 A Staged Strategy to Pathogen Detection and Discovery

Thomas Briese, Ph.D., Associate Professor of Clinical Epidemiology, Mailman School of Public Health, Columbia University

Clinical syndromes are only infrequently specific for single pathogens; thus, diagnostic tools must consider multiple agents simultaneously. As new therapeutics offer growing opportunities to reduce morbidity and mortality through targeted drug therapies, rapid identification of an agent becomes essential. New and emerging pathogens pose continuing challenges to diagnostics in a world with ample opportunity for rapid spread through increasing international travel and trade. To address the need for sensitive, highly multiplexed assays, we are applying multiple new platforms in a staged strategy: the multiplex MassTag PCR platform; the GreeneChip microarray platform; and a high-throughput pyrosequencing approach that identifies truly new agents. In reviewing the strengths and limitations of the various platforms, I will provide examples that illustrate how they can be applied to clinical problems, zoonotic surveillance, and surveillance efforts.

5:15 The Role of Molecular Diagnostics in the Changing Paradigm of Hepatitis C Treatments

David Bernstein, M.D., AGAF, FACP, FACG, Chief, Division of Gastroenterology, Hepatology and Nutrition, North Shore University Hospital/Long Island Jewish Medical Center; Professor of Clinical Medicine , Albert Einstein School of Medicine

Combination interferon and ribavirin-based therapies to treat hepatitis C infection are rapidly evolving with the addition of protease inhibitors, nucleoside and non-nucleside polymerase inhibitors and future interferon free based regimens. These therapies, while more effective in achieving a sustained virological response, have the potential to lead to the development of HCV resistance. Molecular therapies such as quantitative HCV-RNA assays, HCV genotyping and IL28B genotyping are becoming increasingly important in the early management of hepatitis C therapies. This presentation will discuss some of the important issues regarding the use of molecular diagnostics in the new paradigm of hepatitis C treatment.

5:45 Breakout Sessions

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Molecular Diagnostics for Infectious Viral Agents
Moderator: *Christine C. Ginocchio, Hofstra University School of Medicine in collaboration with the North Shore-LIJ Health Syste***m**

Next Gen Sequencing and Infectious Diagnostics
Moderator: *Charles Chiu, UCSF Clinical Microbiology Laboratory*

Clinical Adoption of Mass Spec
Moderator: Robin Patel, College of Medicine, Mayo Clinic

Measurable Outcomes of Rapid Screening Programs
Moderator: Denise Uettwiller-Geiger, John T. Mather Memorial Hospital

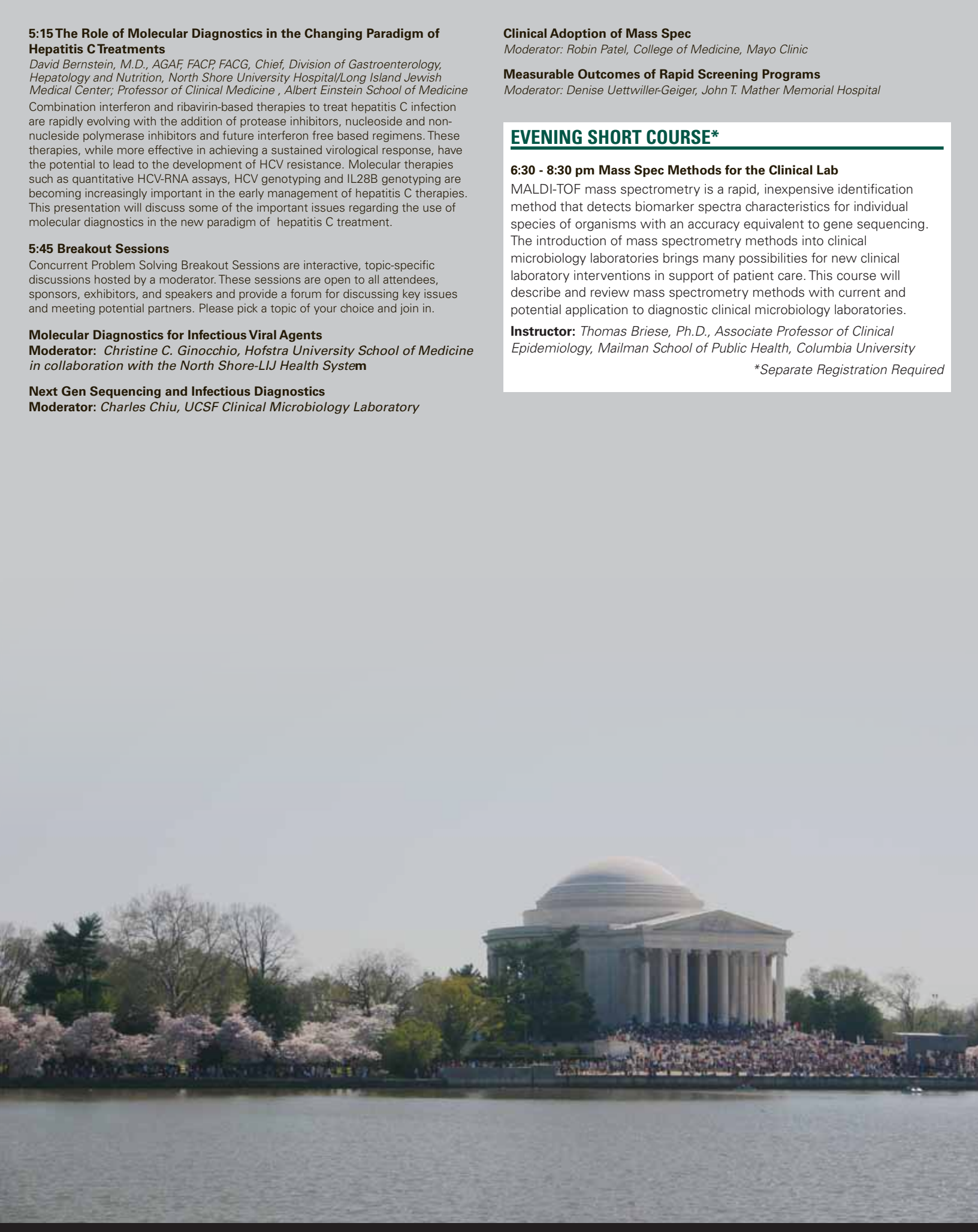
EVENING SHORT COURSE*

6:30 - 8:30 pm Mass Spec Methods for the Clinical Lab

MALDI-TOF mass spectrometry is a rapid, inexpensive identification method that detects biomarker spectra characteristics for individual species of organisms with an accuracy equivalent to gene sequencing. The introduction of mass spectrometry methods into clinical microbiology laboratories brings many possibilities for new clinical laboratory interventions in support of patient care. This course will describe and review mass spectrometry methods with current and potential application to diagnostic clinical microbiology laboratories.

