

Cover

Conference-at-a-Glance

Plenary Keynote Session

Short Courses

Enabling Point-of-Care Diagnostics

Predictive Cancer Biomarkers

Companion Diagnostics

Coverage and Reimbursement of
Advanced Diagnostics

Clinical NGS Assays

Molecular Diagnostics for
Infectious Disease

Clinical Application of Cell-Free DNA

Commercialization of
Molecular Diagnostics

Diagnostics to Guide
Cancer Immunotherapy

NGS Diagnostics: Annotation
and Interpretation

Leveraging Pharmacies for
Rapid Diagnostics

Sponsor & Exhibit Opportunities

Hotel & Travel Information

Registration Information

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Bringing Together All the Major Players in the Diagnostics Industry

Seventh Annual
Next Generation
August 18-20, 2015
Capital Hilton, Washington, DC
SUMMIT



MOVING ASSAYS TO THE CLINIC

CONFERENCE PROGRAMS

August 18-19

- Enabling Point-of-Care Diagnostics
- Predictive Cancer Biomarkers
- Companion Diagnostics
- Coverage and Reimbursement of Advanced Diagnostics
- Clinical NGS Assays

August 19-20

- Molecular Diagnostics for Infectious Disease
- Clinical Application of Cell-Free DNA
- Commercialization of Molecular Diagnostics
- Diagnostics to Guide Cancer Immunotherapy
- NGS Diagnostics
- Leveraging Pharmacies for Rapid Diagnostics

PLENARY SESSION

In the Best Interest of the Patient:
Balancing Innovation and Regulation

Co-Organized with 



Moderator: Elaine Lyon, Ph.D., Medical Director, Molecular Genetics, ARUP (AMP 2014 President and Member, AMP Professional Relations Committee)

Panelists:



Jordan S. Laser, M.D., Medical Director, Pathology and Laboratory Medicine, North Shore Long Island Jewish Health System (Member, AMP Professional Relations Committee)



Jamie McDonald, MS, Licensed Genetic Counselor, Co-Director, HHT Center of Excellence; Assistant Professor, Department of Pathology, University of Utah



Stephen P. Day, Ph.D., IVD Consultant (Member, AMP Professional Relations Committee)

IMPACT OF PAMA REGULATIONS ON IVDS



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

The Impact of PAMA on Molecular Tests



Julie Khani, Senior Vice President, American Clinical Laboratory Association

Panelists:



John F. Warren, Senior Director, McDermott+Consulting LLC



Donna Polizio, Senior Director, Managed Care & Reimbursement, Genomic Health



Paul W. Radensky, M.D., Partner, Health Products Regulation Group, McDermott Will & Emery LLP

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Event-at-a-Glance

Monday	Pre-Conference Short Courses*					
Tuesday AM-PM	Enabling Point-of-Care Diagnostics	Predictive Cancer Biomarkers	Companion Diagnostics	Coverage and Reimbursement of Advanced Diagnostics	Clinical NGS Assays	
Wednesday AM	Enabling Point-of-Care Diagnostics	Predictive Cancer Biomarkers	Companion Diagnostics	Coverage and Reimbursement of Advanced Diagnostics	Clinical NGS Assays	New! Leveraging Pharmacies for Rapid Diagnostics
	Plenary Keynote Session					
Wednesday PM	Molecular Diagnostics for Infectious Disease	Clinical Application of Cell-Free DNA	Commercialization of Molecular Diagnostics	Diagnostics to Guide Cancer Immunotherapy	NGS Diagnostics: Annotation and Interpretation	New! Leveraging Pharmacies for Rapid Diagnostics
	Dinner Short Courses*					
Thursday AM	Molecular Diagnostics for Infectious Disease	Clinical Application of Cell-Free DNA	Commercialization of Molecular Diagnostics	Diagnostics to Guide Cancer Immunotherapy	NGS Diagnostics: Annotation and Interpretation	New! Leveraging Pharmacies for Rapid Diagnostics
Thursday PM	Molecular Diagnostics for Infectious Disease	Companion Diagnostics: Technology and Reimbursement	Commercialization of Molecular Diagnostics	Diagnostics to Guide Cancer Immunotherapy	NGS Diagnostics: Annotation and Interpretation	New! Leveraging Pharmacies for Rapid Diagnostics

