

Cambridge Healthtech Institute's Second Annual

Next Generation

*Development, Commercialization,
Clinical Adoption of Novel Assays*



**MOVING
ASSAYS**
to the Clinic

Summit



Enabling Point-of-Care Diagnostics



Trends in Cancer Diagnostics



Molecular Diagnostics for Infectious Disease



Co-Development of Drugs and Diagnostics

SHORT COURSES

Roadmap for Accelerating
Commercialization of
Molecular Diagnostics

Micro- and Nanofluidics in
Diagnostics and Life Sciences:
Technologies and Applications

Future of Point-of-Care
Platforms

FEATURED SPEAKERS

SHAPING THE FUTURE OF CANCER PATHWAY-BASED MEDICINE



**Comprehensive Cancer Genome Diagnostics in the Era
of Targeted Therapy**
Jeffrey S. Ross, M.D.
Albany Medical College and Foundation Medicine

THE FUTURE OF POINT-OF-CARE FOR INFECTIOUS DISEASE



Clinical Diagnostics – Where Are We Going?
Franklin R. Cockerill, III, M.D.
Mayo Medical Laboratories and Mayo Collaborative Services, Inc.



New Developments in Rapid Molecular Testing for Respiratory Viruses
Christine C. Ginocchio, Ph.D., M.T. (ASCP)
North Shore-LIJ Health System Laboratories

AUGUST 24-26, 2010
The Ritz-Carlton
Washington, DC



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Record Attendance Expected This Year!

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Monday, August 23 Tuesday, August 24 Wednesday, August 25 Thursday, August 26

AM		Enabling Point-of-Care Diagnostics	Enabling Point-of-Care Diagnostics	Molecular Diagnostics for Infectious Disease
	Pre-Conference Short Courses: (SC1) Roadmap for Accelerating Commercialization of Molecular Diagnostics	Enabling Point-of-Care Diagnostics	Plenary Keynote Session Molecular Diagnostics for Infectious Disease	Molecular Diagnostics for Infectious Disease
PM		Trends in Cancer Diagnostics	Trends in Cancer Diagnostics	Co-Development of Drugs and Diagnostics
AM	(SC2) Micro- and Nanofluidics in Diagnostics and Life Sciences: Technologies and Applications	Trends in Cancer Diagnostics	Plenary Keynote Session Co-Development of Drugs and Diagnostics	Co-Development of Drugs and Diagnostics
PM			Dinner Short Course: (SC3) Future of Point-of-Care Platforms	

ATTENDEE QUOTES FROM THE **2009 Next Generation **D_x** Summit**

"The venue encourages interaction amongst all pertinent parties (developers, users, regulators) in a very effective manner."

President, ACMC Medical Staff, Chairman, Pathology, Director, Clinical Laboratory, Alameda County Medical Center/Highland General Hospital

"Multi-faceted meeting that created new collaborations!"

Research Scientist, Lab of Molecular Technology, SAIC-NCI Frederick

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Reasons You Should Share Your Research Poster at the Next Generation **D_x** Summit:



- Your poster will be exposed to our international delegation
- Receive \$50 off your registration
- Your poster abstract will be published in our conference materials
- Your research will be seen by leaders from top pharmaceutical, biotech, academic and government institutes

Poster Deadline is July 28, 2010

PRE-CONFERENCE SHORT COURSES* • Monday, August 23 • 2:00-5:00pm

(SC1) ROADMAP FOR ACCELERATING COMMERCIALIZATION OF MOLECULAR DIAGNOSTICS

This short course is focused on development of molecular diagnostics as they make their way from biomarker discovery and initial proof of clinical performance through to commercial launch and market development. The course will emphasize identification of critical hurdles that, when addressed early, can materially accelerate progress. Vital areas to be covered include reimbursement strategies, regulatory path decisions, physician education and key opinion leader development. A case study of an early stage molecular diagnostics company will be shared to illustrate a real world roadmap including:

- Rationale for reimbursement – understanding coverage
- FDA clearance and navigating claims language and timing
- Maximizing clinical study results while addressing costs

Instructors:

William Cook, MBA, Principal, Strategy and Business Development, Clinical Diagnostics, WECA

Patrick Terry, CEO, Applied Clinical Genomics, Technic Solutions, LLC

Bruce Quinn, M.D., Ph.D., Senior Health Policy Specialist, Foley Hoag LLP

(SC2) MICRO- AND NANOFUIDICS IN DIAGNOSTICS AND LIFE SCIENCES: TECHNOLOGIES AND APPLICATIONS

The course is designed for scientists, managers, technicians and engineers who would like to acquire a comprehensive overview of the field of microfluidics. Starting with the underlying physical principles of miniaturization, the course includes an introduction into microfabrication technologies for microfluidic devices covering a wide range of existing materials (glass, silicon, polymers) and manufacturing technologies and describes the complete development cycle of a microfluidic device from the design to the ready-to-use device. Applications of microfluidics in point-of-care and clinical diagnostics, analytical and synthetic chemistry, biotechnology and cell biology will be presented. The course will also provide an insight into the business aspects of the field and the uptake of microfluidic technology in various markets.

Learning Objectives:

- 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
- Get to 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

DINNER SHORT COURSE* • Wednesday, August 25 • 6:30-8:30pm

(SC3) FUTURE OF POINT-OF-CARE PLATFORMS

- How are Dx POCT markets changing?
- Which platforms will win? What's going to happen to the big box diagnostic companies?
- Hospital, MD offices, or home?
- What are the bottlenecks as markets change?
- Where will the new markets be and how will they be organized?
- What strategies make sense for Dx and POCT companies?

Instructors:

Keith F. Batchelder, CEO, Genomic Healthcare Strategies

Peter S. Miller, COO, Genomic Healthcare Strategies

*Separate registration required

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FOR MORE INFORMATION, PLEASE CONTACT:

Arnie Wolfson

Manager, Business Development

Phone: 781-972-5431

Email: awolfson@healthtech.com

HOTEL & TRAVEL INFORMATION

Conference Venue and Hotel:

The Ritz-Carlton, Washington, DC
1150 22nd Street, NW
Washington, DC 20037
Phone: 202-835-0500
Fax: 202-835-1588

Room Rate: \$220 s/d

Reservation Cutoff: August 2, 2010



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.

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ENABLING POINT-OF-CARE DIAGNOSTICS

Moving Towards Rapid Diagnosis



MONDAY, AUGUST 23

1:00-2:00 pm Short Course Registration

2:00-5:00 Pre-Conference Short Courses*

(SC1) ROADMAP FOR ACCELERATING COMMERCIALIZATION OF MOLECULAR DIAGNOSTICS

(SC2) MICRO- AND NANOFUIDICS IN DIAGNOSTICS AND LIFE SCIENCES: TECHNOLOGIES AND APPLICATIONS

4:00 – 5:00 Main Conference Registration

*Separate registration required.

See page 3 for details.

TUESDAY, AUGUST 24

7:30 am-6:00 pm Registration

7:30 Morning Coffee

KEYNOTE PRESENTATIONS

8:30 Chairperson's Remarks

Matthew Lorence, Ph.D., M.B.A., Vice President, Marketing and Sales, Tessarae, LLC

8:40 Retrospective Study, 1918 Pandemic Virus and 2009 H1N1: Lessons for POCT

Jeffery K. Taubenberger, M.D., Ph.D., Chief, Viral Pathogenesis and Evolution Section, Laboratory of Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health
Novel influenza A virus strains that are transmissible in humans can cause global pandemics. There have been four such pandemics in the last one hundred years - 2009, 1968, 1957, and 1918. The address will examine the genetic relationships between these pandemic and seasonal influenza viruses and discuss diagnostic approaches for different influenza virus strains.

9:10 Point-of-Care Testing Transforming Health Care and Improving Outcomes

Christopher Price, Ph.D., Visiting Professor in Clinical Biochemistry, Oxford University

The challenges in health care today include improving the access to, efficiency and effectiveness of care, as well as poor history of innovation. Point-of-care testing has the potential to address these challenges through transforming clinical practice to improve health outcomes. In order to achieve this there has to be a better understanding of clinical need and evidence of effectiveness, as well as a commitment to changing practice.