Instructor: *Thomas Briese, Ph.D., Associate Professor of Clinical Epidemiology, Mailman School of Public Health, Columbia University*

**Separate Registration Required*



Third Annual

MOLECULAR DIAGNOSTICS FOR INFECTIOUS DISEASE

WEDNESDAY, AUGUST 24

11:00 am-12:15 pm Registration

PLENARY KEYNOTE SESSION

KEYNOTE DISCUSSION

11:50 Changing Regulation of LDTs

Moderator: *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.*

Featured Guest: *Alberto Gutierrez, Ph.D., Deputy Director, Office of In Vitro Diagnostic Device Evaluation and Safety, Food & Drug Administration*

Audience will be asked to submit questions in advance for the discussion.

MULTI-STAKEHOLDER PANEL

12:30 Future of Reimbursement for Molecular Diagnostics

Moderator: *Thomas A. Gustafson, Ph.D., Senior Policy Advisor, Arnold & Porter LLP*

- Status of CPT coding and fee schedules (clinical lab vs. physician fee)
- Impact of new CPT coding for reimbursement of tests
- What do changes in regulation portend for suppliers and reimbursement?

Panelists: *Ann-Marie Lynch, Executive Vice President, Payment and Health Care Delivery Policy, AdvaMed*

David Mongillo, M.P.H., M.S.M., Vice President, Policy and Medical Affairs, American Clinical Laboratory Association

1:20 - 2:20 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

2:20 - 2:30 Session Break

NOVEL TECHNOLOGIES FOR CLINICAL DIAGNOSTICS – AN OVERVIEW OF THE FIELD

2:30 pm Chairperson's Remarks

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.

2:35 The Rapidly Changing Era of Molecular Diagnostics: New Technologies and New Promises

Christine C. Ginocchio, Ph.D., MT(ASCP), Senior Director, Division of Infectious Disease Diagnostics, North Shore-LIJ Health System; Associate Professor, Department of Pathology and Laboratory Medicine and Department of Molecular Medicine, Hofstra University School of Medicine in collaboration with the North Shore-LIJ Health System

Global travel, the threat of new pandemics, and the spread of re-emerging infectious diseases highlight the need for comprehensive pathogen detection. Identification of the 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. To meet these challenges, innovative technologies have been developed that detect single pathogens, multiple syndromic related pathogens and genotypic drug resistance. This lecture will provide an overview of new technologies including cartridge based test systems for point of care diagnostics, chip and bead based arrays, next-gen sequencing platforms, and mass spectrometry analysis. Their current and future roles in clinical diagnostics will be discussed.

CLINICAL APPLICATIONS OF MASS SPEC IN INFECTIOUS DISEASE

3:05 Bacterial and Yeast Identification in the Clinical Microbiology Laboratory Using Matrix-Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry

Robin Patel, M.D.(CM), FRCP(C), (D)ABMM, FACP, Consultant, Divisions of Clinical, Microbiology and Infectious Diseases, Professor of Microbiology and Medicine, College of Medicine, Mayo Clinic

Traditional microbial identification in the clinical microbiology laboratory is accomplished by phenotypic analysis using manual, automated, and molecular approaches. Most require hours to days to final results. Matrix-assisted laser desorption ionization–time of flight (MALDI-TOF) mass spectrometry (MS) can rapidly identify and analyze signature bacterial and fungal proteins in colonies of these organisms, enabling identification of grown organisms within minutes. Mass spectrometers, software and microbial mass spectrum libraries have been compiled into automated systems resulting in user-friendly platforms for microbial identification using MALDI-TOF MS.

3:35 MALDI-MS and NGS for Diagnosis of Infectious Disease

Dag Harmsen, Ph.D., Professor, University Münster, Germany

Matrix-assisted laser desorption ionization-time of flight mass spectrometry (MALDI-TOF) has emerged as a rapid, cost-effective, and highly intra- and inter-laboratory reproducible method for bacterial species identification. Next generation sequencing (NGS) has fundamentally altered genomic research. New developments will bring NGS costs and performance down to an everyman's technology with extreme potential for ultra fast and accurate molecular bacterial typing as it provides the ultimate whole genome information. Currently, however, bioinformatics constraints restrict the application of NGS to a few highly experienced laboratories.

4:05 Networking Refreshment Break with Exhibit and Poster Viewing

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

4:45 A Staged Strategy to Pathogen Detection and Discovery

Thomas Briese, Ph.D., Associate Professor of Clinical Epidemiology, Mailman School of Public Health, Columbia University

Clinical syndromes are only infrequently specific for single pathogens; thus, diagnostic tools must consider multiple agents simultaneously. As new therapeutics offer growing opportunities to reduce morbidity and mortality through targeted drug therapies, rapid identification of an agent becomes essential. New and emerging pathogens pose continuing challenges to diagnostics in a world with ample opportunity for rapid spread through increasing international travel and trade. To address the need for sensitive, highly multiplexed assays, we are applying multiple new platforms in a staged strategy: the multiplex MassTag PCR platform; the GreeneChip microarray platform; and a high-throughput pyrosequencing approach that identifies truly new agents. In reviewing the strengths and limitations of the various platforms, I will provide examples that illustrate how they can be applied to clinical problems, zoonotic surveillance, and surveillance efforts.

