Final Agenda

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Cambridge Healthtech Institute's Premiere

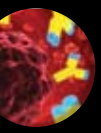
Next Generation Dx Summit

Moving Assays to the Clinic

Development, Commercialization, Clinical Adoption of Novel Assays

August 10-12, 2009 • The Ritz-Carlton • Washington, DC

Enabling Point-of-Care Diagnostics



Trends in Cancer Diagnostics

Molecular Diagnostics for Infectious Disease

Clinical Adoption of Next Generation Diagnostics

PLENARY KEYNOTE SESSIONS

ENSURING THE SAFETY AND VALIDITY OF MOLECULAR DIAGNOSTIC TESTS

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

BRINGING POINT-OF-CARE HIV DIAGNOSTICS TO MARKET: FDA PERSPECTIVES

Elliot Cowan, Ph.D., Chief, Product Review Branch, Division of Emerging and Transfusion Transmitted Diseases, FDA/CBER/OBRR

PRE-CONFERENCE SYMPOSIA

(SC1) CIRCULATING TUMOR CELLS AS SURROGATE ENDPOINTS IN CLINICAL TRIALS

(SC2) REALITY CHECK ON COMPANION DIAGNOSTICS

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Next Generation Dx Summit

EVENT-at-a-GLANCE

	Sunday, August 9	Monday, August 10	Tuesday, August 11	Wednesday, August 12
AM		Enabling Point-of-Care Diagnostics	Enabling Point-of-Care Diagnostics	Clinical Adoption of Next Generation Diagnostics
			Plenary Keynote Session	
PM	Pre-Conference Symposium 1: Circulating Tumor Cells as Surrogate Endpoints in Clinical Trials	Enabling Point-of-Care Diagnostics	Clinical Adoption of Next Generation Diagnostics	Clinical Adoption of Next Generation Diagnostics
AM		Trends in Cancer Diagnostics	Trends in Cancer Diagnostics	Molecular Diagnostics for Infectious Disease
			Plenary Keynote Session	
PM	Pre-Conference Symposium 2: Reality Check on Companion Diagnostics	Trends in Cancer Diagnostics	Molecular Diagnostics for Infectious Disease	Molecular Diagnostics for Infectious Disease

PRE-CONFERENCE SYMPOSIA • Sunday, August 9 • 2:00-5:00pm

(SC1) CIRCULATING TUMOR CELLS AS SURROGATE ENDPOINTS IN CLINICAL TRIALS

CTCs

To be Announced

Circulating Tumor Cells as Biomarkers in Castration-Resistant Prostate Cancer

Howard I. Scher, M.D., D. Wayne Calloway Chair in Urologic Oncology, Chief, Genitourinary Oncology Service, Department of Medicine, Sidney Kimmel Center for Prostate and Urologic Cancers, Memorial Sloan-Kettering Cancer Center

Role of Circulating Tumor Cells in Epithelial Mesenchymal Transition and Disseminated Disease

James M. Reuben, Ph.D., Associate Professor, Hematopathology, M.D. Anderson Cancer Center

Micrometastases and Cancer Stem Cells: on Lethal Seeds and Supportive Soil

Marija Balić, Ph.D., Division of Oncology, Department of Internal Medicine, Medical University of Graz

(SC2) REALITY CHECK ON COMPANION DIAGNOSTICS

Richard Bender, M.D., FACP, Chief Medical Officer, Agendia, Inc.

Felix Frueh, Ph.D., Vice President, Personalized Medicine, Medco Health Solutions Inc

M.J. Finley Austin, Director, US External Science Policy, F Hoffmann La Roche Inc

- Landscape of the companion diagnostic space today
- Types of companion diagnostics tests
- Clinical areas for companion diagnostic tests
- Potential new companion diagnostic tests that will impact the market
- Three fundamental steps in companion diagnostics
- Impact on healthcare improvement and healthcare cost reduction
- Where is the revenue coming from?
- Who are the key players?
- Where are the gaps?

Third Annual

Enabling Point-of-Care Diagnostics

Challenging the Limits

August 10-11 • The Ritz-Carlton • Washington, DC

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

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Hakan Sakul, Ph.D., Senior Director and Global Head, Diagnostics, Molecular Medicine Group, Pfizer Global R&D

SUNDAY, AUGUST 9

4:00-5:00pm Early Registration

MONDAY, AUGUST 10

7:30-8:30am Registration and Morning Coffee

CONNECTIVITY, DISEASE MANAGEMENT and e-HEALTH

8:30 Chairperson's Remarks
Thomas Li, Ph.D., Senior Director, Technology Management, Chief Technology Office, Roche Diagnostics, Pleasanton

8:40 Keynote Presentation
Enabling the New Point of Care: Care Beyond the Hospital
Mark N. Blatt, M.D., MBA, Director, Healthcare Industry Solutions, Digital Health Group, Intel Corporation

Hear about new clinical and business trends that are empowering clinicians in the developed world to provide care to citizens directly in their homes. These concepts are being applied in the developing world to better enable rural healthcare workers to care for citizens in remote village settings.

9:10 e-Health and Point of Care Technology - Opportunities for the World
Craig Lehmann, Ph.D., CC (NRCC), FACB, Interim Executive Dean, Health Sciences Center, Dean, School of Health Technology & Management, Professor, Clinical Laboratory Sciences, Health Sciences Center, Stony Brook University

In World Population Prospects (2004), the United Nations projected that in 2005, globally, the number of individuals 60 and older was 672 million and is expected to reach 1.9 billion by 2050. Of the 58 million deaths in developed and developing countries, approximately 35 million will be a direct result of heart disease, stroke, cancer, chronic respiratory diseases and diabetes. These chronic diseases are the number one killers of adults in the world and, in the next ten years, are expected to increase by 17 percent (WHO 2005). This presentation will discuss the use of e-health and POC technology in community health environments in the United States and Kenya.

9:40 Industry Perspective on Connectivity
Becky Clarke, Executive Vice President, Telcor

When utilizing POC testing as part of disease management, one must consider efficient and effective ways to a. transmit the data b. integrate the data and c. communicate the data to clinicians. Relying on manual methods, rather than automating these activities, exposes everyone to delays, omissions and errors, all of which can affect timely and proper treatment.

10:10 Networking Coffee Break, Exhibit and Poster Viewing

Expert Panel: BARRIERS TO NEXT GENERATION POINT-OF-CARE DIAGNOSTICS AND ROLE OF STANDARDS

11:00 *Moderator: Steven Buchsbaum, Ph.D., Senior Program Officer, Global Health Technologies, Bill & Melinda Gates Foundation*

- What do we know about the key product specifications for a POC diagnostic platform for both developed and developing world markets

Roger Peck, Research Scientist, PATH

- What are the key technical barriers to creating a high performance POC platform

Mickey S. Urdea, Ph.D., Chief Executive Officer and Chairman, Tethys Bioscience, Inc.

- What are the key business and IP barriers to creating a high performance POC platform and how might we address them

Andrew Leon, Associate General Counsel in Global Health, Bill & Melinda Gates Foundation

- POC Platforms for Global Health

Boris Nikolic, M.D., Senior Program Officer, Bill & Melinda Gates Foundation (invited)

12:00pm Development of a Next Generation Point-of-Care Immunoassay System
Herbert Schmidt, Ph.D., (former Roche Diagnostics), Consultant to Atonomics A/S, Copenhagen, Denmark

Sponsored by atonomics

Current PoC immunoassay systems widely used for cardiac markers are not meeting all requirements of health care professionals. Atonomics, a Danish venture capital company, has developed a new PoC immunoassay technology and system branded as Atolyzer® System offering excellent correlation with laboratory immunoassay systems and outstanding analytical performance such as high precision and analytical sensitivity below 1 pg / ml. Only 36 µl of a whole blood sample (finger prick or venous) is processed in a disposable assay cartridge without any intervention of the operator. A small reader controls the assay processing and displays the results. The turn-around-time of below 15 minutes enables the physician to make fast on-site decisions. Atonomics has completed the development of the Atolyzer® System and is up-scaling manufacturing to enable the launch of the system early 2010.

The session will focus on the following:

- Applied technologies and intellectual property of Atonomics
- Technical design of the PoC Immunoassay system
- Analytical performance of the BNP Atolyzer® System assay
- Customer benefits of the system

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

NEAR PATIENT DIAGNOSTICS

2:00 Chairperson's Remarks
Matthew Lorence, Ph.D., M.B.A., Vice President, Marketing and Sales, Tessarae, LLC

2:10 From the Laboratory Bench to a Point-of-Care Device – How the CUDA Platform will Enable Decentralized Molecular Diagnostic Testing
Richard Lee, Ph.D., Senior Manager, Development, Gen-Probe, Inc.