9:40 Regulation of Novel Molecular Diagnostic Devices for POC Testing

Francisco Martinez-Murillo, Ph.D., Staff Fellow, Food & Drug Administration
Advances in molecular biology research and technology drive innovation in the design and development of new *in vitro* diagnostic devices. In particular, automation, portability, and usability are making these devices more amenable to function within a point-of-care environment. The talk will cover current FDA approaches to assess the safety and efficacy of new molecular diagnostic IVDs when applied to point-of-care settings.

10:10 Coffee Break

LOW COST APPLICATIONS

10:55 Chairperson's Remarks

Matthew Lorence, Ph.D., M.B.A., Vice President, Marketing and Sales, Tessarae, LLC

11:00 Revolutionizing the Diagnostic of Infectious Diseases with SMART Point-of-Care (POC) CDs that "Read" DNA Instead of Music

Michel G. Bergeron, O.Q., M.D., FRCPC, FCAHS, Professor, Director and Founder, Centre de Recherche en Infectiologie (CRI) de l'Université Laval
In 2010, it still takes at least two days to identify microbes responsible for infections. By merging genomics, bioinformatics, nanotechnologies, microfluidics, biosensor, microarray and compact disc (CD) technologies, we are developing POC-CDs which detect nucleic acid of microbes in less than one hour. These rapid devices should revolutionize clinical practice by insuring real-time diagnosis of infectious diseases at point-of-care.

11:30 Printable Paper-Based Immunodiagnosics

Tomi Erho, Senior Research Scientist, VTT Technical Research Centre of Finland
We modified the structural properties of paper and applied inkjet printing to biofunctionalize paper in order to fabricate inexpensive, sustainable and disposable bioassays. We demonstrated a paper-based immunoassay in which transport of fluids and particles, amount of capturing antibodies, as well as the strength of paper in aqueous conditions were controlled. This research is conducted towards the development and design of paper-based diagnostics in the fields of health, well-being, and environmental POC diagnostics, where the main focus is versatility, novel test formats with new design opportunities and low-cost mass production.

12:00 pm Thread-Based Microfluidics and Their Possible Use in Semi-Quantitative Diagnostics

Wei Shen, Ph.D., Associate Professor, Australian Pulp and Paper Institute, Department of Chemical Engineering, Monash University
Multi-filament hydrophilic threads are able to transport liquid through capillary wicking. It has been shown that 3D microfluidic liquid transport channels can be fabricated by sewing a hydrophilic thread onto a supporting material such as a polymer film, or by knitting hydrophilic and hydrophobic threads into a simple pattern. Thread-based microfluidic devices can be used to conduct semi-quantitative chemical and biochemical analysis and therefore have potential in POC applications. In this presentation we report our preliminary studies of the fabrication and application of the thread-based and the thread-paper-based microfluidic devices.

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

REIMBURSEMENT FOR MOLECULAR DIAGNOSTICS: Measuring Value

2:00 Chairperson's Remarks

Harry Glorikian, Managing Partner, Scientia Advisors

2:10 Assessing the Wider Benefits and Economic Impact of a New Diagnostic/Treatment: The UK Experience

Mirella Marlow, M.B.A., Programme Director – Devices and Diagnostic Systems, Centre for Health Technology Evaluation, National Institute for Health and Clinical Excellence

NICE provides national guidance and sets standards on good health promotion and the prevention and treatment of ill health for the UK's NHS. NICE uses comparative effectiveness to achieve consistent clinical standards across the NHS and to ensure uptake of cost-effective healthcare innovations. Dr. Garner will present NICE's new arrangements for the evaluation of diagnostic technologies and discuss the implications.

2:40 Cradle to Grave Issues with Reimbursement

Vickie Baselski, Ph.D., D(ABMM), FAAM, Professor, Department of Pathology and Laboratory Medicine, University of Tennessee Health Science Center
One of the major factors enabling point-of-care diagnostics is the ability to correctly code and get adequately paid for testing performed. Accomplishing this requires both time and effective interaction between many stakeholders including the IVD industry, the laboratory industry, the physician community, professional societies representing these groups, particularly AMA for correct coding, and most importantly, both CMS and other third party payers who establish fee schedules and criteria for payment. This presentation will describe the many issues that may arise during this complex set of interrelated interactions.

3:10 Refreshment Break

MARKET SUCCESS OF POCT: What is the Impact of New Technology?

4:00 Point-of-Care Testing Beyond Glucose Management: Enhancing Clinical Decision Making through Patient Side Testing

Yolanda A. Cillo, M.D., M.B.A., Medical Director, Abbott Point of Care
Clinical diagnostic and therapeutic decisions are judgments made by health care providers arrived at through the collection and analysis of information including patient history, physical examination and available diagnostic information. Providing lab quality diagnostic information rapidly at the patient's side provides real time information that can expedite the diagnosis, treatment and ultimately disposition of a patient to the proper hospital

setting or to home. Streamlining the process associated with laboratory analysis through patient side testing can enhance compliance with guidelines and may impact safety and diminish the amount of blood required to be drawn for analysis.

4:30 Exporting Cervical Cancer Prevention to the Developing World: The Promise and the Challenges

Philip Castle, Ph.D., Senior Investigator, Hormonal and Reproductive Epidemiology Branch, Division of Cancer Epidemiology and Genetics, U.S. National Cancer Institute, NIH, DHHS

Cervical cancer is the second most common female tumor worldwide, with almost 500,000 incident cases and 275,000 related deaths annually. Low-cost molecular screening tools for detection of human papillomavirus, the necessary cause of cervical cancer, may provide a robust method for secondary prevention for this highly preventable disease.

5:00 Opening Reception in the Exhibit Hall

6:00 Close of Day

WEDNESDAY, AUGUST 25

7:00 am Registration

7:30-8:15 am Breakfast Presentation (Sponsorship Available)

CURRENT POINT-OF-CARE SYSTEMS

8:25 Chairperson's Remarks

Shuqi Chen, Ph.D., Chief Executive Officer, IQuum, Inc.

8:30 Digital Microfluidics as an Enabling Technology for Point-of-Care Diagnostics

Michael G. Pollack, Ph.D., Co-Founder, Advanced Liquid Logic, Inc.

Digital microfluidics, characterized by precise, programmable manipulation of liquid droplets using electrowetting, is being applied in an increasing number of clinical diagnostics applications. For near-patient and point-of-care testing, digital microfluidics can potentially provide sample-to-answer automation of complex analysis protocols. Advantages of this approach include the ability to handle a wide range of physiological specimens, to perform rapid and efficient sample processing, to flexibly implement complex analytical techniques, and to integrate all of this on a simple, low-cost and compact system.

9:00 Simple/Rapid Quantitative HIV-1 RNA Testing: Validation Criteria and Application for Clinical Trials and Clinical Care

Robert W. Coombs, M.D., Ph.D., Professor Laboratory Medicine and Medicine, Vice-chair for Research, Department of Laboratory Medicine, Director, University of Washington Retrovirology Laboratory

The laboratory validation of point-of-care (POC) testing will be reviewed and data presented for a simple/rapid POC HIV-1 RNA assay. The use of POC tests for clinical trials will be reviewed and additional applications discussed.

9:30 Sponsored Presentations (Opportunities Available)

10:00 Networking Coffee Break, Exhibit & Poster Viewing

EXPEDITING DEVELOPMENT OF LOW COST DIAGNOSTICS

10:40 Chairperson's Remarks

Steven Buchsbaum, Ph.D., Senior Program Officer, Global Health Technologies, Bill & Melinda Gates Foundation

10:45 Working Towards Standards for Global Health POC Diagnostics

Steven Buchsbaum, Ph.D., Senior Program Officer, Global Health Technologies, Bill & Melinda Gates Foundation

We believe one approach to lower cost, higher performance POC Diagnostics appropriate for use in the developing world is to establish standards that facilitate the integration of the best available technologies. Under the Grand Challenges in Global Health Initiative, we are proceeding with a set of investments that we hope will begin the development of these types of standards. I would like to provide a short discussion of our approach in this work.