5:15 The Role of Molecular Diagnostics in the Changing Paradigm of Hepatitis C Treatments

David Bernstein, M.D., AGAF, FACP, FACG, Chief, Division of Gastroenterology, Hepatology and Nutrition, North Shore University Hospital/Long Island Jewish Medical Center; Professor of Clinical Medicine , Albert Einstein School of Medicine

Combination interferon and ribavirin-based therapies to treat hepatitis C infection are rapidly evolving with the addition of protease inhibitors, nucleoside and non-nucleside polymerase inhibitors and future interferon free based regimens. These therapies, while more effective in achieving a sustained virological response, have the potential to lead to the development of HCV resistance. Molecular therapies such as quantitative HCV-RNA assays, HCV genotyping and IL28B genotyping are becoming increasingly important in the early management of hepatitis C therapies. This presentation will discuss some of the important issues regarding the use of molecular diagnostics in the new paradigm of hepatitis C treatment.

5:45 Breakout Sessions

Concurrent Problem Solving Breakout Sessions are interactive, topic-specific discussions hosted by a moderator. These sessions are open to all attendees, sponsors, exhibitors, and speakers and provide a forum for discussing key issues and meeting potential partners. Please pick a topic of your choice and join in.

Molecular Diagnostics for Infectious Viral Agents
Moderator: *Christine C. Ginocchio, Hofstra University School of Medicine in collaboration with the North Shore-LIJ Health System*

Next Gen Sequencing and Infectious Diagnostics
Moderator: *Charles Chiu, UCSF Clinical Microbiology Laboratory*

Mass Spec – Clinical Adoption

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

THURSDAY, AUGUST 25

7:30 am Breakfast Presentation *(Sponsorship Opportunity Available)* **or Morning Coffee**

FROM MASS SPEC TO SEQUENCE-BASED PATHOGEN ID, CHARACTERIZATION, SCREENING AND VALIDATION

8:25 Chairperson's Remarks

8:30 Being Provocative! Culture Negative, Nucleic Acid Detection Positive, PCR/ESI MS

Robert Bonomo, M.D., Professor of Medicine & Director, Cleveland VAMC GRECC

Rapid molecular diagnostics using PCR/ESI-MS offer significant advantages when compared to conventional methods that identify bacteria. In addition to pathogen identification, clinicians can also learn the genetic relatedness of pathogens and, in some cases, their antibiotic resistance. An entire new set of clinical questions arises when one detects the presence of bacterial, viral, or fungal DNA ("DNAemia") in the absence of positive cultures. More importantly, can "DNAemia " be used to reduce antibiotic therapy? Algorithms will need to be devised to address these new diagnostic dilemmas.

9:00 Beyond Bacterial Identification, Application of MALDI-TOF Mass Spectrometry

Nathan A. Ledeboer, Ph.D., Assistant Professor of Pathology, Medical Director, Clinical Microbiology and Molecular Diagnostics, Dynacare Laboratories and Froedtert Hospital

MALDI-TOF mass spectrometry analysis is a rapid method for the direct identification of bacteria from culture and clinical specimens. While many publications have evaluated this technique for identification of bacterial colonies, we report the clinical impact of rapid identification of bacteria from positive blood cultures and evaluate additional applications of this technology.

9:30 KEYNOTE PRESENTATION

Comparing Virus-Specific PCR and Next Generation Sequencing to Study Viral Causes of Fever in Children

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

We used virus-specific PCR and next-generation sequencing to analyze causes of fever without a focus in children 2-36 months of age. Virus-specific PCR was more sensitive for most viruses, but sequencing revealed additional viruses that were not tested for by PCR and provided more detailed information about implicated viruses.

10:00 Networking Coffee Break with Exhibits and Poster Viewing

10:45 Talk Title to be Announced

Andrea Ferreira-Gonzalez, Chair, Molecular Diagnostics, Virginia Commonwealth University

11:15 Clinical Diagnostics and Pathogen Discovery by Deep Sequencing

Charles Chiu, M.D., Ph.D., Assistant Professor, Department of Laboratory Medicine and Medicine/Infectious Diseases; Director, UCSF-Abbott Viral Diagnostics and Discovery Center; Associate Director, UCSF Clinical Microbiology Laboratory

Deep sequencing technologies are promising new diagnostic tools in clinical microbiology. These tools enable the detection of pathogens in clinical samples on a comprehensive scale not previously possible by routine laboratory testing. The applications are myriad and include clinical diagnostics, outbreak investigation, and novel pathogen discovery. With recent improvements in throughput, cost, turnaround time, and computational analysis, we can soon envision deep sequencing as a practical front-line diagnostic for unknown pathogens in clinical samples.

11:45 Pathogenica: Next-Generation Sequencing Assays for Clinical Diagnostics *Sponsored by* PATHOGENICA

Adeyemi Adesokan, Ph.D., CEO, Pathogenica, Inc.

A new generation of DNA sequencing technology has provided timely and valuable forward momentum for genomics research efforts. Single molecule resolution of nucleic acids is now within the reach of moderately equipped research laboratories, leading to fascinating breakthroughs in our understanding of disease. The presentation will address Pathogenica's technology in next generation sequencing assays for clinical diagnostics, which will provide higher sensitivity and accuracy than existing nucleic acid tests, at a significantly reduced cost.

12:15 pm Randox Biochip Array Technology (BAT); A Revolutionary Step in Multiplex Infectious Disease Diagnostics *Sponsored by* RANDOX

Scott McKeown, Ph.D., R&D Consultant, Randox Laboratories Research Solutions, Randox Laboratories

Randox have developed award winning Biochip Array Technology (BAT) for rapid proteomic and more recently genomic diagnostics. Utilizing multiplex PCR, spatially tethered specific probes and chemiluminescence detection methods, we have infectious disease arrays for sexually transmitted and respiratory infections to simultaneously identify 32 pathogens in patient samples within 3 hours.

1:15 Session Break

SEQUENCING RAPID MOLECULAR METHODS IMPACTING DETECTION AND CONTROL OF HOSPITAL INFECTIONS

1:50 Chairperson's Remarks

Adeyemi Adesokan, Ph.D., CEO, Pathogenica, Inc.