A next-generation, point-of-care Closed Unit-Dose Assay (CUDA) platform will be described. This platform uses actuator-driven fluidic movement to perform a complete sample-to-result molecular diagnostic assay in one hour. The platform harnesses Gen-Probe's magnetic bead–based target capture and isothermal real-time Transcription-Mediated Amplification (TMA) technologies. All reagents required to perform the assay are contained in stabilized form in a disposable pouch. The user introduces sample into the pouch through an easy-to-use entry port, places the pouch in the instrument, and initiates the assay in a single-touch operation. In this presentation, examples of real-time qualitative and quantitative assays for use on the CUDA platform will be given and the technical and non-technical challenges encountered during the development of the CUDA platform will be discussed.

2:40 Differentiation Makes The Difference: HX Diagnostics' fluID and panfluID Rapid POC Tests
Wendy Benson, President and Chief Executive Officer, HX Diagnostics, Inc.

HX Diagnostics is focused on rapid diagnostics for infectious diseases. The fluID™ rapid influenza test developed is the only rapid, point-of-care platform to differentiate H1N1 and H3N2 subtypes, offering advantages for rapid diagnosis and treatment. The panfluID™ rapid H5 test offers the same easy-to-use format with application in a wide variety of settings. Our technology allows for continued product development and expansion of the current platform to develop a pipeline of highly sensitive and specific rapid POC tests for respiratory and other emerging diseases.

3:10 Networking Refreshment Break, Exhibit and Poster Viewing

Expert Panel: VALUE OF PUBLIC-PRIVATE PARTNERSHIPS: Highlighting Open Platforms

4:10 *Moderator: Todd Merchak, Program Specialist, Division of Extramural Science Programs, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, DHHS*

- Hardware Platforms for Point-of-Care testing
- Informatics Standards for Connectivity and Data Integration
- Clinical Applications in Disease Monitoring and Management

Panelists:

Craig Lehmann, Ph.D.

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

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

5:00 **Networking Reception**

6:00 **Close of Day One**

TUESDAY, AUGUST 11

8:00am **Morning Coffee**

CASE STUDIES IN DISEASE MANAGEMENT

8:30 **Chairperson's Remarks**

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

8:40 **The Value of POC Testing in the Hospital Environment**

Joseph M. Campos, Ph.D., D(ABMM), F(AAM), Director, Microbiology Laboratory, Molecular Diagnostics Laboratory, and Laboratory Informatics, Children's National Medical Center; Professor, Departments of Pediatrics, Pathology, and Microbiology/Immunology/Tropical Medicine, George Washington University Medical Center

Point-of-care testing in the patient care environment offers important advantages over testing conducted in the laboratory. In this presentation I will present cases that illustrate three of these advantages: (1) instant availability of a critical laboratory value, (2) ability to obtain laboratory values from testing very small samples, and (3) enhanced customer satisfaction following immediate intervention triggered by an unexpected test result. In the final analysis, POC testing should be performed not because it is possible to do so, but because it enables provision of a higher quality of care.

9:10 **The Need for Point-of-Care Diagnostics for Vaccine Clinical Trials**

Marco L. Schito, Ph.D., Senior Laboratory Program Manager, HJF-VRP Team Leader, Vaccine Clinical Research Branch, Division of AIDS, NIAID, NIH, DHHS

Antibody responses elicited by experimental HIV vaccines can be detected by commercial HIV antibody tests. This phenomenon, known as vaccine-induced seropositivity (VISP), poses several challenges for identifying true HIV infections especially in resource-limited settings and may result in unintentional unblinding of participants in clinical vaccine studies. Implementation of point-of-care molecular diagnostics would enable the identification of HIV infected individuals irrespective of their vaccination status. Contract No. HHSN272200800014C

9:40 **Computer Assisted Point-of-Care HIV Testing in Clinic and Community Settings**

Freya Spielberg, M.D., MPH, Senior Health Scientist, RTI International

New systems are required for acceptable and cost-effective dissemination of point-of-care testing technologies. We have developed a patient-centered interactive computer tool to provide information on point-of-care testing, health assessment, and testing, treatment and referral recommendations. This tool will facilitate point-of-care testing in clinic and outreach settings, as it requires minimal staff time, while providing the patient all that they need to know to decide to get a test and to pursue appropriate health care. This presentation will discuss research findings from computer assisted point-of-care testing experiences in the US, and will discuss plans for a pilot of a computer-assisted Health Worker Entrepreneur program to disseminate new point-of-care tests in India.

10:10 **Networking Coffee Break, Exhibit and Poster Viewing**

NEXT GENERATION PRODUCTS: New Companies, New Technologies

Commentators: Penny Wilson, Ph.D., Lead Specialist – Detection and Identification of Infectious Agents, Technology Strategy Board and Katherine Tynan, Ph.D., Business Development & Strategic Consulting for Diagnostics Companies, Tynan Consulting LLC

10:40 **MRI on a Chip: A Next Generation Point-of-Care Diagnostic Platform**

Thomas Lowery, Ph.D., Director of Research, Assay Development, T2 Biosystems

T2 Biosystems is pioneering advances in nanotechnology and magnetic resonance to create next generation diagnostics tools. Through the miniaturization of magnetic resonance technology and the unique principles of nanoscale particles, T2 has developed a compact, universal detection platform that has demonstrated sensitive measurements of DNA, proteins and many other target analytes. Because of the magnetic-based detection system, the usual interference in optical assays is obviated. This unique combination of technologies allows for a multiplex and multi-analyte (DNA and protein) system to rapidly quantify biomarkers on dirty samples.

11:00 **Magnotech™ Biosensor Technology For Rapid and Highly Sensitive Point-of-Care Testing**

Dion Klunder, Ph.D., Senior Scientist, Philips

Philips has developed a novel magnetic biosensor technology that enables high-quality point-of-care testing within minutes. Magnotech (TM) technology is based on controlled actuation of magnetic particles in a stationary fluid sample and optical imaging with real-time readout, enabling fast single-step assays and integration into a miniaturized system. The combination of speed, ease-of-use, multiplexing capability, and high analytical sensitivity of our technology makes it well suited for demanding point-of-care medical diagnostics applications that require a short turnaround time, high performance and reliability. In this presentation, we will describe the integrated biosensor technology, present the latest advances in the device as well as the assay technology, including picomolar results in a few minutes, and discuss future directions.

11:20 **Seamless Sample to Answer: The Needed Paradigm Change for Enabling POC Diagnostics**

Michael J. Heller, Ph.D., Professor, Nanoengineering and Bioengineering, University of California San Diego

For most clinical diagnostic applications, it remains a significant challenge to isolate and identify rare cells, bacteria, virus and many important disease related biomarkers from un-processed whole blood. The fact that complex sample processing must be carried out on most clinical samples has been a major impediment for the development of viable point-of-care diagnostic (POC) systems. We have now developed a new generation of electrokinetic devices which are able to interrogate a whole blood sample for specific analytes (virus, DNA/RNA, antibody complexes, etc.), and then rapidly isolate and detect the analytes. These devices essentially make "sample preparation" a relatively seamless or transparent process, where complex clinical and other biological samples like blood, plasma, saliva or urine can now be rapidly and directly analyzed for disease biomarkers.

11:40 **Low-Cost System for Multiple Pathogen, Point-of-Care Infectious Disease Diagnosis**

Michael Lochhead, Ph.D., Vice President, mBio Diagnostics, Precision Photonics Corporation

Cost-effective point-of-care diagnostics remain a critical need for infectious disease management, particularly in resource-limited settings. There currently exists a significant gap between the low-cost, single analyte rapid tests on the market and the multiplexed systems found in clinical laboratories. To address this, mBio Diagnostics has developed a robust, low-cost fluidic cartridge and fluorescence imaging system for point-of-care, multiplexed protein, nucleic acid, and cellular assays. The system capitalizes on advances in volume-manufactured consumer electronic components and microarray technology. Clinical sample data will be presented demonstrating a multiplexed HIV/HCV serology system, as well as influenza subtyping using nucleic acid probes.

PLENARY KEYNOTE SESSION

GAINING REGULATORY APPROVAL FOR MOLECULAR DIAGNOSTIC TESTS

12:00pm **Keynote Introduction and Opening Remarks**

Thomas R. Soriano, President & Chief Executive Officer, DOCRO, Inc.

12:10 **Ensuring the Safety and Validity of Molecular Diagnostic Tests**

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

12:35 **Q&A**

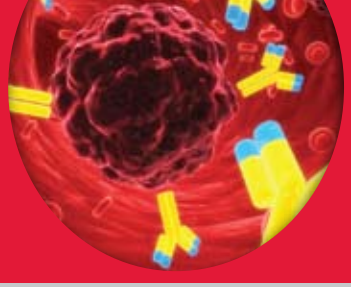
12:45 **Bringing Point-of-Care HIV Diagnostics to Market: FDA Perspectives**

Elliot Cowan, Ph.D., Chief, Product Review Branch, Division of Emerging and Transfusion Transmitted Diseases, FDA/CBER/OBRR

Point-of-care diagnostics for human immunodeficiency virus are playing an important role in helping individuals know their HIV status. FDA is responsible for assuring that these products are safe and effective. This talk will address FDA's expectations for the approval of rapid HIV tests, pitfalls in the process, and challenges posed by home use HIV test kits.