11:15 Point-of-Care Diagnostics for the Developing World: An Analysis of Pertinent Standards and Metrics

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

In this paper, we present a set of compelling needs that drive our motivation to develop ultra-rapid, low-cost, low-complexity point-of-care diagnostic platforms—and the key challenges that must be addressed in order to accomplish the commercialization of these products. We begin with the premise that the successful development of POC diagnostic platforms is predicated on the establishment of meaningful and clearly articulated standards. Specifically we see a hierarchy of standards encompassing platform performance metrics, measurement methodologies (e.g. the means by which

we determine that a particular platform indeed meets certain performance metrics), and interface protocols between platform modules (e.g. standards for integration of components, modules, or sub-assemblies). We will discuss each element in this hierarchy in detail.

11:45 Meaningful Use Requires Meaningful Laboratory Results: Healthcare's Opportunity for Improved Outcomes, Less Cost

Kelly Feist, Vice President, Sunquest Information Systems

This presentation is a review of the role that laboratory testing and results communication plays in the scope of the new "meaningful use" environment as outlined by the HITECH Act. We will discuss the impact that laboratory testing plays in the continuum of care related to patient safety, improved diagnostic outcomes, and overall opportunities for reducing the cost of healthcare related to lab testing, diagnosis, and subsequent treatment plans.

PLENARY KEYNOTE SESSION

THE FUTURE OF POINT-OF-CARE FOR INFECTIOUS DISEASE

(Shared session with Molecular Diagnostics of Infectious Disease)

12:15 pm Chairperson's Remarks

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

12:20 Clinical Diagnostics – Where Are We Going?

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.

Significant advances in clinical diagnostics have occurred following the development of new technologies in the late 20th century and early 21st century. These technologies include immunoassays, nucleic acid amplification and sequencing methods, flow cytometry and mass spectrometry. Refinements and broad applications of these techniques, combined with information management, will promote personalized healthcare of high value.

12:50 New Developments in Rapid Molecular Testing for Respiratory Viruses

Christine C. Ginocchio, Ph.D., M.T. (A.S.C.P.), Senior Director, Division of Infectious Disease Diagnostics, North Shore-LIJ Health System Laboratories; 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

The timely identification of viral respiratory tract infections is of tremendous importance for diagnosis, appropriate patient management, reduction of the unnecessary use of antibiotics, and prevention of nosocomial transmission within health care settings. Comprehensive molecular diagnostic testing also provides key epidemiology and surveillance data and can rapidly identify outbreaks of novel viruses, as was demonstrated during the 2009 influenza A H1N1 pandemic. Novel new testing platforms and advanced multiplex technologies are now available to meet these diagnostic needs. This lecture will highlight the major advances in rapid molecular testing for respiratory viruses.

1:20 Luncheon Presentation (Sponsorship Available) or Lunch on Your Own

2:00 Close of Enabling Point-of-Care Diagnostics Conference

6:30 - 8:30 Dinner Short Course*

(SC3) FUTURE OF POINT-OF-CARE PLATFORMS

- How are Dx POCT markets changing?
- Which platforms will win? What's going to happen to the big box diagnostic companies?
- Hospital, MD offices, or home?
- What are the bottlenecks as markets change?
- Where will the new markets be and how will they be organized?
- What strategies make sense for Dx and POCT companies?

Instructors:

*Keith F. Batchelder, Chief Executive Officer, Genomic Healthcare Strategies
Peter S. Miller, Chief Operating Officer, Genomic Healthcare Strategies*

**Separate registration required.*

See page 3 for details.

TRENDS IN CANCER DIAGNOSTICS

Early Detection and Optimum Therapy

**MONDAY, AUGUST 23**

1:00-2:00 pm Short Course Registration

2:00-5:00 Pre-Conference Short Courses*

(SC1) ROADMAP FOR ACCELERATING COMMERCIALIZATION OF MOLECULAR DIAGNOSTICS**(SC2) MICRO- AND NANOFIUIDICS IN DIAGNOSTICS AND LIFE SCIENCES: TECHNOLOGIES AND APPLICATIONS**

4:00 – 5:00 Main Conference Registration

*Separate registration required.

See page 3 for details.

TUESDAY, AUGUST 24

7:30 am-6:00 pm Registration

7:30 Morning Coffee

**DEEP SEQUENCING OF CANCER GENOMES:
Identifying Candidate Genes****8:30 Chairperson's Remarks***Jorge A. León, Ph.D., President, Leomics Consulting***8:40 Molecular Profiling - The Future of Cancer Treatment***Hans Lehrach, Ph.D., Director, Max Planck Institute for Molecular Genetics, Berlin; Head, Department of Vertebrate Genomics*

It will soon be commercially feasible to apply deep sequencing in the clinic at the full-genome level to clinical patient samples, which makes the development of systems able to take advantage of this new flood of clinical information an urgent matter. We are therefore presenting a system we have developed that has the capacity to integrate these types of data in a "holistic" and comprehensive fashion. The "Virtual Patient" system allows us to create predictive models out of all the information available from any deep molecular characterisation technology, allowing the selection of an optimal therapy for each individual patient.

9:10 Development of Personalized Tumor Biomarkers Using Massively Parallel Sequencings

Rebecca Leary, Ph.D., Post Doctoral Fellow, Oncology, Ludwig Center for Cancer Genetics and Therapeutics, The 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.

9:40 Expression Profiling of microRNAs in Ovarian Cancer Using Deep Sequencing*Chad Creighton, Ph.D., Assistant Professor, Division of Biostatistics, Dan L. Duncan Cancer Center, Baylor College of Medicine*

By comprehensively profiling expression of microRNAs and genes in ovarian cancer, we have identified strong candidate microRNAs and their target genes that may contribute to the pathogenesis of this disease. To date, we have found that miR-100 inhibits mTOR signaling and enhance sensitivity to rapamycin in clear cell cancer cell cultures, and that miR-31 inhibits proliferation and induces apoptosis in those serous cancer cell lines that have a dysfunctional p53 pathway.

10:10 Presentation*Omayma Al-Awar, Ph.D., Director of Sales and Marketing, EdgeBio***10:25 Coffee Break**Sponsored by  **EdgeBio****ONCOLOGY BIOMARKERS****10:55 Chairperson's Remarks***Jorge A. León, Ph.D., President, Leomics Consulting***11:00 High Throughput Cancer Diagnostic Discovery and Development in Using Somamers: Slow Off-Rate Modified Aptamers***Stephen A. Williams, M.D., Ph.D., CMO, SomaLogic, Inc.*

A clinical assay has been developed which uses SOMAmers to measure ~900 proteins simultaneously in 15ul of plasma or serum, with a CV of ~5% and a median LLOQ well below 1pg/ml. This combination of attributes is not currently matched by any other technology platform. The high-throughput assay has been used to discover protein signatures which diagnose cancer or predict recurrence in a number of different cancers. Relevant case studies will be discussed.

11:30 Combined Tissue and Blood Tests Based on a Novel Biomarker for Predicting and Real Time Monitoring of Breast Cancer Recurrence*Ginette Serrero, Ph.D., CEO, Oncology Biomarker, A&G Pharmaceutical, Inc.*

Applying biological screen for target discovery has been a very powerful approach to identify targets in oncology that have therapeutic and diagnostic applications for drug resistant cancers. Using this approach we have discovered a novel biomarker that is over expressed and secreted by breast tumors and plays a critical role in breast tumorigenesis and acquisition to resistance to therapy. A tissue and blood tests were developed to detect this biomarker in breast biopsies as well as in serum. Training trial followed by a validation clinical study enrolling 264 patients have demonstrated and validated that tissue expression of this biomarker was a predictor of recurrence independent of tumor size, tumor grade, disease stage and lymph node status. On-going prospective clinical studies show that serum GP88 measurement can be used for real time monitoring of recurrence. These data and their impact on personalized medicine in breast cancer will be presented.

**FUNDING OPPORTUNITIES IN
CANCER DIAGNOSTICS****12:00 pm NCI Cancer Diagnostics Program***Avraham Rasooly, Ph.D., Program Director, Cancer Diagnosis Program, National Cancer Institute*

Cancer is uncontrolled growth of abnormal cells in the body. Cancer is recognized as a multistep process within the cell, involving multiple genomic alterations that manifest in multiple phases. A trend in cancer treatment is personalized medicine, the tailoring of treatment to the unique "molecular signature" of the patient's cancer. Personalized medicine and the complexity of cancer demand new diagnostics tools to analyze such molecular signatures. The NCI's Cancer Diagnosis Program support research and development of new diagnostics technologies for cancer.