2:00 Next-Gen Sequencing for Infectious Disease Diagnostics

Timothy D. Read, Ph.D., Associate Professor, Department of Medicine, Division of Infectious Diseases & Department of Human Genetics, Emory University School of Medicine; Director, Emory GRA Genomics Center

New technologies for rapid and cheap sequence generation offer the possibility that one day genomics-based pathogen detection in clinical laboratories will be cost-effective. DNA input can be extracted from bacteria or viruses isolated in pure cultures or, more challengingly, direct from clinical samples. Bioinformatic analysis of the complex output data is a major challenge and will rely heavily on the results of population genomic studies of pathogen species.

2:30 Utility of Rapid DNA-Based Methods in the Detection and Identification of Bacteria in Orthopedic Infections

J. William Costerton, Ph.D., Director, Biofilm Research, Center for Genomic Sciences, Allegheny-Singer Research Institute

The diagnosis of device-related and other chronic bacterial infections is complicated by the fact that the bacteria that cause these infections grow predominantly in biofilms. Biofilm bacteria grow poorly, if at all, when they are spread on the surfaces of agar media so these infections, which now constitute fully 80% of infections treated, rarely yield positive cultures. We note that biofilm bacteria are detected by DNA-based methods, and have compared the sensitivity and accuracy of cultures with the DNA-based Ibis technology in detecting and identifying bacteria.

3:00 The Clinical Laboratory's Critical Role in Decreasing Methicillin-Resistant *Staphylococcus aureus* (MRSA) Hospital Acquired Infection by Implementing a Rapid Molecular Screening Program

Denise Uettwiller-Geiger, Ph.D., DLM(ASCP), Director, Laboratory and Clinical Trials, John T. Mather Memorial Hospital

This session will discuss implementation of a rapid screening program to cost effectively detect MRSA colonized and/or infected patients using rapid polymerase chain reaction (PCR) in real time providing clinicians with key test results within one hour, thus reducing MRSA patient to patient transmission. An effective interventional surveillance program along with laboratory testing support will reduce the number of HAIs and the associated morbidity and mortality, thereby improving patient safety by reducing risks of infection and other adverse outcomes.

3:30 Networking Refreshment Break

STANDARDS FOR GENOMIC AMPLIFICATION TESTS

4:00 Standardization and Quality Control of Molecular Diagnostic and Genomic Technologies

Paul Wallace, Ph.D., General Manager, Quality Control, QCMD

4:30 International Standards for Molecular Diagnostic Tests

Aaron Bossler, M.D., Ph.D., Assistant Professor & Director, Molecular Pathology Laboratory & Molecular Infectious Disease, University of Iowa

International standards and reference materials for molecular infectious disease tests are critical for being able to relate patient results across time and methods. Several international standards are in use today, but many more are needed. This presentation will focus on recently developed standards and ongoing initiatives to create new reference materials.

5:00 Clinical Utility of HIV-1 SuperLow Quantification Assay in HIV-Associated Cognitive Impairment

Daniel McClernon, Ph.D., President, McClernon, LLC

Cognitive impairment in HIV positive individuals can persist during antiretroviral therapy. Assessment of whether low levels of HIV-1 RNA in cerebrospinal fluid were associated with inter-individual differences in ART regimens/drug penetration using a proprietary HIV-1 Superlow viral load assay employing isothermal amplification and molecular beacons will be discussed.

5:30 End of Conference

Second Annual

COMPANION DIAGNOSTICS

as an Integral Part of Personalized Medicine

WEDNESDAY, AUGUST 24

11:00 am-12:15 pm Registration

PLENARY KEYNOTE SESSION

KEYNOTE DISCUSSION:

11:50 Changing Regulation of LDTs

Moderator: *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.*

Featured Guest: *Alberto Gutierrez, Ph.D., Deputy Director, Office of In Vitro Diagnostic Device Evaluation and Safety, Food & Drug Administration*

Audience will be asked to submit questions in advance for the discussion.

MULTI-STAKEHOLDER PANEL:

12:30 Future of Reimbursement for Molecular Diagnostics

Moderator: *Thomas A. Gustafson, Ph.D., Senior Policy Advisor, Arnold & Porter LLP*

- Status of CPT coding and fee schedules (clinical lab vs. physician fee)
- Impact of new CPT coding for reimbursement of tests
- What do changes in regulation portend for suppliers and reimbursement?

Panelists: *Ann-Marie Lynch, Executive Vice President, Payment and Health Care Delivery Policy, AdvaMed*

David Mongillo, M.P.H., M.S.M., Vice President, Policy and Medical Affairs, American Clinical Laboratory Association

1:20 - 2:20 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

2:20 – 2:30 Session Break

KEYNOTE SESSION

2:30 Chairperson's Remarks

Richard Ding, Vice President, Strategy and Business Development, Head of Theranostics Unit, bioMerieux

2:35 Regulatory Considerations and Partnering for Success in Combination Product Development

Stafford O'Kelly, M.B.A., President, Abbott Molecular

Pharma companies are increasingly having to choose from a variety of diagnostic company partners to develop companion diagnostics for their therapeutics. There are three factors that tend to influence their choice: 1) Capability of CDx partner to commercialize an IVD product broadly, 2) IP on biomarker or platform and 3) Capability of bringing an IVD product successfully through the regulatory process especially in the U.S. Too often pharma companies get to Phase III without having selected a viable CDx partner. The result can be devastating to the therapeutic approval or timeline for approval in the U.S. in particular. The process gets significantly more complex and expensive if the CDx partner is chosen too late. The relative size of worldwide markets and ambiguity in U.S. regulatory requirements suggests that U.S. regulatory considerations play a significant role in CDx partner selections. In particular, the FDA's decision to exercise oversight of LDT's, and the still pending guidance on Companion Product development adds to uncertainty. This segment will outline the primary diagnostic related regulatory challenges that pharma companies should consider and with suggested solutions to enhance combination product success using real examples, beyond HER2.

3:05 Optimize Pharma-Diagnostics Partnership: Critical Success Factors

Richard Ding, Vice President, Strategy and Business Development, Head of Theranostics Unit, bioMerieux

The clinical and commercial success of personalized medicine requires partnership among different stakeholders, especially pharmaceutical and diagnostics alliance. At the same time, due to differences in development risks, regulatory timeline, commercial strategy and corporate governance, it is also a challenge to optimize the partnership. The presenter will reflect on the partnerships that bioMerieux has formed with Pharmaceutical companies and highlight the important elements during the deal negotiation as well as post signature project execution.