1:10 **Q&A**

1:20 **Close of Enabling Point-of-Care Diagnostics Conference**



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Carlos Cordon-Cardo, M.D., Ph.D., Director, Molecular Pathology Center, Memorial Sloan Kettering Cancer Center, Columbia University Center

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Myla Lai-Goldman, M.D., Managing Partner, Personalized Science, LLC

Jorge A. León, Ph.D., President, Leomics Consulting

Franklyn G. Prendergast, M.D., Ph.D., Professor, Pharmacology, Biochemistry & Molecular Biology, Director of Center for Personalized Medicine, Mayo Clinic

Pre-Conference Symposia

SUNDAY, AUGUST 9

2:00-5:00pm (SC1) CIRCULATING TUMOR CELLS AS SURROGATE ENDPOINTS IN CLINICAL TRIALS

2:00 To Be Announced

2:30 Circulating Tumor Cells as Biomarkers in Castration-Resistant Prostate Cancer

Howard I. Scher, M.D., D. Wayne Calloway Chair in Urologic Oncology, Chief, Genitourinary Oncology Service, Department of Medicine, Sidney Kimmel Center for Prostate and Urologic Cancers, Memorial Sloan-Kettering Cancer Center

Recent trials using an FDA-cleared assay show that CTC number is a biomarker of prognosis and more predictive than posttherapy changes in PSA, raising the possibility that posttherapy changes in CTCs might represent an intermediate endpoint of treatment effi cacy. The question of whether CTC counts are potential surrogates for survival is currently being addressed in the context of a phase 3 registration trial. Also under study are biologic profi ling of these tumors to explore the relationship between specifi c alterations in androgen receptor signaling and the response to novel agents targeting thesealterations.

3:00 Role of Circulating Tumor Cells in Epithelial Mesenchymal Transition and Disseminated Disease

James M. Reuben, Ph.D., Associate Professor, Hematopathology, M.D. Anderson Cancer Center

The presence of circulating tumor cells (CTCs) in peripheral blood of patients with advanced breast cancer has prognostic value and predicts treatment better than radiological imaging and functional PET/CT. Current methods for detecting CTCs are based on the detection of non-leukocytes (CD45-) cells that express EpCAM; however, these methods are incapable of detecting CTCs that lose expression of EpCAM and undergo epithelial-mesenchymal transition (EMT) prior to entering the circulation. EMT is an embryonic program which has been implicated in breast cancer cell dissemination and endowing cancer cells with stem-like properties. Thus, CTC undergoing EMT may escape detection by conventional detection methods and that EMT genes may be involved in their dissemination in a fraction of patients with early or advanced breast cancer.

3:30 Networking Refreshment Break

4:00 Micrometastases and Cancer Stem Cells: on Lethal Seeds and Supportive Soil

Marija Balić, Ph.D., Division of Oncology, Department of Internal Medicine, Medical University of Graz

This talk will address the correlation of micrometastases and cancer stem cells and development of needed novel protocols for detection and characterization of DTC/CTC. The first clinical evidence on association of disseminated tumor cells with the putative breast cancer stem cell phenotype was published in Clin Can Res Okt 2006. Based on this data, novel protocols have been evaluated and established to enhance the sensitivity for DTC detection and enable the characterization of these cells according to the phenotype. In addition, the talk will provide the review of the current and important literature on interaction of DTC/CTC with the host (incl. bone and immune system).

4:30 Q&A with Speakers

5:00 Close of Symposium

2:00-5:00pm (SC2) REALITY CHECK ON COMPANION DIAGNOSTICS

Course Instructors:

Richard Bender, M.D., FACP, Chief Medical Officer, Agendia, Inc.

Felix Frueh, Ph.D., Vice President, Personalized Medicine, Medco Health Solutions, Inc.

M.J. Finley Austin, Director, US External Science Policy, F Hoffmann La Roche Inc

Topics to be covered:

- Landscape of the companion diagnostic space today
- Clinical areas for companion diagnostic tests
- New companion diagnostic tests that will impact the market
- Impact on healthcare improvement and healthcare cost reduction
- Who are the key players?
- Where are the gaps?

MONDAY, AUGUST 10

7:30-8:30am Registration and Morning Coffee

SEQUENCE DATA FOR GENE EXPRESSION PANELS

8:30 Chairperson's Opening Remarks

Jorge A. León, Ph.D., President, Leomics Consulting

8:40 Sequencing the Cancer Genome

Richard K. Wilson, Ph.D., Professor and Director, Genetics, Genome Sequencing Center, Washington University

New technology recently has facilitated the complete sequencing of individual human genomes. As the cost and efficiency of this approach continues to improve, we can envision a powerful new means for the study of genes and other genome elements and mechanisms that underlie cancer and other human diseases. I will discuss some of the discoveries made to date with emerging genome sequencing technologies, and how these methods will allow us to better understand both basic biology and human disease.

9:10 Cancer Biomarkers to Predict Therapeutic Response

Cynthia Gawron-Burke, Ph.D., Director, Scientific Liaison, External Scientific Affairs, Merck & Co., Inc. (invited)

The discovery of pharmacodynamic and patient stratification biomarkers will continue to have a profound effect on the research and development of targeted cancer therapeutics. Novel gene expression signatures that can be used to monitor tumorigenic pathway activity in human tumors have recently been reported. The value of collaborative partnerships in realizing the potential of gene expression signature biomarkers for clinical use will be discussed.

9:40 Personalized Oncology Research: Applying Discovery Technologies in the Clinic Today

Raphael Lehrer, Ph.D., Head, Personalized Oncology Services, CollabRx, Inc.

We will describe an innovative personalized cancer research service that uses an unbiased analysis of whole-genome data to generate actionable therapeutic strategies to target the mechanisms driving an individual's tumor. The service is built on an open platform that can incorporate new technologies and approaches, which we are exploiting to augment our current expression and SNP/CNV methods with full-genome tumor sequencing. Beyond delivery of care to late-stage patients, this approach has important implications to discovery of novel diagnostics and therapeutic combinations.

10:10 Networking Coffee Break, Exhibit and Poster Viewing

PROGNOSTIC MARKERS

10:50 Chairperson's Remarks

Arshad Ahmed, Partner & Co Founder, Scientia Advisors LLC

11:00 Prostate Cancer Microenviroment Biomarkers for Diagnosis and Prognosis

Daniel E. Mercola, M.D., Ph.D., Professor, Pathology and Laboratory Medicine; Director, Translational Cancer Biology, University of California, Irvine

We have previously developed methods for the extraction of cell-type specific gene expression values for the principal cell types occurring in tissue samples used for gene expression analysis, i.e., tumor epithelial cells, stroma cells, and the epithelial cells of BPH and dilated cystic glands. The method uses a linear combination model to express the observed microarray gene intensity as a sum of the individual cell contributions and, when combined with an estimate of percent cell composition, may be solved for gene expression of each gene of the array and for the four cell types. The method has been extended to define differential expression of cell-specific values for tumor compared to not tumor tissue and relapsed compared to nonrelpased tumors. The results indicate that tumor-adjacent stroma exhibits dozens of significant differential gene expression changes that are potentially useful in diagnosis of prostate cancer and assignment of risk of relapse based solely on measurements of the tumor microenvironment. A multiplex PCR-based assay is being developed for general application to FFPE samples.

11:30 The Use of Genome-Wide Profiling of Genetic Alterations to Identify New Prognostic Markers and Therapeutic Targets in Acute Lymphoblastic Leukemia

Charles Mullighan, MBBS(Hons), MSc, M.D., Assistant Member, Pathology, St. Jude Children's Research Hospital

A substantial proportion of patients with acute lymphoblastic leukemia (ALL) experience treatment failure and relapse, which carries a poor prognosis. New tools to identify patients at high risk of relapse are needed, as well as novel targets for therapeutic intervention to improve outcome in high risk ALL. Recent studies have performed high resolution, genome-wide profiling of genetic alterations in ALL, and have identified multiple novel recurring genetic alterations that target key cellular pathways including lymphoid development, apoptosis, tumor suppressors and cell cycle regulation. Transcription factors regulating B lymphoid development are altered

in over 60% of B-progenitor cases, and alteration of the IKZF1 gene, which encodes the early lymphoid transcription factor IKAROS, is associated with very poor outcome in ALL. Moreover, cases harboring IKZF1 alterations have a gene expression profile similar to BCR-ABL1 ALL, a subtype of ALL that also has IKZF1 alteration and poor outcome. Ongoing work has shown that poor outcome, IKZF1-altered (but BCR-ABL1 negative) cases harbor novel mutations in tyrosine kinases that are potentially "druggable". These results demonstrate the power of integrated, cross-platform genomic analyses to identify novel progostic markers and therapeutic targets in ALL.