12:30 Luncheon Presentation (Sponsorship Available) or Lunch on Your Own**SERUM PROFILING****2:00 Chairperson's Remarks***Myla Lai-Goldman, M.D., CEO, CancerGuide Diagnostics, Inc.***2:10 Rapid Mass Spectrometric Metabolic Profiling of Blood Sera Detects Ovarian Cancer with High Accuracy***John McDonald, Ph.D., Professor and Director, Integrated Cancer Research Center, School of Biology, Georgia Institute of Technology*

We report the application of a new mass spectrometric procedure for the measurement of relative metabolite levels in sera combined with a customized functional Support Vector Machine (SVM)-based classification algorithm for diagnostic applications. As an initial test of the diagnostic power of our method, we examined sera from 94 women. The assay was able to distinguish between ovarian cancer and control groups with an unprecedented 99-100% accuracy (100% sensitivity; 99-100% specificity) demonstrating its potential as a clinically significant diagnostic test.

2:40 ColoVantage—A Test for Colorectal Cancer Using Methylated Septin 9 DNA in Plasma

Kasinathan Muralidharan, Ph.D., Senior Director, Molecular Genetics, Quest Diagnostics Nichols Institute

The good prognosis for colorectal cancer (CRC) when detected early has supported the value of CRC screening. However, compliance to CRC screening is low compared to for example prostate cancer screening, partly due to the inconvenience associated with colonoscopy and fecal sampling. The availability of a blood based test for CRC detection can potentially improve compliance. Detection of methylated Septin 9 DNA in plasma has been strongly correlated with CRC with a sensitivity of about 70% and specificity of about 90% in detecting CRC. We here report the development and validation of a test for methylated Septin 9 DNA in plasma.

3:10 Refreshment Break

4:00 Interactive Panel: Practical Approach for Developing Predictive Diagnostics

Moderator: Myla Lai-Goldman, M.D., CEO, CancerGuide Diagnostics, Inc.

- How do we shorten the timeline from concept to delivery?
- Charting the logical approach to make development more efficient
- Avoiding prospective, randomized clinical trials

Panelists:

Stephen Little, Ph.D., Vice President, Personalized Healthcare, QIAGEN (Formerly CEO, DxS Ltd.)

Felix W. Frueh, Ph.D., Vice President, Research & Development & Personalized Medicine, Medco Health Solutions, Inc.

Questions will be collected via email beforehand from the audience.

5:00 Opening Reception in the Exhibit Hall

6:00 Close of Day

WEDNESDAY, AUGUST 25

7:00 am Registration

7:30-8:15 am Breakfast Presentation (Sponsorship Available)

CIRCULATING ENDOTHELIAL AND STEM CELLS

8:25 Chairperson's Remarks

Alexander L. Weis, Ph.D., FRSC, CEO, OncoVista, Inc.; Managing Director, AdnaGen AG; Adjunct Professor, University of Texas Health Science Center, San Antonio

8:30 Microfluidic Chips that Enable the Capture, Enumeration, and Characterization of Circulating Tumor Cells: Current State of the Art and Clinical Implications

Mara Aspinall, President and CEO, On-Q-ity

Gary Palmer, CMO, On-Q-ity

Advances in microfluidics have enabled the capture, enumeration, and characterization of circulating tumor cells. By advancing this technology, On-Q-ity has helped to fulfill the promise of circulating tumor cells in clinical cancer management. The ability to characterize circulating tumor cells has the potential to revolutionize cancer care by enabling better therapy selection, proactive monitoring of treatment efficacy and early detection of relapse.

9:00 Molecular Expressions of Circulating Tumor Cells (CTCs) to Guide Targeted Cancer Therapies and Improve Patient Care

Alexander L. Weis, Ph.D., FRSC, CEO, OncoVista, Inc.; Managing Director, AdnaGen AG; Adjunct Professor, University of Texas Health Science Center, San Antonio

CTCs are one of the fastest growing areas of interest in oncology. Early detection of metastatic activity, prognosis, and "real-time" monitoring of the patient's treatment will dramatically transform the landscape of clinical management of cancer patients. During the treatment of metastatic cancers the presence or absence of CTCs is an early indicator of therapy response or failure, which enables the treating physician to optimize their therapeutic strategies and interventions. In addition, molecular biomarkers of CTCs as companion diagnostic will transform the targeted drug development efforts of companies allowing for the tailoring of cancer treatment for each individual patient. Following the discussion on clinical utility of CTCs and monitoring the performance of drugs in patients, several responding and non-responding cases will be presented. Molecular characterization of CTCs in non-responders, confirmed in many cases by EMT and stem cell like properties of tumor cells circulating in the blood. Targeted elimination of these cell types could provide solutions for metastatic disease and relapse management.

9:30 What can FISH tell us about Rare Circulating Cells?

Mark Carle Connelly, Ph.D., Director, Cellular Research, Veridex, LLC
Brad Foulk, and Chandra Rao Ph.D., Veridex, LLC

The ability to capture, count, and characterize intact rare cells is of growing research interest. Rare circulating cells provide a means by which researchers may investigate a wide variety of cells and cellular processes in health and disease. We have developed methods whereby rare cells isolated using the CellSearch® System, are examined for genomic DNA structure using Fluorescence In situ Hybridization (FISH) technology. Rare cells captured using a variety of capture and detection specificities from cancer patients, and from normal individuals, were examined for gene amplifications and chromosomal abnormalities. Different capture methods can yield different patterns of aneuploidy in both patients and controls. FISH analysis can be extremely useful, and may well be critically important, to a proper understanding of rare cell populations.

10:00 Networking Coffee Break, Exhibit & Poster Viewing

10:40 Targeted Gold Nanoparticles in Cancer Diagnostics of Circulating Tumor Cells

Kattesh Katti, Ph.D., Professor of Radiology; Director, Cancer Nanotechnology Platform, Radiology, University of Missouri

Our collaborative efforts with oncologists over the last 20 years have helped us understand the importance of early cancer diagnostics especially at the single cell levels. We have recently discovered peptide conjugated and engineered gold nanoparticles with specificity toward Gastrin Releasing Peptide (GRP) receptors which are over expressed in prostate and breast tumors. These GRP receptor specific gold nanoparticles undergo selective endocytosis in prostate (PC3) and breast tumor (MCF 7) cells (1-2). The nanoparticle density per tumor cell is optimum for single cell imaging using photoacoustic (PA) techniques. So far we have been able to identify as few as five prostate/breast tumor cells from media consisting of millions of normal cells. The diagnostic capabilities of engineered gold nanoparticle and the accuracy of their detection through PA techniques will result in significant patient benefits, and consequently ensue healthcare cost savings, and provide significant revenue generation opportunities to the pharmaceutical industries. This presentation will highlight recent developments in nanomedicine as it relates to the development and commercialization of new diagnostic technologies based on PA techniques for circulating tumor cell detection.

PREDICTING CLINICAL OUTCOME

11:15 Discovering Biomarkers to Predict Clinical Outcome

K. Stephen Suh, Ph.D., Scientific Director, Tissue Bank, Cancer Research Program, The John Theurer Cancer Center, Hackensack University Medical Center

Developing novel therapies for "personalized" treatment on cancer requires systematic approaches to identify robust and stratified biomarkers for diagnostic and prognostic purposes. Conventionally, researchers use established clinical parameters (i.e. leukemic vs. non-leukemic phase for lymphoma) to design biomarker research projects and hypothesize that those biomarkers will have a strong correlation with clinical outcomes. After examining the drug response data of patients retrospectively, we have concluded that the conventional scientific approach is minimally effective and the research communities need to consider a different road map. Our study demonstrates that clinical outcome data must be constructed first and then analyzed to identify retrospective patient biospecimens that are directly associated with the final clinical outcome. Molecular profiling of these patient samples will provide a set of biomarkers that can be used to preselect patients for "personalized" treatment options.