PHARMACOGENOMICS AND BEYOND

3:35 Pharmacogenetic Testing to Support Warfarin Therapy: A Work in Progress

Gwen McMillin, Ph.D., Medical Director of Toxicology and Trace Elements, co-Medical Director of Pharmacogenomics, ARUP Laboratories, Associate Professor of Pathology, University of Utah School of Medicine

The relationship between genetics and warfarin dose requirements is sound. Diagnostic testing to support warfarin pharmacogenetics, and mathematical algorithms guiding personalized dose selection are both available. However, most warfarin pharmacogenetic testing is currently performed only in the context of clinical studies. This presentation will review challenges, successes, and other lessons learned regarding clinical implementation of warfarin pharmacogenetic testing.

4:05 Networking Refreshment Break with Exhibit and Poster Viewing

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

4:45 Building Biomarker Signatures Adaptively During a Clinical Trial

Donald Berry, Head, Division of Quantitative Sciences, The University of Texas MD Anderson Cancer Center

Biomarker signatures for therapeutic strategies are usually built retrospectively. I describe an adaptive prospective approach to designing a trial of several targeted agents. Patients are allocated with probabilities depending on the results so far in the trial for patients with the same biomarker. The goal is to pair therapies with biomarker signatures that are most responsive to the therapy. I will give an example trial (called I-SPY2) in neoadjuvant breast cancer.

5:15 Towards Comprehensive Somatic Pharmacogenomics of Lung Cancer for Personalized Oncology

Marc Ladanyi, M.D., William Ruane Chair in Molecular Oncology , Attending Pathologist, Molecular Diagnostics Service, Member, Human Oncology and Pathogenesis Program, Memorial Sloan-Kettering Cancer Center

Mutations in key components of the kinase signaling pathways have emerged as important predictive markers of sensitivity or resistance to agents that target these pathways in lung adenocarcinoma. Genotyping tumors for these mutations can direct the care of individual patients, pre-qualify them for upcoming trials, and aid research. Memorial Sloan-Kettering Cancer Center has been an early adopter in clinical mutation testing of solid tumors. Since 2004, our clinical laboratory has tested over 4000 lung adenocarcinomas for EGFR and KRAS mutations, more recently adding testing for the EML4-ALK fusion and other less common driver mutations in BRAF, HER2, and other genes. Based on our extensive genotyping data, we estimate that an actionable, targetable driver mutation can be identified in up to 66% of lung adenocarcinomas.

5:45 Breakout Sessions

Concurrent Problem Solving Breakout Sessions are interactive, topic-specific discussions hosted by a moderator. These sessions are open to all attendees, sponsors, exhibitors, and speakers and provide a forum for discussing key issues and meeting potential partners. Please pick a topic of your choice and join in.

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

THURSDAY, AUGUST 25

7:30 am Breakfast Presentation *(Sponsorship Opportunity Available)* **or Morning Coffee**

ADOPTION OF PGX TESTING

8:25 Chairperson's Remarks

Charles M. (Buck) Strom, M.D., Ph.D., F.A.A.P, F.A.C.M.G., H.C.L.D., Senior Medical Director, Quest Diagnostics Nichols Institute

8:30 Pharmacogenetics Enters the Mainstream

Charles M. (Buck) Strom, M.D., Ph.D., F.A.A.P, F.A.C.M.G., H.C.L.D., Senior Medical Director, Quest Diagnostics Nichols Institute

This presentation will begin with a discussion of the mechanisms by which human variation impact an individual's response to medications. We will then discuss several pharmacogenetic assays that have entered routine use in the medical community, and how the results are being used to impact patient care. A particular emphasis will

be on the pharmacogenetic tests for Clopidogrel and Warfarin, the 2 drugs for which an FDA boxed warning has been mandated recommending pharmacogenetic tests. The presentation will close with a discussion of specific interesting cases illustrative of the power of pharmacogenetics.

9:00 Translating Basic Science to Active Patient Management
Gregory J. Tsongalis, Ph.D., Professor of Pathology, Director of Molecular Pathology, Co-Director of the Translational Research Program and Pharmacogenomics Program, Department of Pathology, Dartmouth Hitchcock Medical Center
More so than ever before, we are seeing a transition of basic science discoveries into the clinical setting at record speeds. This lecture will highlight some recent examples and show how these are revolutionizing the management of the cancer patient. From old genes, such as KRAS and EGFR, to new miRNA discoveries, the ability to detect molecular variants is critical to the treatment of cancer patients.

REALITY CHECK: REIMBURSEMENT, REGULATION

9:30 Companion Diagnostics – Regulatory and Reimbursement Challenges: What's Worked, What's Not, What's Missing & What's Next?
Russel K. Enns, Ph.D., Senior Vice President, Chief Regulatory Officer, Cepheid
A presentation will be made on regulatory and reimbursement strategies and tactics that have successfully worked over the years to introduce new and important molecular diagnostic IVD products, including companion diagnostics, with examples of what has worked. Insights will be presented of examples that have not worked. What's missing today in successful companion diagnostic introductions with respect to regulatory paths and adequate reimbursement? What's next? What are the opportunities for companion diagnostics going forward, and what challenges do they represent to ever changing healthcare dynamics?

10:00 RNAscope®: A Rapid Assay Development Platform for Translating Genomic Discoveries to Companion Diagnostics
Sponsored by ACD
Yuling Luo, President & CEO, Advanced Cell Diagnostics, Inc.
ACD's proprietary RNAscope is a breakthrough in situ hybridization platform capable of detecting the expression of any gene at single molecule sensitivity within individual cells in all major clinical specimen types, including PBMC and FFPE tissue sections.