The Next Generation Dx Summit, entering its seventh year, brings together more than 800 diagnostics professionals from across the world, providing comprehensive programming and valuable networking opportunities. Spanning from clinical diagnostics to business strategy, this year's expanded program encompasses predictive cancer biomarkers, companion diagnostics, infectious disease, point-of-care, pharmacy-based diagnostics, cell-free DNA, commercialization, cancer immunotherapy, and reimbursement. With widespread coverage of all the most relevant diagnostics topics, the Next Generation Dx Summit promises to be a must-attend event to hear the latest announcements and developments in this rapidly evolving field.

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REGISTER EARLY FOR
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Cambridge Healthtech Institute

Plenary Keynote Session

WEDNESDAY, AUGUST 19

11:00am IN THE BEST INTEREST OF THE PATIENT: Balancing Innovation and Regulation

Co-Organized with



Moderator: Elaine Lyon, Ph.D., Medical Director, Molecular Genetics, ARUP (AMP 2014 President and Member, AMP Professional Relations Committee)

Advances in laboratory medicine hold great promise in diagnosing or predicting disease, and guiding therapy decisions. Innovative testing must provide accurate, valid and useful information. How does the field move forward in making such testing available in a timely manner, yet within a regulatory environment to ensure quality of results?

- Feasibility of FDA overseeing LDPs
- Economics
- Innovative regulatory models

Panelists:

Jordan S. Laser, M.D., Medical Director, Pathology and Laboratory Medicine, North Shore Long Island Jewish Health System (Member, AMP Professional Relations Committee)

Jamie McDonald, MS, Licensed Genetic Counselor, Co-Director, HHT Center of Excellence; Assistant Professor, Department of Pathology, University of Utah

Stephen P. Day, Ph.D., IVD Consultant (Member, AMP Professional Relations Committee)

IMPACT OF PAMA REGULATIONS ON IVDS

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

New 2014 legislation, PAMA, is creating the biggest upheaval in laboratory pricing in 30 years, and will affect the whole industry, including clinical chemistry diagnostics, infectious disease diagnostics, point of care diagnostics, and sophisticated molecular tests.

- How has the Medicare agency proposed to implement the law?
- How will advanced molecular tests and more common tests be impacted differentially?
- How will PAMA affect the adoption and acceptance of next generation sequencing?
- When will labs have to start reporting data to CMS, and how will this likely impact IVD manufacturers?

11:45 The Impact of PAMA on Molecular Tests

Julie Khani, Senior Vice President, American Clinical Laboratory Association

11:55 PANEL DISCUSSION:

John F. Warren, Senior Director, McDermott+Consulting LLC

Donna Polizio, Senior Director, Managed Care & Reimbursement, Genomic Health

Paul W. Radensky, M.D., Partner, Health Products Regulation Group, McDermott Will & Emery LLP

Short Courses*

MONDAY, AUGUST 17

9:00 am - 12:00 pm

SC1: Use of FFPE/Fixed Tissues for Clinical Research

P. Mickey Williams, Ph.D., Director, Molecular Characterization & Clinical Assay Development Laboratory (MoCha), Frederick National Laboratory for Cancer Research

Jason Lih, Ph.D., Principal Scientist, Molecular Characterization Group, Leidos Biomedical Research, Inc./Frederick National Laboratory for Cancer Research

Biswajit Das, Ph.D., Senior Scientist, MoCha, Frederick National Laboratory for Cancer Research Leidos Biomedical Research, Inc., National Cancer Institute (NCI)

Christopher R. Kinsinger, Ph.D., Program Manager, Office of Cancer Clinical Proteomics Research, NCI
Ping Guan, Ph.D., Program Director, Biorepositories and Biospecimen Research Branch (BBRB), National Cancer Institute (NCI)

Wendell Jones, Ph.D., Global Head Genomic Bioinformatics, EA Quintiles

SC2: Method Validation According to CLSI Guidelines

Shuguang Huang, Ph.D., Associate Vice President, Biostatistics, Helomics

SC3: Practical Considerations for NGS Data Analysis and Interpretation

Robert D. Daber, Ph.D., Director, Research and Development and Sequencing Operations, Bio-Reference Laboratories