11:45 New Individualized, Cell Based, High Throughput Method for Determining the Drug Sensitivity Pattern in Cancer Patients

Henriette Skribek, Ph.D., Researcher, Microbiology, Tumor and Cell Biology, Karolinska Institute

Primary tumor cells are extracted from fresh patient samples and used in a 3 day drug sensitivity *in vivo* assay; there the cell environment is uniquely mimicking the conditions observed in the human body with the help of a new media formulation. Those primary cells therefore keep their original properties and are not destroyed by the *in vitro* conditions.

Sponsored by



PLENARY KEYNOTE SESSION

SHAPING THE FUTURE OF CANCER

PATHWAY-BASED MEDICINE

(Shared session with Co-Development of Drugs and Diagnostics)

12:15 pm Chairperson's Remarks

Harry Glorikian, Managing Partner, Scientia Advisors

12:20 Comprehensive Cancer Genome Diagnostics in the Era of Targeted Therapy

Jeffrey S. Ross, M.D., Cyrus Strong Merrill Professor & Chair, Department of Pathology & Laboratory Medicine, Albany Medical College and Foundation Medicine

The integration of multigene predictors and molecular diagnostics into the selection, administration, dosing and monitoring of the use of anti-cancer drugs has continued to impact the both current oncology practice and the discovery and clinical development of new anti-cancer drugs. Comprehensive cancer genome diagnostics and continued in depth sequencing of the human cancer cell genome have uncovered a variety of genetic mutations, translocations and amplifications that are playing major roles in the continuing discovery of novel drug – test combinations and have resulted in critical changes in the selection and dosage of anti-neoplastic agents already on the market.

12:50 Emerging Stakeholders in Personalized Medicine

Harry Glorikian, Managing Partner of Scientia Advisors

Personalized medicine represents a fundamental shift in the healthcare industry at a time when change is needed most. The unacceptable cost and efficacy of today's drugs is driving pharmacogenomic tests' strong value proposition to patients, physicians and payors. In fact, the allure of this new paradigm to create additional value and new growth opportunities is attracting new players, ranging from drug distributors to pharmacy benefits managers to entirely new enterprises (e.g. genomic benefits managers) into the fray. This talk will provide an overview of the space, today's active players and an overview of newly active players that are shaping the future of a new healthcare ecosystem.

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

2:00 Close of Trends in Cancer Diagnostics Conference



**WEDNESDAY, AUGUST 25**

11:00 am-12:00 pm Registration

PLENARY KEYNOTE SESSION**THE FUTURE OF POINT-OF-CARE FOR INFECTIOUS DISEASE***(Shared session with Enabling Point-of-Care Diagnostics)***12:15 pm Chairperson's Remarks***John C. Carrano, Ph.D., President, Carrano Consulting, LLC***12:20 Clinical Diagnostics – Where Are We Going?***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.*

Significant advances in clinical diagnostics have occurred following the development of new technologies in the late 20th century and early 21st century. These technologies include immunoassays, nucleic acid amplification and sequencing methods, flow cytometry and mass spectrometry. Refinements and broad applications of these techniques, combined with information management, will promote personalized healthcare of high value.

12:50 New Developments in Rapid Molecular Testing for Respiratory Viruses*Christine C. Ginocchio, Ph.D., M.T. (A.S.C.P.), Senior Director, Division of Infectious Disease Diagnostics, North Shore-LIJ Health System Laboratories; 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*

The timely identification of viral respiratory tract infections is of tremendous importance for diagnosis, appropriate patient management, reduction of the unnecessary use of antibiotics, and prevention of nosocomial transmission within health care settings. Comprehensive molecular diagnostic testing also provides key epidemiology and surveillance data and can rapidly identify outbreaks of novel viruses, as was demonstrated during the 2009 influenza A H1N1 pandemic. Novel new testing platforms and advanced multiplex technologies are now available to meet these diagnostic needs. This lecture will highlight the major advances in rapid molecular testing for respiratory viruses.

1:20 Luncheon Presentation (Sponsorship Available) or Lunch on Your Own**MASS SPEC, SEQUENCING AND EMERGING TECHNOLOGIES FOR INFECTIOUS DISEASE****2:10 Chairperson's Remarks***Garth D. Ehrlich, Ph.D., Professor of Microbiology and Immunology, Drexel University College of Medicine; Executive Director, Center for Genomic Sciences, Allegheny Singer Research Institute***2:15 Rapid Identification of Bacteria, Mycobacteria, and Fungi by MALDI-TOF Mass Spectrometry***Patrick R. Murray, Ph.D., Chief and Senior Scientist, Clinical Microbiology Laboratory, NIH Clinical Center*

Conventional methods for the identification of clinically significant organisms is slow, expensive, and frequently inaccurate. Gene sequencing is highly accurate, but is currently slow, expensive, and technically demanding. In contrast, 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.

2:45 Mass Spec-Based Molecular Diagnostics Provide for Comprehensive Pathogen Screening*Garth D. Ehrlich, Ph.D., Professor of Microbiology and Immunology, Drexel University College of Medicine; Executive Director, Center for Genomic Sciences, Allegheny Singer Research Institute*

The advent of the Ibis T-5000 Universal Biosensor has augured in a new era in molecular diagnostic pathogen detection and characterization. This

technology provides the same breath as cultural techniques for all pathogen classes, and thus is useful for the identification of nearly any species without the need to a priori decide which pathogens to test for. However, it surpasses culture because it can detect any organism regardless of culturability, prior antimicrobial treatment, or metabolic state.

3:15 The Use of High-Resolution Melt Curve Analysis, Pyrosequencing, and DNA Profiling to Identify and Characterize Microorganisms*Gary W. Procop, M.D., M.S., Chair, Department of Molecular Pathology; Section Head, Molecular Microbiology; Director, Mycology, and Parasitology; Professor of Pathology, Cleveland Clinic*

The genomes of medically-important microorganisms are becoming well characterized. This data is providing evidence of unique or signature sequences that can be used for microorganism identification and characterization. In many instances, such information is contained within short segments of DNA, with even single nucleotide polymorphisms providing important information. This information may be obtained using modern molecular techniques that are simple to perform and inexpensive.

3:45 Networking Refreshment Break, Exhibit & Poster Viewing**4:30 Mass Spectrometry-Based Diagnostics for Medical Microbiology***Donna M. Wolk, Ph.D., D(ABMM), Associate Research Professor, BIO5 Institute, Division Chief for Clinical and Molecular Microbiology, Department of Pathology, Arizona Health Science Center and University Medical Center*

The introduction of mass spectrometry methods into clinical microbiology laboratories brings many possibilities for new clinical laboratory interventions in support of patient care. This program will describe and review mass spectrometry methods with current and potential application to diagnostic clinical microbiology laboratories.

5:00 Sequencing-Based & Mass Spectrometric Bacterial Identification in Clinical Microbiology*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*

Identification of bacteria isolated from clinical specimens provides valuable information for patient care, but is challenged by microbial diversity. Traditional methods rely on conventional biochemicals, used either manually or in an automated application. In this presentation, DNA sequencing- and matrix-assisted laser desorption ionization-time of flight mass spectrometry-based bacterial identification for use in clinical laboratories will be explored.

5:30 Break-Out Sessions

The roundtable discussions open to all attendees, sponsors, exhibitors, and speakers provide a forum for discussing key issues and meeting potential partners. Plan to take part and explore the topics in-depth.

Molecular Diagnostics for Infectious Viral Agents*Moderator: Christine C. Ginocchio, Ph.D., M.T. (A.S.C.P.), North Shore-LIJ Health System***Emerging and Novel Technologies for Infectious Molecular Diagnostics***Moderator: Gary W. Procop, M.D., M.S., Cleveland Clinic***The Business of Molecular Diagnostics***Moderator: Daniel R. McClernon, McClernon, LLC***6:30 End of Day****6:30-8:30 Dinner Short Course*****(SC3) FUTURE OF POINT-OF-CARE PLATFORMS**

- How are Dx POCT markets changing?
- Which platforms will win? What's going to happen to the big box diagnostic companies?
- Hospital, MD offices, or home?
- What are the bottlenecks as markets change?
- Where will the new markets be and how will they be organized?
- What strategies make sense for Dx and POCT companies?