10:15 Networking Coffee Break with Exhibit and Poster Viewing

10:45 Companion Diagnostics: A Fast-Forward Look at Medicare Reimbursement
Mitchell I. Burken, M.D., BlueCross BlueShield of Tennessee
The emergence of esoteric laboratory platforms, which are adjunct features of treatment regimens, are progressively being recognized by major payers as posing complex reimbursement issues. The conventional wisdom of laboratory testing being relegated to "commodity status" is being replaced by a much more sophisticated understanding of how the "omics" (i.e., particularly genomics) are becoming the prominent drivers of much more nuanced therapeutic selection. This presentation will provide the audience with an historical overview of how the Medicare program has adapted to this dynamic during the past decade, as well as a trajectory of what to expect at the national level, as well as at the local contractor level, of the Medicare program. It is intended that session participants from the companion diagnostics arena will now be able to approach both national and local coverage policymakers with those tools which are necessary to engage in a more focused, constructive dialogue on the intersection of science and medical necessity.

11:15 Drug-Diagnostic Co-Development – Hunting for the Missing R (Right Test, Right Test, Right Person, Right Evidence)
Steven Gutman, M.D., M.B.A., Associate Director of the Technical Evaluation Center for Blue Cross/Blue Shield
The effort to create a roadmap for evaluating diagnostic tests can be traced to the landmark work of Fryback and Thornbury (1991). These authors clearly and concisely defined the diagnostic decision making process. They also introduced three immutable core questions for any successful diagnostic: what are the analytical validity, clinical validity, and clinical utility of the test. Personalized medicine is likely to be successfully only if stakeholders take heed to the fate of Sisyphus, hold tight to the boulder, and recognize the need to answer these questions.

11:45 Companion Diagnostics: Challenging Dx and Rx Business Models
Sponsored by BOSTON HEALTHCARE
Joseph V. Ferrara, President, Boston Healthcare
While personalized medicine offers the potential to change well-established practices for physicians and patients, the concept presents a direct challenge to two other health care stakeholders essential to the realization of personalized medicine—pharmaceutical and diagnostics companies. At the core of the challenge is the question— how will a personalized medicine paradigm change these companies' innovation and commercialization approaches? This question can be aimed at nearly every aspect of these stakeholders' current strategies.

12:15 pm CCCDx: Commercial Considerations for Companion Diagnostics; Will all these Cs help us SEE the Future?
Sponsored by QIAGEN
Pia Gargiulo, Ph.D., Senior Director, Companion Diagnostic Partnerships, QIAGEN
QIAGEN has demonstrated its capability in the area of CDx by creating successful collaborations with the pharmaceutical industry to engage and explore development paths to deliver the promise of personalized medicine. Despite the rapid increase in CDx partnerships in industry there are few successful commercial examples. A successful launch must address several critical factors: timelines, labelling, adoption, reimbursement, education and advocacy.
We will explore the next phase of collaborations and what is necessary to achieve success.

1:15 Session Break

PHARMA-DIAGNOSTICS PARTNERSHIP: LOGISTICS AND MANAGEMENT

1:50 Chairperson's Remarks
Hal J. Mann, MBA, BSMT, Vice President, Clinical Research Services, ResearchDx, LLC

2:00 KEYNOTE PRESENTATION

Successful Strategic Partnering in Co-Development of Drugs and Diagnostics.
Peter Collins, Vice President, Head of Diagnostics, GlaxoSmithKline

2:30 Diagnostics and Precision Medicine: Start Early and Prepare Carefully
Shane Weber, Ph.D., Director, Diagnostics, Molecular Medicine, Pfizer Global
Pfizer drives innovative therapies in select areas of unmet medical need. What is "Precision Medicine"? How does Precision Medicine drive improved drug development and commercial advantage? Translational medicine requires many capabilities, particularly diagnostics, in order to enable Precision Medicine. This overview will contain Precision Medicine examples from the Figitumumab insulin-like growth factor I receptor inhibition non-small cell lung cancer program to identify patient subsets with differential sensitivity.

3:00 Umbrella Agreements: Comprehensive Partnerships for Drug-Diagnostic Co-Development and Commercialization
M. Trevor Page, M.Sc., M.B.A., Director, Corporate Business Development, Dako North America, Inc.
Past drug-diagnostic co-development strategies were focused solely on increasing the efficacy of a late-stage clinical compound by treating discrete patient populations that have been stratified using a single-biomarker assay. However, state-of-the-art agreements will need to enable the successful commercialization of the drug-diagnostic partners' product portfolios by maximizing long-term market access and value as well as reducing pipeline development risk. Recently, umbrella agreements have been geared to do just this by leveraging combinations of multiple drugs, biomarkers, platforms and channels. Aiming for multiple successes on a mutual basis, such comprehensive partnerships require a dedicated alliance and flexible approach to both forge and execute these complex business relationships

3:30 Networking Refreshment Break

4:00 Navigating Internal Diagnostic and Pharmaceutical Partnerships
Meredith Unger, Ph.D., M.B.A., Global Commercial Leader, Companion Diagnostics Center of Excellence, Johnson & Johnson
Although once distinct businesses, pharmaceuticals and diagnostics are undergoing rapid integration in the era of personalized medicine. Pharmaceutical companies are partnering and acquiring diagnostic assets in record numbers. The result has been a challenge to the existing business models and forced healthcare companies to reconsider traditional approaches to making portfolio decisions. This presentation will focus on the benefits and complications associated with internal pharma/diagnostic partnerships. Emerging valuation tools to evaluate companion diagnostic opportunities will be discussed and a Johnson & Johnson case study will be presented to illustrate the complexity of internal companion diagnostics partnerships.

4:30 Develop Tissue-Based Companion Diagnostic Tests for Oncology Drug Development
Monica Madden Reinholz, Ph.D., Senior Manager, Biomarker Strategy; Director, Clinical Studies, Ventana Medical Systems, Inc., A Member of the Roche Group
The co-development of drug and diagnostic combinations has been discussed in the context of personalized medicine for a quite while. The recent progress and regulatory scrutiny highlight some unique challenges & opportunities. Our goal is to collaborate with Biopharma/Biotech companies to develop robust companion diagnostic assays that can support their oncology drug development, improve drug efficacy, reduce unnecessary risk and shorten the clinical trial time by selecting the right patients for the right drug therapies. Ultimately we want to enable the simultaneous launch of targeted therapies with the FDA-approved companion diagnostic tests to maximize patients' benefits.