Matthew Lebo, Ph.D., FACMG, Director, Bioinformatics, Partners Personalized Medicine; Instructor, Pathology, Brigham and Women's and Massachusetts General Hospitals

2:00 - 5:00 pm

SC5: Microfluidics for Point-of-Care

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

SC6: Establishing the Value of Diagnostic Tests

Lawrence J. Worden, Vice President and Senior Partner, Market Diagnostics International

Mark S. Girardi, Principal Consultant, GfK Bridgehead
Rahul Dhanda, Ph.D., Vice President, Marketing, T2 Biosystems, Inc.

SC7: NGS as a Diagnostics Platform

Jamie L. Platt, Ph.D., Vice President, Genomic Solutions, Molecular Pathology Laboratory Network, Inc.

Jennifer Morrisette, Ph.D., Scientific Director, Clinical Cyto genetics Laboratory, Clinical Director, Center for Personalized Diagnostics (CPD), University of Pennsylvania School of Medicine

SC8: Detection and Characterization of Circulating Biomarkers

Sonya Parpart-Li, Ph.D., Associate Scientist, Personal Genome Diagnostics

5:30 - 8:30 pm DINNER SHORT COURSE:

SC9: Regulatory Compliance in Molecular Diagnostics

Melina Cimler, Ph.D., Senior Vice President, Quality & Regulatory, Adaptive Biotechnologies

William Pignato, Founder and Principal, W.J. Pignato & Associates, LLC

Pamela Swatkowski, Director, Global Regulatory Affairs, Abbott Molecular

WEDNESDAY, AUGUST 19

DINNER SHORT COURSES 6:30 - 8:30 pm

SC10: Use of CLIA-Waived POC and Rapid Diagnostic Tests in Community Pharmacies

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

Donald G. Klepser, Ph.D., MBA, Assistant Professor, Pharmacy Practice, University of Nebraska Medical Center College of Pharmacy
Allison Dering-Anderson, Pharm.D., RP, Clinical Assistant Professor, Pharmacy Practice, University of Nebraska Medical Center College of Pharmacy

SC11: NGS for Infectious Disease Diagnostics

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

SC12: Regulatory and Reimbursement Considerations with NGS and Other Multiplex Assays

Žilvana Težak, Ph.D., Associate Director, Science and Technology, Personalized Medicine, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD), Center for Devices and Radiological Health (CDRH), FDA

Girish Putcha, M.D., Ph.D., Director, Laboratory Science, Palmetto GBA (MoIDX)

*Separate registration required; for detailed agendas, visit NextGenerationDx.com

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RECOMMENDED SHORT COURSES*

SC5: Microfluidics for Point-of-Care: Technologies, Applications and Products**SC12: Use of CLIA-Waived POC and Rapid Diagnostic Tests in Community Pharmacies**

*Separate registration required, please see page 3 for details

TUESDAY, AUGUST 18

7:30 am Main Conference Registration & Morning Coffee

WEARABLE AND HOME USE TECHNOLOGIES

8:30 Chairperson's Opening Remarks

Eric van Gieson, Ph.D., Director, R&D, Diagnostics and Biosurveillance, MRIGlobal

» 8:40 KEYNOTE PRESENTATION: A Bionic Pancreas for Automated Type 1 Diabetes Management

Edward R. Damiano, Ph.D., Professor, Biomedical Engineering, Boston University

We have developed a bionic pancreas for automated management of type 1 diabetes. The device consists of a continuous glucose monitor, subcutaneous infusion pumps to deliver insulin and glucagon, and an iPhone, which executes mathematical algorithms that determine the precise amount of insulin and glucagon to deliver. Results of our outpatient clinical trials testing the system in people with type 1 diabetes will be presented.

9:10 Wearable Devices in the Real World – A Patient's Perspective

Anna McCollister-Slipp, Co-Founder, Galileo Analytics

9:25 Wearable Diagnostics in Clinical Practice

James V. Lawler, M.D., MPH CDR MC USN, ACESO Director, NMRC - Frederick

In experiments our group previously conducted at USAMRIID, analysis of telemetry signals of vital signs and cardiac electrical activity was able to identify fatal cases of Ebola-challenged primates prior to the development of symptoms. Exploiting real-time physiologic signals could greatly expand providers' insight into patient health over time and potentially identify acute illness. The growing availability of personal monitoring devices, such as FitBit, are revolutionizing the fitness world but have yet to be incorporated into daily medical practice. This will inevitably change. Real-time and continuous monitoring will have a profound impact on future medical practice.