Instructors:

Keith F. Batchelder, Chief Executive Officer, Genomic Healthcare Strategies
Peter S. Miller, Chief Operating Officer, Genomic Healthcare Strategies

THURSDAY, AUGUST 26

7:00 am Registration

7:30 Breakfast Presentation (Sponsorship Available)

COMPARISON, INTEGRATION AND DEVELOPMENT OF NOVEL TECHNOLOGIES

8:25 Chairperson's Remarks

Daniel R. McClernon, McClernon, LLC

8:30 Pathogen Detection and Discovery – A Staged Approach

Thomas Briese, Ph.D., Associate Professor of Clinical Epidemiology, Center for Infection and Immunity, Mailman School of Public Health, Columbia University
Recent advances in molecular technologies have revolutionized clinical microbiology. To address the needs for sensitive, highly multiplexed assays in pathogen detection, surveillance and discovery, we pursue a staged strategy using multiple platforms: multiplex MassTag PCR, GreeneChip microarrays, and unbiased pyrosequencing to discover truly new agents. I will review strengths and limitations of the different approaches and illustrate our strategy using examples from recent outbreaks, surveillance efforts, and zoonotic diseases.

9:00 Regulatory Challenges of Molecular *in vitro* Diagnostics

Tamara Feldblyum, Scientific Reviewer, Division of Microbiology Devices, FDA/CDRH/OIVD

Molecular methods for diagnosing infectious disease have recently been introduced and readily translated into current medical practice. Novel approaches have been implemented by FDA to overcome the regulatory challenges in evaluating the performance of these complex devices. The regulatory and scientific review processes used to review molecular *in vitro* diagnostics will be discussed in the presentation.

9:30 Metagenomic Approaches to Pathogen Detection and Discovery

David Wang, Ph.D., Departments of Molecular Microbiology and Pathology and Immunology, Washington University in St. Louis

In recent years, metagenomic approaches such as DNA microarrays and high throughput sequencing have revolutionized the process of viral detection and discovery. Application of these culture independent methods to clinical samples from patients with myriad diseases has lead to an unprecedented rate of discovery of novel agents. A challenge that remains is that of establishing causal links between the novel agents and human disease.

10:00 Networking Coffee Break, Exhibit & Poster Viewing

10:45 How Do Novel Technologies and Diagnostics Integrate in the Pharmaceutical Realm

Cathy A. Petti, M.D., Associate Professor (Adjunct) of Medicine, Stanford University Medical Center

11:15 Emerging Technologies for Infectious Disease (Sponsorship Available)

Moderator: Daniel R. McClernon, McClernon, LLC

11:30 Multiplex Pathogen Detection via Next Generation Sequencing Technology

Prof. George Church, Ph.D., Co-Founder, Pathogenica, Professor of Genetics, Harvard Medical School

New high throughput sequencing technologies are opening up completely new opportunities for high content and high sensitivity diagnostics, but the genomic information delivered must provide clear clinical benefits. Pathogenica™ has developed a unique BioDetection assay to identify and quantify a large number of infectious organisms from tissue samples, providing cast-iron clinically relevant diagnostic information. Pathogenica's technology allows the multiplexing of tens of thousands of specifically designed assays in a single sequencing reaction, taking advantage of high bandwidth sequencing platforms to drive down the cost of individual DxSeq assays below the \$1 price point. Low cost multiplexed diagnostic assays offer a convincing solution to questions over healthcare reimbursement for nucleic acid tests, and can save millions of dollars of unnecessary single pathogen assays. In this presentation we outline Pathogenica's strategy toward CLIA certification and FDA-approved diagnostic panels, present proof of concept application of Pathogenica's technology for detection of multiple pathogens, and discuss new approaches to diagnostic monitoring enabled by this low-cost technology.

12:00 pm Sponsored Presentations (Sponsorship Available)

12:30 Luncheon Presentation

Nucleic Acid Amplification Tests for Diagnosis of Clostridium difficile-Associated Disease

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

Because of changes in the spectrum of disease, emergence of an epidemic, hypervirulent strain, increased prevalence in both community and healthcare settings, and decreased response to metronidazole the accurate and timely diagnosis

of C. difficile-associated disease (CDAD) has never been more important. Nucleic acid amplification tests (NATs) are now the new gold standard for the diagnosis of CDAD and several FDA-cleared NATs for detection of C. difficile toxin B gene are currently available. The challenges in the diagnosis of CDAD, the evolution of testing, and common misconceptions about the use of these tests will be reviewed with an emphasis on the role of NATs. In addition the impact of NAT deployment on the laboratory and the healthcare system will be described.

1:00 Luncheon Presentations (Sponsorship Available) or Lunch on Your Own

RAPID VIRAL TESTING & DRUG RESISTANT MUTANTS

2:15 Chairperson's Remarks

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

2:20 PCR ESI-MS: A Novel Detection Method for Multi-Drug Resistant Pathogens

Robert A. Bonomo, M.D., Professor of Medicine; Director, Cleveland VAMC GRECC
Multidrug resistant pathogens represents one of the most significant clinical challenges in infectious diseases. The timely administration of appropriate, pathogen-directed therapy can be life-saving. Presently, physicians rely heavily upon clinical, epidemiological and demographic factors to assist with the choice of empiric therapy. A summary of the contribution that PCR ESI MS with the Ibis Biosensor can make to the diagnosis of MDR infections is presented. As a rapid test, the T5000 Biosensor uses strategically designed PCR primers that amplify "information rich" regions of the bacterial genome and determine their precise DNA sequence by mass spectrometry analysis. Rapid bacterial identification can assist in the choice of therapy, can help determine the clonal relatedness of strains, and even detect resistance genes. In balance, the significance of finding bacterial DNA when a pathogen is not cultured will represent a significant challenge.

2:50 New Sensitive Genotyping Technologies to Detect Low-Level Drug Resistant Viral Variants: Clinical Implications

Michael J. Kozal, M.D., Associate Professor of Medicine, Yale University School of Medicine; Chief, Section of Infectious Diseases, VA CT Healthcare System
Genotypic resistance assays are recommended as the preferred resistance testing method to guide therapy in HIV-infected patients. However, a major limitation of the clinically available genotyping technology is the inability to detect drug resistant viral variants that exist at low-levels within the circulating viral population (at <20% levels). Recent data has demonstrated that resistant viral variants that exist at ~ 0.5 to 1% levels of the viral population are clinically important as they can rapidly grow under drug selection pressure and lead to therapy failure. This paper will discuss the clinical importance of low-level resistant viral variants and describe some of the new sensitive genotypic approaches used to detect low-level drug resistant HIV, HCV and HBV.

3:20 Detection and Genotyping of HPV—An Overview of Technologies in Use

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

Numerous studies have demonstrated the relationship between persistent high-risk human papillomavirus (HR-HPV) infection and development of high-grade cervical intraepithelial neoplasia (CIN) and cervical cancer. Therefore, HR-HPV testing is recommended in combination with cervical cytology for evaluation of equivocal results, clinically relevant cervical lesions and as a screening adjunct for women >30 yr. Identification of HPV types, such as 16, 18 and 45 may help to identify women at highest risk for ≥CIN3 and permit less aggressive management of women with other HR-HPV infections. This lecture will discuss the various technologies developed for the detection and typing of HR-HPV DNA and for the detection of HR-HPV E6/E7 mRNA, with the intent to improve specificity of detection of clinically relevant disease.

4:00 Refreshment Break

4:30 Challenges and Strategies for Influenza Diagnostic Testing Support in Public Health Laboratories

Stephen Lindstrom, Ph.D., Team Lead, Diagnostics Development Team, Virus Surveillance and Diagnosis Branch, Influenza Division, NCIRD, Centers for Disease Control and Prevention

5:00 International Standards and Reference Materials for Quantitative Molecular Infectious Disease Testing

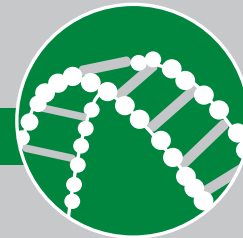
Marcia J. Holden, Ph.D., Research Biologist, Biochemical Science Division, National Institute of Standards and Technology

Certified standards are critical to accurate determination of viral load to monitor patient status. The availability of appropriate standards is limited; the variety of methods used and lack of comparability between labs all contribute to measurement variability. The presentation will address different approaches to the development of certified standards and the challenges in developing standards that are fit for purpose.