12:00pm **Panel Discussion: The Road To Commercialization – Navigating The Critical Issue At the Convergence of Molecular Dx & Oncology** *Sponsored by* TSG

Panel Moderator:
Panna Sharma, CEO & Managing Partner, TSG

Panelists:
R.S.K. Chaganti, Ph.D., Founder & Chairman, Cancer Genetics, Inc.
John C. Schafer, CEO, Diagnocure

12:30 **Luncheon Presentation** *Sponsored by* nextgen sciences
New Method Provides the Solution for the Bottleneck in Protein Assay Development
Michael Pisano, Ph.D., President and CEO, NextGen Sciences

A new method used to develop protein assays, called peptide MRM, is rapidly being recognized as a solution to the current bottlenecks in protein biomarker development. This new method does not use antibodies for quantitation of proteins and high specificity is determined prior to assay development. Assay development time range from a week to several months (not years) and can cost less than $2K per protein

2:00 **Chairperson's Remarks**

2:10 **Novel Biomarkers Located at 3p22.1 And 10q22.3 Offer a Non-Invasive Diagnosis of Lung Cancer in Induced Sputum Samples by Combination of Cytology and Fluorescence in Situ Hybridization (FISH)**
Michal Daniely, Ph.D, Director for Research & Test Development, Biology, BioView Ltd.

Lung cancer results from a series of genetic and epigenetic alterations. Recently, two biomarkers located at 3p22.1 and 10q22.3, were found to be altered in early stage lung cancer. The study was aimed to evaluate a new assay combining FISH and cytology for detection of lung cancer by induced sputum (IS). We blindly tested 83 IS samples from advanced and early stage lung cancer patients and from healthy smokers and non-smoking controls (19, 18, 36 and 10 samples, respectively). 36/37 lung cancer patients (97.37% sensitivity) were detected, with a specificity of 82.22%. In colnclusion, combined analysis of cytology and FISH in IS samples can be used as a non-invasive diagnostic test for early detection of lung cancer.

2:40 **Analysis of AFP-L3 in Hepatocellular Carcinoma Patients**
Akihiro Kondo, Ph.D., Professor, Graduate School of Medicine, Osaka University

Alpha-fetoprotein (AFP) is an oncofetal glycoprotein that contains a single glycosylation site at the level of asparagine 232, and is a well-known tumor marker for hepatocellular carcinomas (HCC). Recently, the Lens culinaris agglutinin (LCA)-reactive fraction of AFP (AFP-L3) has been measured as a more specific marker for HCC. AFP-L3 reflects HCC-specific changes in the glycans of AFP. The N-glycan structures of the AFP-L3, a tumor marker of HCC, were analyzed in relationship to glycosyltransferases and LCA-affinity electrophoresis, using HPLC and MALDI-TOF MS.

3:10 **Networking Refreshment Break, Exhibit and Poster Viewing**

4:00 **Break-out Sessions: Collaborating to Bring Novel Diagnostics to Market**

5:00 **Networking Reception**

6:00 **Close of Day One**

TUESDAY, AUGUST 11

8:00am **Morning Coffee**

TRANSLATION OF COMPANION DIAGNOSTICS INTO CLINICAL PRACTICE: Moving Beyond Her2 Neu

8:30am **Chairperson's Remarks**
Myla Lai-Goldman, M.D., Managing Partner, Personalized Science, LLC"

- What has been done to make the biomarker successful?
- Implementation
- Science

8:40 **The Payer Industry View of Personalized Medicine**
Bruce Quinn, M.D., Ph.D., Senior Health Policy Specialist, Foley Hoag

The more innovative a product is, the more challenges it may face with the current coding & reimbursement systems used by insurers. Understanding how decisions are made in the current system is critical for successful commercialization. Key differences between decision making at the FDA and at Medicare and private payers will be presented.

9:10 **How Payers Utilize Cancer Diagnostics for Cancer**
Lee N. Newcomer, M.D., Senior Vice President, Oncology, UnitedHealthcare

Examples from UnitedHealthcare's programs using HER2, KRAS and prognostic assays for breast cancer will be reviewed. The guiding principles for coverage and use of diagnostics will be discussed.

9:40 **Gene Methylation and Cancer**
Steven M. Anderson, Chief Scientific Officer and Vice President, LabCorp

Gene methylation is an important epigenetic regulatory mechanism in cancers, playing a significant role in cancer initiation and progression. In addition, methylation of some genes, such as DNA repair genes (i.e., MGMT), may impact response to specific cancer therapies. In this presentation the importance of gene methylation in cancer will be discussed using the MGMT as a model.

10:10 **Networking Coffee Break, Poster & Exhibit Viewing**

THERANOSTIC DEVELOPMENTS

11:00 **EGFR and Beyond: Evolution of a Molecular Classification and Treatment Strategy for Lung Cancer**
Neal Lindeman, M.D., Assistant Professor, Pathology, Harvard Medical School; Associate Pathologist, Pathology, Brigham and Women's Hospital

The discovery of somatic mutations in the EGFR gene that predispose lung cancers with these mutations to successful treatment with targeted anti-EGFR therapy has had a profound impact on the diagnosis and treatment of lung cancer, which is the most lethal cancer in the United States, by a wide margin. The success of anti-EGFR therapy in EGFR-mutant lung cancer has ushered in a wave of discovery of other genetic alterations in lung cancer, which are mutually exclusive with EGFR mutations, and which form the basis for a new way to classify lung cancer - by genetic alteration, rather than by microscopic analysis alone. Because the molecular alterations that define the new categories of lung cancer can simultaneously be both diagnostic markers and therapeutic targets, this molecular classification strategy affords the potential for more specific and more effective treatments. This is not exclusive to lung cancer, and similar molecular alterations are being actively studied in other cancer systems as well.

11:30 **To be Announced**

PLENARY KEYNOTE SESSION

GAINING REGULATORY APPROVAL FOR MOLECULAR DIAGNOSTIC TESTS

12:00pm **Keynote Introduction and Opening Remarks**
Thomas R. Soriano, President & Chief Executive Officer, DOCRO, Inc.

12:10 **Ensuring the Safety and Validity of Molecular Diagnostic Tests**
Alberto Gutierrez, Ph.D., Deputy Director, OIVD, Office of in Vitro Diagnostic Device Evaluation and Safety, Food & Drug Administration

12:45 **Bringing Point-of-Care HIV Diagnostics to Market: FDA Perspectives**
Elliot Cowan, Ph.D., Chief, Product Review Branch, Division of Emerging and Transfusion Transmitted Diseases, FDA/CBER/OBRR

Point-of-care diagnostics for human immunodeficiency virus are playing an important role in helping individuals know their HIV status. FDA is responsible for assuring that these products are safe and effective. This talk will address FDA's expectations for the approval of rapid HIV tests, pitfalls in the process, and challenges posed by home use HIV test kits.

1:20 **Close of Trends in Cancer Diagnostics Conference**

Inaugural

Molecular Diagnostics for Infectious Disease

Advancing the Development and Approval of Practical Tests with Clinical Utility

August 11-12 • The Ritz-Carlton • Washington, DC

Scientific Advisory Board

Penny Wilson, Ph.D., Lead Specialist, Detection and Identification of Infectious Agents, Technology Strategy Board

Christine C. Ginocchio, Ph.D., Director, Microbiology, Virology and Molecular Diagnostics, North Shore-LIJ Health System Laboratories

Daniel R. McClernon, McClernon, LLC

TUESDAY, AUGUST 11

11:00am-12:00pm Registration

PLENARY KEYNOTE SESSION

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12:35 Q&A

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1:10 Q&A

1:20 Luncheon Presentation *(Opportunity Available)* **or Lunch on your Own**

POINT-OF-CARE MOLECULAR TESTS FOR DETECTION OF INFECTIOUS DISEASE

2:30 Chairperson's Remarks
Penny Wilson, Ph.D., Lead Specialist, Detection and Identification of Infectious Agents, Technology Strategy Board

2:40 Point-of-Care Diagnostics
Franklin R. Cockerill, III, M.D., Ann & Leo Markin Professor of Medicine and Microbiology, Consultant and Professor, Infectious Diseases and Internal Medicine, Mayo Clinic and Mayo Clinic College of Medicine; Chair, Laboratory Medicine and Pathology; President and Chief Executive Officer, Mayo Collaborative Services, Inc. (MCSI)

3:10 Bringing Molecular Diagnostics toward Point-of-Care in Developing Countries
Mark D. Perkins, M.D., Chief Scientific Officer, Foundation for Innovative New Diagnostics

Infectious diseases still account for a huge burden of disease in developing countries. Despite the fact that molecular testing offers speed and sensitivity, NAAT has had very little impact on clinical care of infectious diseases developing countries. This is primarily because of issues relating to the cost and complexity of the test methods, and the frailty of health systems. This talk will examine a recent model of phased development and implementation of simplified NAAT methods that bring infectious disease diagnosis to the point of care in disease endemic countries.