9:40 Wearable Technology for Threat Awareness

Christian Whitchurch, Manager, Detection, Diagnostics & Biosurveillance, Defense Threat Reduction Agency (DTRA)

Two very interesting fields of technology are converging: wearable technologies for health monitoring, and biomarker discovery for exposure/infection. Progress in these fields predicts the development of a wear-and-forget, host-based sensor suite that continually monitors the soldier/doctor/first responder for signs of infection or exposure to chemical or biological hazards. If realized, this could be a hugely enabling technology for the warfighter, the first responder, healthcare workers, BSL4 staff, and others.

9:55 A Next-Generation Wearable Physiological Monitoring System

Andreas Caduff, Ph.D., CEO, Biovotion AG

Wearables and wearable monitoring along with digital health or mHealth are often heard terms these days. But what will need to be done to make such solutions sustainable offerings that have the potential to be used over a longer period of time? What will really need to be offered to allow for truly added value that succeeds to outweigh often seen inconveniences? This talk will illustrate relevant elements and considerations to arrive at value creating offerings.

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

11:00 The rHEALTH Technology for Universal Biomedical Diagnosis

Eugene Chan, M.D., Founder, CEO, DNA Medicine Institute

We have developed the rHEALTH technology for measurement of many laboratory tests off a single drop of blood. To date, the technology has been demonstrated on over 22 tests, many of which against FDA gold-standards. These include blood counts, chemistry, biomarkers, small molecules, and vital signs. The rHEALTH technology is designed to empower individuals and professionals to get as much access to individual biomedical information as possible.

11:15 Science Fiction Becoming a Reality

Grant R. Campany, Senior Director & Prize Lead, Qualcomm Tricorder XPRIZE & Nokia Sensing XCHALLENGE

In the fictional TV/movie series Star Trek, Captain Kirk talks to his crew via a communicator, has his medical officers assess conditions through a handheld tricorder, and synthesizes food and physical goods using his replicator. This, of course, is science fiction, however, in some cases it is becoming science reality. Many of the technologies that we saw in Star Trek are actually beginning to materialize. Captain Kirk's communicator could be seen as inspiration for today's smartphones, 3D printing could be compared to Star Trek's replicator, and most recently, the \$10M Qualcomm Tricorder XPRIZE is challenging teams to develop a mobile device capable of giving consumers access to diagnostic tools that deliver meaningful information about their health status.

INITIATIVES AND VISION FOR THE FUTURE

11:30 PANEL DISCUSSION:

Moderator: Eric van Gieson, Ph.D., R&D Director, Diagnostics and Biosurveillance, MRIGlobal

Participants will discuss the steps necessary to extract diagnostic value from wearable monitoring systems and home-use diagnostic applications, given that most products destined for home-use are not able to provide specific diagnosis or provide early warning of potential disease onset. The discussion will center on reliability, regulatory hurdles that need to be overcome, and the likelihood of user adoption (how to engage users through a positive user experience and perception of utility).

Panelists:

Noam Ziv, Founder & CEO, Kesembe, Inc.

Donald Jones, CEO, Trial Fusion, Inc.

Robert Matthews, Ph.D., CEO, NudgeWorX

Matthew C. Lorence, Ph.D., Executive Vice President, Marketing and Sales, Edge Biosystems, Inc.

Edward R. Damiano, Ph.D., Associate Professor, Biomedical Engineering, Boston University

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**12:30 Genedrive®- An Innovative Point-of-Care Device
for Rapid Disease Diagnosis and DNA Genotyping in Near Patient Settings**

Sponsored by

epistem*Peter Foster, Ph.D., Technical Director, Research and Development, Epistem Ltd.*

Epistem's Genedrive® portable PCR device enables the rapid diagnosis of disease and DNA genotyping in a Point of Care setting. Genedrive assays are low cost, simple to use and can be deployed in resource limited settings as well as near patient testing for companion diagnostics. Approval in India has been granted for the detection of Tuberculosis and antibiotic resistance. Tests for the detection and quantitation of viruses and companion diagnostic have also been developed.