5:30 Close of Conference

CO-DEVELOPMENT OF DRUGS AND DIAGNOSTICS

Accelerating Progress of Companion Diagnostics

**WEDNESDAY, AUGUST 25**

11:00 am-12:00 pm Registration

PLENARY KEYNOTE SESSION

SHAPING THE FUTURE OF CANCER PATHWAY-BASED MEDICINE

*(Shared session with Trends in Cancer Diagnostics)***12:15 pm Chairperson's Remarks***Harry Glorikian, Managing Partner, Scientia Advisors***12:20 Comprehensive Cancer Genome Diagnostics in the Era of Targeted Therapy***Jeffrey S. Ross, M.D., Cyrus Strong Merrill Professor & Chair, Department of Pathology & Laboratory Medicine, Albany Medical College and Foundation Medicine*

The integration of multigene predictors and molecular diagnostics into the selection, administration, dosing and monitoring of the use of anti-cancer drugs has continued to impact the both current oncology practice and the discovery and clinical development of new anti-cancer drugs. Comprehensive cancer genome diagnostics and continued in depth sequencing of the human cancer cell genome have uncovered a variety of genetic mutations, translocations and amplifications that are playing major roles in the continuing discovery of novel drug – test combinations and have resulted in critical changes in the selection and dosage of anti-neoplastic agents already on the market.

12:50 Emerging Stakeholders in Personalized Medicine*Harry Glorikian, Managing Partner of Scientia Advisors*

Personalized medicine represents a fundamental shift in the healthcare industry at a time when change is needed most. The unacceptable cost and efficacy of today's drugs is driving pharmacogenomic tests' strong value proposition to patients, physicians and payors. In fact, the allure of this new paradigm to create additional value and new growth opportunities is attracting new players, ranging from drug distributors to pharmacy benefits managers to entirely new enterprises (e.g. genomic benefits managers) into the fray. This talk will provide an overview of the space, today's active players and an overview of newly active players that are shaping the future of a new healthcare ecosystem.

1:20 Luncheon Presentation (Sponsorship Available) or Lunch on Your Own

UNDERSTANDING THE PROCESS

2:10 Chairperson's Remarks*Robert E. Yocher, M.H.Sc., RAC, FRAPS, Vice President, Regulatory Affairs and Corporate Quality Compliance, Genzyme Corporation***2:15 Immunohistochemistry and Companion Diagnostics--Know Your Target, Start Early, Fail Often**

Robert Dunstan, Ph.D., Distinguished Investigator, PCDS, Biogen Idec
Immunohistochemistry (IHC) is often the first method considered for a companion diagnostic for solid tumors, especially for antibody-based therapies. However FDA-approved IHC assays are far from robust. This asks the question whether IHC assays be designed that can be used for accurate prognostic or predictive biomarker development?

2:45 The PMC Public Policy Efforts on Companion Diagnostics*Robert E. Yocher, M.H.Sc., RAC, FRAPS, Vice President, Regulatory Affairs and Corporate Quality Compliance, Genzyme Corporation*

This talk will enumerate how an extremely diverse group of major stakeholders came together to guide policy and provide comprehensive input to one of the most requested FDA guidance documents to date.

3:15 Evidence Based Evaluation of New Molecular Diagnostic Tests – Going for the Gold*Steve Gutman, Ph.D., Technology Evaluation Center, Associate Director, Blue Cross and Blue Shield Association*

While all diagnostic tests can be important, pharmacogenomic tests developed in conjunction with new drug development or for already available drugs are particularly important because the benefit and risks of the diagnostic test become inextricably linked to those of the drug. While the requisites for good method evaluation have now been well defined in the ACCE and EGAPP models, making good evidence based decisions remains a complex and challenging process. There is no substitute for good data and good science in making the right decisions on the proper use of new test.

3:45 Networking Refreshment Break, Exhibit & Poster Viewing**4:30 New Challenges in Health Economics and Reimbursement***Anita J. Chawla, Ph.D., Vice President, Analysis Group*

In the emerging evidence-based marketplace of drugs and diagnostics, clinical evidence alone is no longer sufficient for reimbursement. Successful companies need to develop a robust evidence package, built on a solid foundation of outcomes data—including data that demonstrate value, or benefits versus costs. This presentation will examine the challenges diagnostic companies face in conducting rigorous studies to collect such data, and provide a case study review examining where molecular diagnostic tests have been successful -- and where they have failed.

5:00 Adoption of Companion Diagnostics by Industry and Academia*Peter Tolias, Ph.D., Executive Director, Institute of Genomic Medicine; Research Director, The Autism Center; Professor, Department of Pediatrics, UMDNJ New Jersey Medical School*

Drug developers are facing unprecedented challenges in formulating new efficacious therapeutic products. The traditional model of developing medicine prescribed to a large segment of the available patient pool has been challenged by the reality that most blockbuster drugs have already been discovered. Another issue is an evolving regulatory process for increased safety and efficacy that has raised the bar for FDA approval. Both CLIA lab-developed and FDA-approved diagnostics represent a tool for drug developers to address these challenges by leveraging activities performed during drug development such as biomarker discovery, validation and clinical development and partnering with diagnostic companies to co-develop and launch drugs with companion tests. An instrumental role for successful market introduction and adoption of companion drugs and tests are academic medical centers that function as trial and educational sites to train medical students, fellows and physicians on how to best use the new technologies in clinical practice.

5:30 Break-Out Sessions

The roundtable discussions open to all attendees, sponsors, exhibitors, and speakers provide a forum for discussing key issues and meeting potential partners. Plan to take part and explore the topics in-depth.

Evaluating Commercial Need for a Companion Diagnostic - How Do You Decide?*Moderator: Charlie Raffin, CJR Advisors, LLC (formerly Vice President, Commercial Assessment, J&J)***Coping with Changing Evidence in a Changing Regulatory Environment - Is it Possible to Plan Ahead?***Moderator: Finley Austin, Ph.D., US Head, External Research & Innovation Environment, Roche Discovery Technologies***To Partner or Not to Partner, That is the Question. The Dance between Pharma and Diagnostics Companies.***Moderator: Brian T. Edmonds, Ph.D., Research Advisor, Global External Research & Development, Lilly Corporate Center***Topic to be Announced***Moderator: Anita J. Chawla, Ph.D., Vice President, Analysis Group***Topic to be Announced***Moderator: Stephen Naylor, Ph.D., CEO and Chairman, Predictive Physiology & Medicine Inc.***6:30 End of Day****6:30-8:30 Dinner Short Course* *Separate registration required. See page 3 for details. (SC3) FUTURE OF POINT-OF-CARE PLATFORMS**

- How are Dx POCT markets changing?
- Which platforms will win? What's going to happen to the big box diagnostic companies?
- Hospital, MD offices, or home?
- What are the bottlenecks as markets change?
- Where will the new markets be and how will they be organized?
- What strategies make sense for Dx and POCT companies?

Instructors:

Keith F. Batchelder, Chief Executive Officer, Genomic Healthcare Strategies
Peter S. Miller, Chief Operating Officer, Genomic Healthcare Strategies

7:00 am Registration**7:30-8:15 am Breakfast Presentation (Sponsorship Available)**

SUCCESSFUL PARTNERSHIPS IN PERSONALIZED MEDICINE

8:25 am Chairperson's Remarks*Brian T. Edmonds, Ph.D., Research Advisor, Global External Research & Development, Lilly Corporate Center***8:30 Tailored Therapeutics at Eli Lilly: Our Strategy for the Co-Development of Diagnostics with Therapeutics***Brian T. Edmonds, Ph.D., Research Advisor, Global External Research & Development, Lilly Corporate Center*

One approach to improving the clinical outcome for individual patients is to marry the predictive power of certain diagnostic tests with a specific treatment regimen. This is not a novel concept to clinical practice, but with the advent of powerful molecular biology tools, new vistas and associated challenges are appearing. This presentation will outline Eli Lilly's approach to coordinating the disparate development work streams of diagnostics and therapeutics with emphasis on choosing partners, how those relationships are managed, and the implications on therapeutic product sales and support.