QUANTITATIVE PCR & HIGHLY MULTIPLEXED ASSAYS

3:40 Multiplex Respiratory Virus Detection: Diagnosis, Infection Control, Epidemiology and Surveillance
Christine C. Ginocchio, Ph.D., M.T. (A.S.C.P, Director, Microbiology, Virology and Molecular Diagnostics, North Shore-LIJ Health System Laboratories, Lake Success, NY; Department of Microbiology and Genetics, School of Medicine, State University of New York at Stony Brook

Advances in the development of molecular-based pathogen detection systems have lead to the discovery of new respiratory viruses and have provided rapid, sensitive and accurate methods for viral diagnostics. The comprehensive identification of respiratory pathogens has allowed for a better understanding of the pathogenesis and clinical course of respiratory infections, differences and similarities in syndromes and the impact of co-infections. In addition, we now can study the true epidemiology of respiratory viral infections and can use this information to establish surveillance programs. This lecture will discuss the role of comprehensive respiratory virus detection for diagnosis, infection control, epidemiology, and bio-threat surveillance.

4:10 Networking Refreshment Break, Exhibit and Poster Viewing

4:45 The Critical Role of Controls and Calibrators in Molecular Infectious Disease Testing
David R. Hillyard, M.D., Professor, Pathology, University of Utah School of Medicine; Director, Molecular Infectious Disease Testing, ARUP Laboratories

5:15 Quantitative Assays for Diagnosis and Management of Infectious Diseases
Gregory A. Storch, M.D., Ruth L. Siteman Professor of Pediatrics, Professor of Medicine and of Molecular Microbiology, Director, Divisions of Pediatric Infectious Diseases and Laboratory Medicine, Department of Pediatrics, Washington University School of Medicine, Medical Director, Clinical Laboratories, St. Louis Children's Hospital

This presentation will discuss the role of quantitative molecular testing in diagnostic virology. The emphasis will be on CMV, EBV, and BK virus. For CMV, the talk will address the role of quantitative testing in determining need for therapy, monitoring therapy, and detection of resistance to antiviral drugs. EBV is the main cause of post-transplant lymphoproliferative disorder (PTLD). This talk will discuss the relationship between viral load and PTLD. BK virus is the cause of transplant nephropathy in renal transplant recipients and hemorrhagic cystitis in hematopoietic stem cell transplant recipients. The talk will focus on the relationship between viral load and these clinical entities.

5:45 Questions from the Floor

6:00 Close of Day

WEDNESDAY, AUGUST 12, 2009

8:00am Morning Coffee

8:25 Introduction – Clinical Applications of Novel Technologies
Daniel R. McClernon, McClernon, LLC

Molecular Diagnostics has given us twenty-first century tools that have transformed the industry of clinical laboratory medicine. Utilization of these novel technologies such as real-time quantitative PCR, high-throughput sequencing, point of care testing and bioinformatics bring together new growth possibilities for clinical applications. Development of novel molecular technologies in parallel with clinical evaluation can substantially increase successful implementation of technologies into the realm of clinical practice. Here we describe a modified HIV-1 viral load assay for monitoring low level HIV replication in cerebral spinal fluid among individuals with HIV associated neurocognitive disorders. Demonstrating the utility of an assay that could readily be made available to practicing clinicians could help guide management of patients and accelerate progress towards a clinically applicable patient management tool for HIV-associated neurocognitive disorders.

8:40 Clinically Useful Diagnostics for Infectious Diseases
Penny Wilson, Ph.D., Lead Specialist, Detection and Identification of Infectious Agents, Technology Strategy Board

The UK's Technology Strategy Board has created an Innovation Platform (IP) for the Detection and Identification of Infectious Agents. Innovation platforms are challenge led, as opposed to technology driven, initiatives established to address societal needs, create wealth and enhance quality of life. The challenge is to reduce the impact of human and animal infectious diseases by supporting the development and adoption of clinically useful diagnostics. The IP has developed an integrated plan to encourage and support consortia to deliver high quality appropriate tests to users. An overview of trends, technical capabilities, enablers and barriers will be presented.

Molecular Diagnostics for Infectious Disease

Advancing the Development and Approval of Practical Tests with Clinical Utility

Continued

9:10 **Emerging Diagnostic Showcases – Clinical Applications of Novel Technologies**

Showcase One:
Novel Automated Quantitative Multiplex Platform for Infectious Disease Detection *Sponsored by* PrimeraDx

Vladimir Slepnev, Ph.D., Chief Technology Officer, PrimeraDx

Cytomegalovirus, Epstein Barr virus, and BK virus are among the frequently diagnosed post-transplant viral infections. Infection with one or more of these viruses may play a significant role in organ rejection, graft dysfunction and other complications. PrimeraDx has created an automated platform, ICEPlex, which allows quantitative multiplexing of dozens of nucleic acid targets in a single reaction. Primera's first quantitative multiplex assay, ViraQuantTM, is designed to detect and quantify CMV, EBV, BK, HHV-6 and HHV-7 using plasma and whole blood. This user-friendly quantitative multiplex platform can be easily adapted in laboratories, and can be applied to broad range of infectious targets such as viruses, bacteria and fungi.

9:30 **Showcase Two:**

RAP for VAP: Real-time Array PCR, a Novel Hybrid Technology for Multiplex Pathogen and Antibiotic Resistance Testing *Sponsored by* eppendorf Biochip Systems

Christof Henne, Ph.D., Key Account Manager Diagnostics, Eppendorf Biochip Systems

Eppendorf has developed a novel hybrid technology combining major advantages of Real-time PCR (qPCR) and microarray technologies, namely the multiplexing capabilities and specificity of detection of microarrays with the speed, sensitivity, wide dynamic range, and potential for quantitative results characteristic of qPCR. Real-time Array PCR (RAP) introduces a unique combination of multiplexing, automation, and speed, overcoming limitations of qPCR in multiplexing and addressing unmet clinical needs in the emerging era of personalized medicine. First results of RAP in rapid detection of pathogens and antibiotic resistance associated with ventilator-associated pneumonia (VAP) will be presented.

9:50 **Showcase Three:**
SampleTanker® A Dried Specimen Transport, Storage & Recovery System *Sponsored by*

Robert M. Lloyd Jr., President/CEO, Research Think Tank, Inc.

SampleTanker®* Dry Specimen Transport Matrix is a device for the collection, storage and transportation of liquid biological suspensions. This device provides a cost effective method for specimen handling in a dry and stable fashion. SampleTanker is suitable for a variety of biological specimens including: whole blood, plasma, serum, urine, saliva, semen, bone marrow, cerebrospinal fluid and many more. Each dried unit is stable at room temperature for storage or transportation for a long as required. When the time comes for sample testing, the SampleTanker unit is simply reconstituted and eluate is ready for analysis. Uses of SampleTanker currently lie in nucleic acid diagnostic testing for infectious diseases.

10:10 **Networking Coffee Break**

MICROBE HUNTING – SEQUENCING, GENOTYPING & BEYOND

10:40 **Chairperson's Remarks**

Mark D. Perkins, M.D., Chief Scientific Officer, Foundation for Innovative New Diagnostics

10:45 **Next Generation Microbial Genomics**

George Weinstock, Ph.D., Associate Director, Genome Center at Washington University; Professor, Genetics, Washington University School of Medicine

New DNA sequencing technologies are having a major impact on microbial and infectious disease genomics through dramatic reductions in cost and increases in data production. Some of the more impressive applications are the ability to sequence thousands of individual organisms, for example to build a catalog of the human microbiome; sequencing complex communities of microbes (metagenomes) from different health states to correlate the microbiome to health and disease; deep sequencing of patient samples to discover new (viral) etiologic agents; and many more. These applications and technologies will be discussed.

11:15 **Microbe Hunting in the 21st Century**

Gustavo Palacios, Ph.D., Assistant Professor, Center for Infection and Immunity, Mailman School of Public Health, Columbia University

Recent advances in nucleic acid diagnostic methods have revolutionized microbiology by facilitating rapid, sensitive microbial surveillance and differential diagnosis of infectious diseases. Implementation of these methods may enable intervention when the prognosis is optimal for limiting replication, dissemination, transmission, morbidity and mortality. It may also reveal unappreciated links between infection and chronic diseases. In this lecture I will discuss mechanisms of microbial pathogenesis, routes to proving causation, and a staged strategy for surveillance and discovery. In reviewing the strengths and limitations of various analytical platforms, I will provide examples that illustrate how each platform can be used to investigate clinical problems.