5:00 Panel Discussion: Internal Vs. External Partnering in Drug-Diagnostics Co-Development

6:00 End of Conference

Inaugural

COMMERCIALIZATION OF MOLECULAR DIAGNOSTICS

Learning through Case Studies

WEDNESDAY, AUGUST 24

11:00 am - 12:15 pm Registration

PLENARY KEYNOTE SESSION

KEYNOTE DISCUSSION:

11:50 Changing Regulation of LDTs

Moderator: *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.*

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MULTI-STAKEHOLDER PANEL:

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Moderator: *Thomas A. Gustafson, Ph.D., Senior Policy Advisor, Arnold & Porter LLP*

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Panelists: *Ann-Marie Lynch, Executive Vice President, Payment and Health Care Delivery Policy, AdvaMed*

David Mongillo, M.P.H., M.S.M., Vice President, Policy and Medical Affairs, American Clinical Laboratory Association

1:20 - 2:20 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

2:20 – 2:30 Session Break

REIMBURSEMENT AND BILLING STRATEGIES

2:30 pm Chairperson's Remarks

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

2:35 What Payors are Looking For

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

This presentation will focused on customer targeting of the payer market. A review of what, why, and how to deliver on what "payors" would like to see from you. A discussion of the overall "Payor" mix and new control points will be highlighted (e.g., private third party payers, Medicare, provider networks, pharmacy benefit managers, etc.). A case study of business approaches directed to the evidence review process, standards, priorities, and sequence will also be highlighted.

3:05 Pricing & Reimbursement Has Become More Sophisticated: How Will This Affect Your Commercialization Strategy?

Gerard Conway, Vice President, Payor Contracting & Reimbursement, Metamark Genetics

This presentation will focus on how to develop, implement and monitor an effective pricing and reimbursement strategy for molecular diagnostics. The talk will include practical insights and tools used to prepare and articulate your strategy to key stakeholders. Audience participants will be able to return to their organizations with concrete ideas on how to better organize, launch and optimize reimbursement of existing and new molecular tests.

3:35 Partnering with Payers for Value Based Reimbursement – Collaborations in Clinical Utility and Cost Effectiveness

Bryan Dechairo, Ph.D., Senior Director, Head of Extramural R&D, Medco Research Institute

We will examine healthcare priorities and an overview of the partnering pipeline. Case studies of Medco/diagnostic company current collaborations will be reviewed. Finally, we will translate teachable moments in market penetration.

4:05 Networking Refreshment Break with Exhibit & Poster Viewing

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

ADOPTION AND UPTAKE OF NEW MOLECULAR DIAGNOSTIC PRODUCTS

4:40 Chairperson's Remarks

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

4:45 Successful Development of Diagnostic Assays: From Proof of Concept to Commercialization

Brian E. Ward, Ph.D., COO, On-Q-ity

The path from scientific discovery to successful clinical assay commercialization is fraught with challenges, pitfalls and opportunities for accelerated development. Together we will outline the developmental process and explore some of the common mistakes that plague this process such as lack of quality control, underpowered discovery studies and inadequate performance and discuss how to avoid such errors. We will also highlight opportunities for acceleration of commercialization such as the role of product management in meeting goals, the benefit of a well-structured publication strategy and the creation of reimbursement assistance programs to accelerate insurance reimbursement.

5:15 Screening for Cystic Fibrosis: The Last 20 Years

Glenn E. Palomaki, Ph.D., Associate Director, Division of Medical Screening and Special Testing, Department of Pathology, Women & Infants Hospital of Rhode Island, Alpert School of Medicine at Brown University

The genetic basis of cystic fibrosis was discovered in 1989 allowing development of molecular based tests. In 2001, ACOG endorsed prenatal screening and ACMG recommended a standard mutation panel. The subsequent uptake of screening will be reviewed in the context of factors that encouraged, or discouraged, its use.

5:45 CASE STUDY EXERCISE: Applying New Tools Learned

The audience will be invited to participate in a case-study discussion on a companion diagnostic test that illustrates criteria for success. This will include a debate on issues of evidence, regulation, pricing, reimbursement, and commercialization.

Co-Moderators:

Bryan Dechairo, Ph.D., Senior Director, Head of Extramural R&D, Medco Research Institute®

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

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

THURSDAY, AUGUST 25

7:30 am Breakfast Presentation *(Sponsorship Opportunity Available)* **or Morning Coffee**

DIAGNOSTIC CLINICAL STUDIES

8:25 Chairperson's Remarks

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

8:30 Clinical Studies and Validation of Molecular Diagnostics

Andrea Ferreira-Gonzalez, Ph.D., Chair, Division of Molecular Diagnostics, Virginia Commonwealth University; Professor, Pathology, George Washington University School of Medicine

9:00 Pharmacogenomic Test Adoption: Early Discovery to Full Utilization

Hawazin Faruki, Dr.PH., Vice President, Clinical Development, Laboratory Corporation of America

Assimilation of pharmacogenomic based diagnostics into standard medical practice remains challenging despite the promise of improved health outcomes. This presentation will focus on some of the key drivers of test acceptance along a continuum from early discovery to full utilization.

LAUNCHING IN EUROPE

9:25 Chairperson's Remarks
Andrew Fish, J.D., Executive Director, AdvaMed Dx

9:30 Development and Use of Companion Diagnostics and the Impact on the Business Model of the Pharmaceutical, Diagnostic and Biotechnology Industry
Alain Huriez, M.D., Chairman, EPEMED: European Personalized Medicine Association
We will be discussing the need for guidelines, and the European case for market access issues.

10:00 Networking Coffee Break with Exhibit and Poster Viewing

10:45 Products or Services? IVDs, LDTs, and Regulatory Compliance on the Road to Personalized Patient Care
Roger Klein, M.D., J.D., Medical Director, Medical Oncology, Blood Center of Wisconsin and Clinical Assistant Professor, Pathology, Medical College of Wisconsin
This presentation will compare and contrast alternative pathways and regulatory requirements for bringing clinical laboratory procedures into medical practice.