**1:00 Luncheon Presentation: Designing Point-of-Care
Instruments: Challenges and Proven Tools for Success**

Sponsored by

Invetech
For your most important projects*David James, Senior Vice President, Diagnostics, Invetech*

Developing market-leading instruments and consumables to meet the demanding requirements for point-of-care requires specialist skills and experience. Stakeholders with competing priorities are often challenged to find a method to agree on the "critical few" requirements that will provide the best product solutions. In this session we discuss proven tools and processes critical to defining a winning design and then delivering a robust and competitive final product in the shortest time to market.

1:30 Refreshment Break in the Exhibit Hall with Poster Viewing**CELL-BASED ASSAYS AND METHODS FOR DIAGNOSTICS****2:00 Chairperson's Remarks***Holger Becker, Ph.D., Founder & CSO, microfluidic ChipShop GmbH***2:05 Point-of-Care Diagnostics for Clinical Hematology: Towards Novel
Cell-Based Hemostasis Assays and Patient-Operated Self-Tests***Wilbur A. Lam, M.D., Ph.D., Assistant Professor, Pediatrics and Biomedical Engineering, Emory University and Georgia Institute of Technology*

Hematologic disorders, almost by definition, can be diagnosed via sampling and analysis of blood and as such, are especially amenable for point-of-care and cell-based diagnosis. In this presentation, newly developed microfluidic cell-based assays for assessing hemostatic function that offer improvements over standard clinical tests will be described. In addition, a clinical assessment of a recently developed patient-operated, disposable, self-test for anemia will also be discussed.

2:35 POC Diagnostics – A New Era for Portable Devices*James F. Leary, Ph.D., Professor, Basic Medical Sciences & Biomedical Engineering, Purdue University*

Portable devices required evolution of new technologies (e.g. low-power LEDs, nanophotonic sensors, "smart-nanoparticles") that permit small, light-weight, low-power instruments to be brought to the patient. This represents a fundamental paradigm shift in medicine changing the way healthcare decisions can be made. If rapid tests can be made within 15-20 minutes, important medical decisions can be made during an initial patient visit to improve patient outcomes.

**3:05 Cell-Based Microfluidic Assays for Cardiovascular and
Ocular Diagnostics***Shashi K. Murthy, Ph.D., Associate Professor, Chemical Engineering, Northeastern University*

Cell-based microfluidic assays have advanced significantly, particularly in targeting circulating tumor cells. The mode of operation of such assays is typically target cell identification followed by enumeration. However, it is now possible to leverage cellular function to obtain diagnostic readouts. This presentation will describe examples of both current generation and next generation cell-based microfluidic diagnostic assays in the context of cardiovascular and ocular diagnostics, respectively.

**3:35 Reimagining the Future of Point-of-Care
Molecular Diagnostics for Infectious Disease**

Sponsored by

Lucigen
Simplifying Diagnostics*Hemanth Shenoj, Ph.D., Director, Business Development, Lucigen*

Lucigen is developing ClariLight™, a CLIA-waivable molecular diagnostic platform that provides results in about 30 minutes. The simple format will be usable by laboratory and non-laboratory health care staff to accurately diagnose infectious diseases at the point-of-care. Our initial focus is hospital-acquired infections, specifically *Clostridium difficile* infection. This presentation will describe the patented isothermal amplification technology, pre-clinical data and plans for a dual 510(k) and CLIA-waiver clinical trial.

4:05 Refreshment Break in the Exhibit Hall with Poster Viewing**INTEGRATED MICROFLUIDICS****4:45 Smart Microfluidic and Its Impact on
POC Diagnostics**

Sponsored by

FUNAI*Yimin Guan, Ph.D, Microfluidic Business Development, Funai TSG Group*

Funai, a leader in inkjet technology innovation, has developed novel microfluidic modules based on MEMS process of thermal inkjet technology, which include on-chip pico pump, mixer, filter and output jetting array. Fabricated by using standard semiconductor process and with built-in CMOS control, the modules are low-cost, small, intelligent and ready for mass production. The integration of these intelligent, low-cost modules will enable various new POC diagnostic platforms.