11:45 **Luncheon Presentations** *(Opportunity Available)* **or Lunch on Your Own**

1:00pm **Developing Rapid Diagnostics for Bacterial Pathogens**

Barry N. Kreiswirth, Ph.D., Director, Public Health Research Institute, TB Center; Professor of Medicine, University of Medicine and Dentistry of New Jersey

The challenges in developing rapid diagnostics for the identification and sub-speciation of bacterial pathogens range from processing diverse primary samples to providing epidemiological information for infection control practitioners. In addition to testing for the specificity and sensitivity of the assays; speed, cost, stability of reagents, reproducibility, scalability, platform size and ease of interpretation are all significant variables that need to be evaluated in developing tools that will serve the population in need. This talk will discuss the challenges in identifying MRSA in surveillance swabs and in replacing the classic acid fast smear for the identification of *M. tuberculosis.*

FROM MICROBES TO FUNGAL PATHOGENS

1:30 **Molecular Diagnostic Work Detecting Bacterial and Fungal Bloodstream Infections**

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

A rapid and reliable diagnostic platform of high sensitivity is needed for diagnosis of bloodstream infections, which carry high morbidity and mortality. An RNA-dependent NASBA amplification and molecular beacon detection system in multiplex format was developed for bacterial and fungal infections at the sub-kingdom/genus level with a sensitivity of 1-50 genomes. In a blood bottle study, the sensitivity and specificity for pan-GramPos and pan-GramNeg probes were 99.71%, 100%, and 98.6%, 96.3%, respectively; PPV and NPV was 100%, 91.7% and 99.36%, 99.4%, respectively. Pan-fungal and pan-Candida probes showed 100% sensitivity, specificity, PPV and NPV; pan-Aspergillus probe showed 100% NPV.

2:00 **Emerging and Re-Emerging Infectious Diseases: Molecular Diagnostic Approaches**

Juan P. Olano, M.D., Associate Professor, Department of Pathology, Director, Residency Training Program; Member, Center for Biodefense and Emerging Infectious Diseases, University of Texas Medical Branch

More than 50 novel infectious human pathogens (viral, bacterial, fungal and parasitic) have been described since 1967, the year in which the war against infectious diseases was declared won. Many of these pathogens have been characterized because of the great advances in molecular biology. Diagnosis of these diseases remains challenging and most of them are alarmingly underdiagnosed due to the lack of commercially available assays. The application of molecular diagnostic tools opens a new era of clinical diagnostics for traditionally neglected pathogens in the clinical setting. The arrival of point-of-care testing for emerging and re-emerging infections is not far away and would eliminate the high complexity associated with molecular testing currently performed in large hospitals, reference and research laboratories. However, several hurdles still remain such as cost-effectiveness, commercial availability, automation, diagnostic platforms, and high throughput technologies. Current and promising diagnostic techniques and detection systems will be discussed.

PCR AND POINT-OF-CARE DIAGNOSTIC DEVELOPMENT – VIRUSES

2:30 **EXPERT PANEL**
Viral Load Measurement in the Transplant Setting
Featuring... CMV, EBV, HHV-6, HHV-7, JC, Adenovirus

- Novel Tests, Development Challenges, Future Goals

3:00 **Networking Refreshment Break**

3:40 **LAMP & Novel PCR Methodologies for HIV Detection**

S. Michele Owen, Ph.D., Diagnostics Team Lead, Lab Branch, Division of HIV/AIDS Prevention, Centers for Disease Control and Prevention

Point-of-care diagnostics for HIV offers great promise in linking HIV infected individuals to health care and has the potential for decreasing HIV transmission, particularly if the tests could detect early HIV infection. To facilitate early HIV infection at point-of-care, our lab is developing several nucleic acid based techniques. These include rapid PCR using microfluidic technology and LAMP to detect HIV in multiple sample types with the goal of moving HIV nucleic acid techniques to point-of-care HIV testing. The current state of these technologies with various specimen types will be discussed.

4:10 **Rapid Detection of Tamiflu Resistant Viruses with Smart Amplification Method**

Alexander Lezhava, Ph.D., Senior Scientist, LSA Technology Development Unit, LSA Technology Development Group, Omics Science Center, RIKEN Yokohama Institute

We have developed a sensitive, accurate, rapid, and simple DNA amplification method called the SMart Amplification Process 2 (SmartAmp2) for pharmacogenomics-based drug discovery applications through to point-of-care diagnostic tests. This method employs a unique primer design and background suppression technology that can amplify target sequences from crude cell lysates and no thermocycling is required.

4:40 **Questions from the Floor**

5:00 **Close of Molecular Diagnostics for Infectious Disease Conference**

Inaugural

Clinical Adoption of Next Generation Diagnostics

August 11-12 • The Ritz-Carlton • Washington, DC

Scientific Advisory Board

Valerie Ng, Ph.D., M.D., President-Elect, ACMC Medical Staff; Chairman, Pathology; Director, Clinical Laboratory, Alameda County Medical Center/Highland General Hospital

Myla Lai-Goldman, M.D., Managing Partner, Personalized Science, LLC

Clinical adoption of molecular diagnostic by the medical community is vital to the success of novel tests. The process by which new testing protocols become accepted and get incorporated will be explored. Experts from the medical and regulatory community will be speaking on a diverse range of issues. Find out what factors influence the adoption and acceptance of your diagnostic test, and how to navigate the changing regulatory requirements.

TUESDAY, AUGUST 11

11:00am - 12:00pm Registration

PLENARY KEYNOTE SESSION

GAINING REGULATORY APPROVAL FOR MOLECULAR DIAGNOSTIC TESTS

12:00pm Keynote Introduction and Opening Remarks
Thomas F. Soriano, President & Chief Executive Officer, DOCRO, Inc.

12:10 Ensuring the Safety and Validity of Molecular Diagnostic Tests
Alberto Gutierrez, Ph.D., Deputy Director, OIVD, Office of in Vitro Diagnostic Device Evaluation and Safety, Food & Drug Administration

12:35 Q&A

12:45 Bringing Point-of-Care HIV Diagnostics to Market: FDA Perspectives
Elliot Cowan, Ph.D., Chief, Product Review Branch, Division of Emerging and Transfusion Transmitted Diseases, FDA/CBER/OBRR

Point-of-care diagnostics for human immunodeficiency virus are playing an important role in helping individuals know their HIV status. FDA is responsible for assuring that these products are safe and effective. This talk will address FDA's expectations for the approval of rapid HIV tests, pitfalls in the process, and challenges posed by home use HIV test kits.

1:10 Q&A

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

HEALTH ECONOMICS AND ADOPTION

2:30 Chairperson's Remarks

2:40 Tamoxifen and CYP2D6: Using Pharmacogenetics to Individualize Breast Cancer Hormonal Therapy
Matthew P. Goetz, M.D., Assistant Professor, Oncology, Assistant Professor, Pharmacology, Mayo Clinic

Tamoxifen has been the most important drug world-wide for the prevention and treatment of estrogen receptor positive breast cancer. Cytochrome P450 (CYP) 2D6 is the hepatic enzyme necessary for the metabolic activation of tamoxifen to endoxifen, a substantially more potent metabolite which differs from 4-OH tamoxifen in regard to its effect on ERα degradation. Multiple independent studies in the adjuvant setting (nine) have demonstrated that patients with decreased CYP2D6 metabolism have a higher risk of recurrence compared to CYP2D6 extensive metabolizers. Given that thereis no difference between tamoxifen and aromatase inhibitors in terms of breast cancer mortality, CYP2D6 pharmacogenetics appears to be a tool to individualize adjuvant hormonal therapy.

3:25 Industry and the Reasons for Advancing Standards in New Diagnostics
Jared N. Schwartz, M.D., Ph.D., FCAP, President, College of American Pathologists

This presentation will focus on the critical role industry must play to advance the introduction of new diagnostics in the era of Personalized or Precision Medicine. We will cover the state-of-the-art and illustrate how the significant improvement in standards will facilitate adoption.

4:10 Networking Refreshment Break, Exhibit and Poster Viewing

4:40 A New President, A New Congress and the Path to Personalized Medicine
Robert Wells, Partner, Co-Founder, HealthFutures LLC

The Obama Administration and the leadership of the 111th Congress have both identified the need for dramatic reforms in health care. But can the country afford them amid the most severe financial crisis since the Great Depression? And how will the new administration and Congress incorporate genomics and the personalization of medicine into those plans?

5:25 Close of Day

WEDNESDAY, AUGUST 12, 2009

8:00am **Morning Coffee**

ESTABLISHING CLINICAL UTILITY

8:30 **Chairperson's Remarks**
Valerie Ng, Ph.D., M.D., President, ACMC Medical Staff, Chairman, Pathology, Director, Clinical Laboratory, Alameda County Medical Center/Highland General Hospital

8:40 **Establishing Clinical Utility of Assays**
Valerie Ng, Ph.D., M.D., President, ACMC Medical Staff; Chairman, Pathology, Director, Clinical Laboratory, Alameda County Medical Center/Highland General Hospital

Getting an assay into clinical use is a long and arduous process. First, a clinically relevant analyte has to be identified. Then an assay must be developed that can accurately measure this analyte. Well designed statistically valid clinical trials must then demonstrate assay reliability when used by the intended user in the appropriate clinical setting. Finally, implementation of the assay into a clinical setting is dependent on individual healthcare setting unique issues (e.g., desired turnaround time, staffing, personnel training and expertise, cost, environment/facility issues, etc.). This talk will highlight the decision making process occurring at the clinical end of this process. It will include examples of how and why a particular manufacturer's assay, from an array of commercial assays for the single analyte under consideration, is ultimately chosen by a clinical site for patient care.