9:00 Choosing a Companion Diagnostic Partner*Cynthia Gawron-Burke, Ph.D., External Scientific Affairs, Merck Research Laboratories, Merck, Sharp & Dohme Corp.*

The development and commercialization of companion diagnostics is highly dependent upon successful partnerships between biopharmaceutical and diagnostic companies. Pharmaceutical company considerations in choosing a diagnostic partner will be discussed. Contractual considerations, as well as best practices to ensure successful partnerships will also be addressed.

9:30 A CDx Case Study in NSCLC

Hakan Sakul, Ph.D., Senior Director, Translational Oncology, Oncology Business Unit, Pfizer
Companion diagnostics play an integral role in the pursuit of personalized medicine. Most pharmaceutical companies rely on collaborations with diagnostics companies for the development and commercialization of companion diagnostics assays. While the pharma and the Dx companies traditionally have different paths to markets, each party has to rely on the success of the other to reach the finish line together in the co-development of Rx and Dx. This presentation will focus on one such collaboration for the development of a companion diagnostic assay for NSCLC.

10:00 Networking Coffee Break, Exhibit & Poster Viewing**10:45 The Drivers and Financial Benchmarks of Personalized Medicine***Peter Keeling, Chief Executive Officer, Diaceutics*

A personalized or targeted therapy is not the same as a one-size-fits-all therapy, often requiring different drivers and financial metrics to ensure successful launch and adoption. This presentation will address the drivers necessary to ensure the successful launch of a personalized or targeted therapy and how to optimize resources behind those drivers. We will begin by looking at a suggested model of drivers necessary to ensure optimal net present value of a personalized medicine is achieved. This discussion will lay the foundation for consideration of resource requirements necessary to power those drivers to guarantee achievement of the targeted therapies goals for return on investment without loss of resource.

11:15 RNAScope™, a Novel RNA *In Situ***Hybridization Platform for Companion Diagnostics***Yuling Luo, Ph.D., Founder, President & CEO, Advanced Cell Diagnostics, Inc.*

Companion diagnostics exploiting molecular biomarkers is a critical component of personalized medicine. In oncology, most companion diagnostic tests are based on *in situ* detection of protein or DNA biomarkers using IHC or FISH, respectively. However, *in situ* detection of RNA has not been recognized as a viable diagnostic platform due to low sensitivity and specificity of current methodologies. As a result, RNA biomarkers are currently analyzed by RT-PCR at the expense of destroying the tissue context, which is often highly heterogeneous in clinical specimens. ACD has developed RNAScope™, the first RNA *in situ* hybridization platform with single molecule detection sensitivity, enabling rapid development of RNA-based companion diagnostics.

11:30 Sponsored Presentations (Opportunities Available)**12:30-1:00 Luncheon Presentations (Sponsorship Available) or Lunch on Your Own**

MODELS FOR COMPANION DIAGNOSTICS

2:15 Chairperson's Remarks*Charlie Raffin, CJR Advisors, LLC (formerly Vice President, Commercial Assessment, J&J)***2:20 KEYNOTE PRESENTATION****HLA Markers Predict Adverse Reactions from Drugs?**

Munir Pirmohamed, MB, ChB (Hons), Ph.D., FRCP, FRCPE, Professor, The Wolfson Centre for Personalised Medicine, Department of Pharmacology, University of Liverpool
The major histocompatibility complex (MHC), which includes the HLA class I and II alleles, is the most polymorphic region of the human genome. The variability in the HLA alleles, while protecting individuals against certain infectious disease, can paradoxically predispose other individuals to serious, immune-mediated adverse drug reactions. The availability of high resolution genotyping techniques, together with the use of whole genome approaches, has led to the identification of striking associations between certain HLA alleles and drugs such as abacavir, carbamazepine, allopurinol, flucloxacillin and lumiracoxib, some of which have led to drug label changes, and are being used in clinical practice.

2:50 Lumiracoxib - Seeking a New Path Forward Through Use of a Companion Diagnostic*Charles Paulding, Ph.D., Senior Group Head, Pharmacogenetic Analysis, Biomarker Development Novartis Institutes for BioMedical Research*

Lumiracoxib, a selective COX-2 inhibitor, was approved and sold in several countries worldwide but was withdrawn from most markets after reports of treatment-associated severe hepatic adverse events. Recently, a predictive genetic biomarker, the DQA1*0102 allele in the MHC Class II region, has been discovered which can identify patients potentially at risk for lumiracoxib-associated hepatotoxicity. Novartis is currently in discussions with several health authorities around the world about a new path forward for lumiracoxib. In December 2009, a new marketing authorization application was submitted to the European Medicines Agency seeking reintroduction of lumiracoxib in the European Union. In this scenario, patients carrying the risk allele would be excluded from treatment with lumiracoxib. Using pharmacogenetic data for the reintroduction of a drug withdrawn from the market for safety reasons has never been achieved previously and, if successful, may represent an important milestone in personalized medicine.

3:20 How to Optimize Drug-Companion Diagnostics Co-Development between the Pharma- and Diagnostic Industries?*Henrik Winther, Ph.D., Research & Development Director, ImmunoHistology and IHC PharmDx, Dako Denmark A/S*

The development of oncology companion diagnostics needs to take place in close collaboration with the specific drug development, and the successful outcome of this collaboration has demonstrated increased efficacy rate of the drug and thereby increased safety of the patients. Delivering and commercializing an automated, work-flow adapted, reliable, robust, regulatory approved, reimbursable predictive assay at the right time requires that both the pharma- and diagnostic industries are fully committed to this kind of co-development.

4:00 Refreshment Break**4:30 Challenges of Co-Development of Therapeutics and Companion Diagnostics**

Andrea H. Lauber, Ph.D., Head, Technology Transactions for Clinical Biomarkers & Pharmacodiagnosics Strategic Transactions Group, Bristol-Myers Squibb
Successful partnerships between therapeutic and diagnostic partners can be challenging. We evaluate some workable ways forward.

5:00 The Joy of CDx: A Guide to K-RAS Pharma Partnering*Stephen Little, Ph.D., Vice President, Personalized Healthcare, QIAGEN (Formerly CEO, DxS Ltd.)*

When it comes to the co-development of companion diagnostics with Pharma partners, QIAGEN (formerly DxS Ltd) have always been leaders in the field. With their RT-PCR Mutation Test Kit for the K-RAS oncogene they produced the first companion diagnostic of its kind for Amgen's Vectibix® and later BMS/Imclone System's Erbitux® - setting the standard for the industry. This presentation outlines the process from inception through to regulatory approval and launch of a companion diagnostic.

5:30 Companion Diagnostics for EP4 Agonist IBD Therapy*Christoph Borchers, Ph.D., Associate Professor and Director, Biochemistry and Microbiology, University of Victoria, UVic Genome BC Proteomics Centre*

Inflammatory Bowel Disease (IBD) is a chronic relapsing inflammatory disorder of the gastrointestinal tract characterized by periods of remission and exacerbation of inflammatory disease that can severely impair a patient's quality of life. We are developing an EP4 agonist to maintain and restore the epithelial barrier, with the potential to alter the course of IBD by reducing permeability, antigen presentation and inflammatory flare-ups, thereby maintaining patients in remission for longer terms. The clinical development of IBD therapeutics is however, challenged by the natural waxing and waning of the disease to create large placebo effects that mask clinical outcome. We are therefore identifying reliable clinical protein biomarkers in parallel to the compounds development that would enable more effective assessment of disease activity and response to treatment in clinical trials and potentially enable the design of individualized treatment strategies in the future. The development of the IBD protein biomarker panel and assay is being performed by means of modern mass spectrometric techniques in particular LC-MS/MS using the Multi-reaction monitoring approach for targeted and absolute quantitation of multiplex proteins in a highly reproducible and fast manner.

6:00 Close of Conference



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☐ (SC1) Roadmap for Accelerating Commercialization
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Life Sciences: Technologies and Applications

Wednesday, August 25

☐ (SC3) Future of Point-of-Care Platforms

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