DEMONSTRATING CLINICAL UTILITY

11:10 Chairperson's Remarks
Andrew Fish, J.D., Executive Director, AdvaMed Dx

11:15 You Can Build It, Promote It, and Sell It….But Will She Order It, Will He Run It, and Will They Pay For It? Demonstrating Clinical Utility of Personalized Diagnostics
Nicholas T. Potter, Ph.D., FACMG, CSO & Director, Molecular Diagnostics, Molecular Pathology Laboratory Network, Inc.; Clinical Associate Professor, Pathology, University of Tennessee Medical Center
The changing landscape of molecular diagnostics presents many challenges for the rapid adoption and acceptance of molecular testing yet the era of personalized medicine is already here. What lessons and strategies can be learned from past experiences to assure future success in this rapidly developing niche of laboratory medicine?

11:45 New Technology Assessment: Disparate Views Among Reimbursement Experts
Sponsored by SIGNALGENETICS
Greg Richard, Executive Vice President, Commercial Operations, Signal Genetics
Numerous organizations have been formed to provide unbiased reviews of innovative technologies in an effort to optimize finite financial resources. Disparate conclusions are sometimes reached for the same technology. Whose advice should you take?

12:00 pm Commercialization of a Novel Multiplexed Molecular Panel for Gastrointestinal Infections: A European Experience
Sponsored by Luminex
Nancy Krunic, Vice President, Luminex Molecular Diagnostics
The xTAG® Gastrointestinal Pathogen Panel (GPP) is a first of its kind multiplexed molecular test directed at the top causes of infectious diarrhea. Commercialization as well as the challenges of introducing a culture replacementproduct will be discussed.

12:15 Simulation Reduces Risk Earlier in IVD Instrument Development Programs
Sponsored by Elbit Systems of America, Medical - KMC Systems
Jack Kessler, Ph.D., Senior Principal Systems Engineer, KMC Systems, Inc.
IVD instrument development programs have varying degrees of risks depending on the level of uncertainty or speculation in marketing requirements, business value proposition and/or technology maturity. Early simulation has proven effective in exposing requirements, design conflicts, and technical risks. Simulation provides a platform to resolve these issues.

1:15 Session Break

CASE STUDIES

1:50 Chairperson's Remarks
Bill Cook, Principal, WECA, William E. Cook Associates, Strategy and Business Development for Clinical Diagnostic Companies

2:00 Case Study: TruTouch - Intercepting Intoxication before It Does Harm
Richard D. Gill, M.D., Board Member, Launchpad Venture Group
The commercialization of a point-of-care non-invasive sample-free instant alcohol intoxication & biometric determination device - TruTouch - intercepting intoxication before it does harm.

2:30 Case Study: Co-Development and Commercialization of a Companion Diagnostic
Kuo Bianchini Tong, M.S., CEO, Quorum Consulting
The objectives of this session will be to understand how regulatory, reimbursement, and commercialization activities were developed for a new therapy and a companion diagnostic. Specific milestones and timelines will be discussed so that the audience can benchmark their own experiences and future plans.

3:00 Commercialization of Oncotype Dx: Lessons Learned
Premal Shah, Ph.D., Director, Business Development, Genomic Health
The healthcare environment is rapidly changing, especially in the US. With the pending implementation of evidence and outcomes-based medicine, the personalization of medicine is upon us. We will share our perspectives on the definition of personal medicine and how to successfully bring a diagnostic assay from conception to commercialization. More importantly, we will discuss how our test has been delivered to 175,000 patients in 56 countries worldwide. We will discuss the nuances of different cancer products on the market and how partnerships can be leveraged to successfully bring a product to patients across the globe. Finally, we will discuss our perspectives on what it will take to be successful going forward and how companies should position themselves amongst other healthcare stakeholders.

3:30 Networking Refreshment Break

4:00 CASE STUDY EXERCISE: Applying New Tools Learned
The audience will be invited to participate in a case-study discussion on the CF genetic screen that illustrates the issues of evidence, adoption, regulation, pricing, reimbursement, and commercialization.
Co-Moderators:
Glenn E. Palomaki, Ph.D., Associate Director, Division of Medical Screening and Special Testing, Department of Pathology, Women & Infants Hospital of Rhode Island, Alpert School of Medicine at Brown University
Keith F. Batchelder, M.D., Founder and CEO, Genomic Healthcare Strategies

5:00 End of Conference

PRICING INFORMATION

CONFERENCE PRICING

SUMMIT PRICING — BEST VALUE!

(Includes access to 2 conferences, excludes short courses)	Commercial	Academic, Government, Hospital-affiliated
Advance Registration Discount until July 29, 2011	$2095	$945
Registrations after July 29, 2011, and on-site	$2295	$995

SINGLE CONFERENCE

(Includes access to 1 conference, excludes short courses)	Commercial	Academic, Government, Hospital-affiliated
Advance Registration Discount until July 29, 2011	$1495	$625
Registrations after July 29, 2011, and on-site	$1695	$695

August 23-24	August 24-25
Enabling Point-of-Care Diagnostics	Molecular Diagnostics for Infectious Disease
Emerging Molecular Markers of Cancer	Companion Diagnostics
Translating Proteomics into the Clinical Laboratory	Commercialization of Molecular Diagnostics
Mass Spectrometry in Clinical Diagnostics	

SHORT COURSES

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

Monday, August 22nd – Morning	Monday, August 22nd – Afternoon	Wednesday, August 24th – Dinner
SC1 Micro- and Nanofluidics in Diagnostics and Life Sciences	SC4 Applications of Detection Theory in Diagnostics	SC8 The Future of Point-of-Care Diagnostics
SC2 Smarter Studies: Boosting Omics and Biomarker Projects through Study Design	SC5 Automation Solutions for Molecular Diagnostics	SC9 Mass Spec Methods for the Clinical Lab
SC3 Advances in Molecular Pathology, Pt. I (Basic)	SC6 Business Strategies for Companion Diagnostics	
	SC7 Advances in Molecular Pathology, Pt. II (Advanced)	

CONFERENCE DISCOUNTS

Poster Submission-Discount ($50 Off)

Poster abstracts are due by **July 26, 2011**. 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.*

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ADDITIONAL REGISTRATION DETAILS

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

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