9:10 **Good Laboratory Practices for Molecular Genetic Testing for Heritable Diseases and Conditions**
Bin Chen, Ph.D., Health Scientist, Division of Laboratory Systems, National Center for Preparedness, Detection, and Control of Infectious Diseases, CDC

As molecular genetic testing is increasingly used in healthcare, concerns have been raised regarding the adequacy of regulatory oversight and quality assurance measures in this area of laboratory testing. Since 1997, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services have been working with other stakeholder groups and organizations to promote the quality of genetic testing and improve the appropriate use of genetic tests in healthcare. This presentation will discuss the recommended good laboratory practices for molecular genetic testing for heritable diseases and conditions in a CDC Morbidity and Mortality Weekly Report (MMWR) document published in spring 2009. The MMWR document, developed based on the recommendations of the Clinical Laboratory Improvement Advisory Committee (CLIAC), addresses good laboratory practices in the total testing process, responsibilities of laboratories for authorized persons, confidentiality of patient information and test results, personnel competency, issues to consider before introducing molecular genetic testing or offering new molecular genetic tests, and the potential benefits of the quality management system approach in molecular genetic testing. These recommendations are intended to serve as a guide for considering and implementing good laboratory practices to improve the quality and healthcare outcomes of molecular genetic testing for heritable diseases and conditions.

9:40 **From R&D to Commercial Launch: Roadmap for MDx**
Bill Cook, M.B.A., Consultant, Strategy and Business Development Clinical Diagnostics, WECA

This talk will review a case study for a new molecular diagnostic as it makes its way from biomarker discovery through to a commercial launch, emphasizing the identification of critical hurdles such as reimbursement, physician education, KOL (Key Opinion Development), etc. It will also address strategies on how to address critical parts of the roadmap to success.

10:10 **Networking Coffee Break**

10:45 **So, you think that you have the Next PSA - The Sequel**
Thomas F. Soriano, President & Chief Executive Officer, DOCRO, Inc.
Sponsored by

This session will provide the participant with an overview of the issues, concerns, and important hurdles facing the clinical adoption of any new in vitro diagnostic test. Past and current experience with well-know tests (e.g., PSA) will be used to frame changes that will influence how new tests become considered to be "standard of care." A brief Question and Answer period will be available at the end of this session. Each participant will understand:

- Examples of how new IVD tests (e.g., PSA) have become standard of care
- Issues, concerns, and stumbling blocks for the wide spread use of any promising new IVD test
- Regulatory and reimbursement matters which impact clinical adoption of new tests
- Gossip and prognostications of the future

11:15 **Sponsored Presentations** *(Opportunity Available)*

11:45 **Luncheon Presentations** *(Opportunity Available)* **or Lunch on Your Own**

ON THE PATH FOR PERSONALIZED DIAGNOSIS

1:00pm **Personalized Medicine on Deck - Home Run or Strike Out Ahead?**
Mara G. Aspinall, President and Chief Executive Officer, VivirHealth

The good news is that the scientific power to diagnose, monitor and personalize patient treatment is greater today than ever before. The bad news is that physician adoption of these advances is frequently uneven and slow. Ms. Aspinall will discuss her current view of personalized medicine: opportunities, challenges and what we must do before its full promise can be achieved.

1:30 **Experience with Adoption of Pharmacogenomics Testing on a National Scale**
Robert S. Epstein, M.D., M.S., Senior Vice President, Medical & Analytical Affairs & Chief Medical Officer, Medco Health Solutions, Inc.

Pharmacogenomics was a scientific curiosity until very recently, when large organizations stepped up and adopted various pathways for coverage. This talk will describe the experiences by Medco, a company covering approximately 70 million Americans, in advocating coverage and encouraging adoption by patients and physicians for the commonly used breast cancer adjuvant drug tamoxifen. Data will be shared on the accelerators and decelerators of adoption, and future directions will be shared.

2:00 **Break-out Sessions: Influencing Adoption to Bring a New Diagnostic to Market**

3:00 **Networking Refreshment Break**

STANDARDS DEVELOPMENT TO IMPROVE PERFORMANCE OF TESTS

3:30 **Chairperson's Remarks**
Jared N. Schwartz, M.D., Ph.D., FCAP, President, College of American Pathologists

3:40 **A Standards Lab to Evaluate Diagnostic Tests: Would it Accelerate the Pipeline?**
Jeffrey Cossman, Ph.D., Chief Scientific Officer, C-Path Institute

A concept is proposed to provide a neutral, non-regulatory testing service to evaluate IVDs and LDTs for performance. If a manufacturer chooses to use the service, the results could be used for FDA submission, reimbursement decisions, marketing, comparisons, due diligence and by providers in selecting tests for clinical use.

4:10 **Standards for Multiplex Technologies: What they are and Why they are Important for Next Generation Laboratory Medicine**
Michael D. Amos, Ph.D., Biosciences Advisor, Director's Office, Chemical Science and Technology Laboratory, National Institute of Standards and Technology

New measurement technologies can play an important role in expanding the current vision of personalized medicine from mostly encompassing pharmacogenomics and electronic health records to one involving early detection and prevention of the chronic diseases (cancer, diabetes, cardiovascular and other diseases) that cause massive pain and suffering and represent more than 80% of U.S. health care spending. New multiplex measurement tools are making it possible to, for the first time, analyze the complex biomolecular network systems and gain a better understanding of the molecular pathology of diseased cells. DNA microarray, IVD-MIA products are reaching market and the signatures they can discern appear to possess greater diagnostic and prognostic value than single measurements alone. The same will probably be true for multiplex proteome analysis. However, because these technologies are considerably more complex, their utility in the clinic will require entirely new and innovative approaches to standards to enable their further development and deployment.

4:40 **Speaker to Be Announced**

5:10 **Close of Clinical Adoption of Next Generation Diagnostics Conference**

HOTEL & TRAVEL Information

HOTEL & TRAVEL

Conference Venue and Hotel:

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

Discounted Room Rate: $205 s/d

Discounted Room Rate Cut-off Date:
July 17, 2009

Please visit our website to make your reservations online or call the hotel directly to reserve your sleeping accommodations. Identify yourself as a Cambridge Healthtech Institute conference attendee to receive the reduced 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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Manager of Business Development
Phone: 781-972-5431
E-mail: awolfson@healthtech.com

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❑ **Yes! Please register me for the Next Generation Dx Summit**

Key Code 980F

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Country _____

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How would you prefer to receive notices from CHI? Email: ❑Yes ❑No Fax: ❑Yes ❑No

Email* _____ Fax _____

*Email is not a mandatory field. However, by excluding your email you will not receive notification about online access to pre-conference presenter materials, conference updates, networking opportunitites and requested eNewsletters.

Summit Pricing BEST VALUE!

(Includes access to 3 conference days, excludes pre-conference symposia)

	Commercial	Academic, Government, Hospital-affiliated
Early Registration Deadline until May 15, 2009	❑ $1645	❑ $795
Advance Registration Deadline until July 10, 2009	❑ $1795	❑ $875
Registrations after July 10, 2009 and on-site	❑ $1995	❑ $945

REQUIRED - Please select the TWO conferences you're most likely to attend.

August 10-11 (Choose One)
- ❑ Enabling Point-of-Care Diagnostics
- ❑ Trends in Cancer Diagnostics

August 11-12 (Choose One)
- ❑ Molecular Diagnostics for Infectious Disease
- ❑ Clinical Adoption of Next Generation Diagnostics

Single Conference Pricing

(Includes access to 1.5 conference days, excludes pre-conference symposia)

	Commercial	Academic, Government Hospital-affiliated
Early Registration Deadline until May 15, 2009	❑ $1245	❑ $625
Advance Registration Deadline until July 10, 2009	❑ $1395	❑ $695
Registrations after July 10, 2009 and on-site	❑ $1595	❑ $795

REQUIRED - Please select the ONE conference you're most likely to attend.

August 10-11
- ❑ Enabling Point-of-Care Diagnostics
- ❑ Trends in Cancer Diagnostics

August 11-12
- ❑ Molecular Diagnostics for Infectious Disease
- ❑ Clinical Adoption of Next Generation Diagnostics

Pre-Conference Symposia Pricing (includes access to the symposia ONLY)

Afternoon Symposium (August 9, 2009)	❑ $645	❑ $345

REQUIRED - Please select the symposium you will attend. (Choose One)

❑ (SC1) Circulating Tumor Cells As Surrogate Endpoints In Clinical Trials ❑ (SC2) Reality Check On Companion Diagnostics

DISCOUNTS:

Alumni Discount	❑ 25%	❑ 25%
Poster Discount	❑ $50	❑ $50

☛ **REGISTER 3 - 4th IS FREE** Individuals must register for the same conference or conference combination and submit completed registration form together for discount to apply. Please reproduce this registration form as needed.

GROUP DISCOUNTS AVAILABLE! Special rates are available for multiple attendees from the same organization. For more information on group discounts contact **David Cunningham at 781-972-5472**

❑ I cannot attend but would like to purchase the **Next Generation Dx Summit** conference CD for $750 (plus shipping). Massachusetts delivery will include 5% sales tax.

❑ Please send information on exhibiting and opportunitites to present workshops.

PAYMENT INFORMATION

❑ Enclosed is a check or money order payable to Cambridge Healthtech Institute, drawn on a U.S. bank, in U.S. currency.

❑ Invoice me, but reserve my space with credit card information listed below.
Invoices unpaid two weeks prior to conference will be billed to credit card at full registration rate. Invoices must be paid in full and checks received by the deadline date to retain registration discount. If you plan to register on site, please check with CHI beforehand for space availibility.

❑ Please charge: ❑ AMEX (15 digits) ❑ Visa (13-16 digits) ❑ MasterCard (16 digits)

Card # _____

Cardholder _____

Signature _____

Cardholder's Address (if different from above) _____

City/State/Postal Code _____

Country _____

FAX OR MAIL REGISTRATION TO

Cambridge Healthtech Institute, 250 First Avenue, Suite 300, Needham, MA 02494
Phone: 781-972-5400 or Toll-free in the U.S. 888-999-6288 • Fax: 781-972-5425 • NextGenerationDx.com

Present a Poster and Save $50!

Cambridge Healthtech Institute encourages attendees to gain further exposure by presenting their work in the poster sessions.To secure a poster board and inclusion in the conference CD, your abstract must be submitted, accepted and registration paid in full by **July 16, 2009.** Register online to use the Poster Abstract Submission form or, if you register by phone, fax, or mail, you will receive Poster Abstract Submission guidelines via email.

I am interested in presenting a poster at ❑ **Next Generation Dx Summit** and will submit a completed one-page abstract by **July 16, 2009**
(Please Note: Registration must be paid in full to present poster. After submitting your registration,a form will appear allowing you to submit your poster abstract information)

Title _____

CAMBRIDGE HEALTHTECH MEDIA GROUP

Yes! I would like to receive a FREE eNewsletter subscription to: www.chimediagroup.com

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The latest industry news, commentaryand highlights from Bio•IT World

❑ eCliniqua
Innovative management in clinical trials

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Informatics tools and strategies driving decisions

CHI Insight Pharma Reports
A series of diverse reports designed to keep life science professionals informed of the salient trends in pharmaceutical technology, business, clinical development, and therapeutic disease markets.
For a detailed list of reports, visit **InsightPharmaReports.com**, or contact Rose LaRaia, rlaraia@healthtech.com, 781-972-5444.

Barnett Educational Services
Barnett is a recognized leader in clinical education, training, and reference guides for life scienceprofessionals involved in the drug development process. For more information, visit **www.barnettinternational.com.**

Additional Registration Details
Each registration includes all conference sessions, posters and exhibits, food functions, and a copy of the conference CD.

Group Discounts
Special rates are available for multiple attendees from the same organization. **Contact David Cunningham at 781-972-5472** to discuss your options and take advantage of the savings.

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

Substitution/Cancellation Policy
In the event that you need to cancel a registration, you may:
- Transfer your registration to a colleague within your organization. Credit your registration to another Cambridge Healthtech Institute program.
- Request a refund minus a $100 processing fee per conference.
- Request a refund minus the cost ($750) of ordering a copy of the CD .

NOTE: Cancellations will only be accepted up to two weeks prior to the conference.
Program and speakers are subject to change.

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

CAMBRIDGE HEALTHTECH INSTITUTE OFFERS AN EXPANSIVE SUITE of information resources specific to Biomarkers and Diagnostics. Follow these links for articles, social networking, research, seminars and conferences all pertaining to Biomarkers and Diagnostics.

Bio·IT World
Technologies Driving Discovery, Development, and Clinical Trials

Insights on Biomarkers and Diagnostics

Bio-IT World magazine – CHI's flagship publication – publishes critical insight, analysis, and opinion on the tools and results of predictive biology, drug discovery, informatics, clinical research, and personalized medicine, in addition to the strategic decisions made by companies in these areas. Please visit **www.bio-itworld.com** to view feature articles, white papers, and podcasts on the life sciences industry and to subscribe to the magazine.

A series of insightful and informative articles focusing on Biomarkers and Diagnostics are below. Please click on each article link to read.

- **Using Molecular Diagnostics**
  By Larry Hand
- **Amgen's Personalized Medicine Story**
  By Kevin Davies, Ph.D.
- **The Biomarker Business**
  By Christopher Huels
- **Merck-Moffitt Partnership Breaks Down Silos**
  By Catherine Varmazis
- **Dutch Drug Development Heats Up**
  By Allison Proffitt

Related Web Site

Introducing **www.eCliniqua.com** – a web site focusing on the clinical trials industry.

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Informatics tools and strategies driving decisions.

CHI's Biomarker Series: Six Years of Success

CONFERENCES HEALTHTECH.COM

CHI's Biomarker Series features several biomarker related events annually, attracting upwards of 500 participants. Due to an overwhelming response from the scientific community and a consistent track-record of delivering cutting-edge programs and an expert audience, this series has shown a positive growth and has branched out to include coverage in Translational Medicine, Biomarker Assay Development, Personalized Medicine, Oncology, and Clinical Pharmacology to name a few. In order to bring you the solutions and strategies that impact the bottom line, as well as provide a forum to address the most timely opportunities and the most burning issues industry-wide, we spent years researching the issues pertaining to biomarker implementation and staying in close contact with pharmaceutical executives and leading scientists. We believe that the potential value of biomarkers can best be exploited by working together and sharing information. We invite you to join us in this process. The Biomarker Series flag ship event is the Fifth Annual Biomarker World Congress, to be held May 27-29, 2009 in Philadelphia. This event features more than 500 attendees, 30 exhibits, 60 presentations and numerous networking opportunities.

- **The Biomarker World Congress**
- **Biomarker Assay Development**
- **Translational Cancer Medicine**
- **Translational Medicine**
- **Biomarker Discovery Summit**
- **Biomarkers Europe**
- **ADAPT**
- **Protein Biomarkers**

Biomarker BRIDGE

What is the Biomarker Bridge?

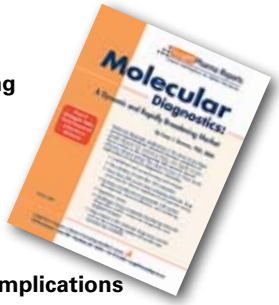
An interactive collaborative network community for pharmaceutical, clinical and IT professionals who are interested in gaining and sharing knowledge about technologies, research, and regulatory issues around life science. **Sign up today!**

Insight Pharma Reports

Insight Pharma Reports Targets Cardiotoxicity and Biomarker SOPs

Insight Pharma Reports is the premier life science information provider. Insight Pharma Reports offer unparalleled coverage of key issues in biomarkers and diagnostics. Our reports are used by leading pharmaceutical, biotech, diagnostic, and other life science companies to keep abreast of the latest developments in pharmaceutical R&D and their potential applications and business impacts. The reports are written by experts in consulting and industry, and are supported by hundreds of hours of primary and secondary research.

- **Molecular Diagnostics: A Dynamic and Rapidly Broadening Market**
- **Cancer Biomarkers: Adoption Is Driving Growth**
- **Disease-Related Biomarkers: Their Potential in Patient Screening, Prognosis, and Stratification**
- **Biomarker SOPs: Getting Optimum Value from Your Biomarker Programs**
- **Biomarkers in Clinical Development: Implications for Personalized Medicine and Streamlining R&D**



BARNETT EDUCATIONAL SERVICES

Barnett Seminars Keep You Informed on the Latest in Biomarkers and Diagnostics Issues

CHI's Barnett International is the premier provider of clinical research training resources. Through its live courses, web-based training, eLearning, and in-house training and consulting services, and publications, Barnett partners with leading sponsors, CROs and clinical research sites to ensure that research teams are trained according to FDA, ICH and global regulatory standards. Featured events and services include:

- **Biomarkers of Drug Efficacy and Safety Training**
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D·I·A·E·C

The Drug Safety Executive Council (DSEC) is a peer-to-peer membership of over 1,500 drug safety leaders with the common objective of advancing the development of better and safer medicines.