**5:00 Ultrasensitive Rare Cell Disease Diagnostics on Hybrid Microfluidic/
Microelectronic Chips***David Issadore, Ph.D., Assistant Professor, Bioengineering and Electrical Engineering, University of Pennsylvania*

The impact of the growth in microelectronics has been profound - computing is pervasive and portable, communication is instant and global, and information is ubiquitously gathered and shared. My research aims to harness these same electrical engineering approaches, which have enabled the microelectronic revolution, to solve high impact problems in medical diagnostics. To accomplish this goal my lab develops hybrid microchips, where microfluidics (i.e. micrometer sized plumbing) are built directly on top of semiconductor chips.

**5:25 Low Cost, Non-Invasive, Onsite Paper-Based Multiplex Device for
Early Prediction of Kidney Damage***Kadamb Patel, Ph.D., Program Manager, Biosensor, Research Scientist, Centre of Molecular Diagnostics, School of Applied Science, Temasek Polytechnic*

We have developed simple, user-friendly, inexpensive, noninvasive, and accurate, low cost, point-of-care paper-based multiplex device for early prediction of kidney damage. Paper-based device was developed using selected urine biomarkers with high sensitivity and specificity, namely the Kidney injury molecule-1 (KIM-1) and Neutrophil gelatinase-associated lipocalin (NGAL) which can be used for early prediction of acute kidney injury.

**5:50 Wine & Cheese Pairing Welcome Reception in the Exhibit Hall with
Poster Viewing****6:50 Close of Day**

Impacting Patient Care

WEDNESDAY, AUGUST 19

7:15 am Registration

7:30 – 8:25 Problem-Solving Breakout Discussions with
Continental Breakfast

TRENDS IN POCT-VISION OF THE FUTURE

8:25 Chairperson's Opening Remarks

Gyorgy Abel, M.D., Ph.D., Director, Molecular Diagnostics, Immunology & Clinical Chemistry, Laboratory Medicine, Lahey Hospital & Medical Center

» 8:30 KEYNOTE PRESENTATION: Coming to a Lab Near You:
Global Review of POCT

Gyorgy Abel, M.D., Ph.D., Director, Molecular Diagnostics, Immunology & Clinical Chemistry, Laboratory Medicine, Lahey Hospital & Medical Center

Clinical demand, convenience, and technological advancements have contributed to the increasing popularity of point-of-care testing (POCT) world-wide. Yet there are considerable differences in the utilization of POCT depending on the different medical needs, health care delivery and reimbursement systems in various countries. The presentation reviews these differences, the key drivers, challenges, trends, and the attitudes toward POCT by geographic/economic region.

9:00 Use of a POC Laboratory to Successfully Manage
Ebola Patients

James C. Ritchie, Ph.D., Medical Director & Professor, Pathology & Laboratory Medicine, Emory University

Our hospital has successfully treated 4 Ebola patients. These patients were entirely managed using laboratory values generated by a point-of-care testing laboratory located within the treatment unit. We will discuss the instrumentation used, the staff preparation, and the teamwork needed to make this approach viable. We will also briefly discuss the results for the common chemistry analytes on these patients throughout their treatment course. Finally we will discuss the shipping of specimens and decontamination of equipment and the laboratory after the patients depart.

9:30 Ambulatory POCT for Ebola, Lassa, Fever and Trace Infections

Mustapha S. Fofana, Ph.D., Associate Professor, Mechanical, Biomedical and Manufacturing Engineering, Worcester Polytechnic Institute

The Ambulatory Point-of-Care Testing (POCT) vehicles are designed for rapid verification of people suspected of Ebola, Lassa, Fever and Trace (ELFT) infections. We will discuss the basic mechanics for POCT, explain engineering innovations of the POCT vehicles, outline new approach of POCT for ELFT infections, discuss safety topics related to renewable standards for evaluating and treating ELFT patients.

10:00 Improving Patient Care through Decentralizing
Molecular Diagnostic Tests for Infectious Diseases

John Clarkson, Ph.D., CEO, Atlas Genetics Ltd.

Diagnostic test accuracy and turn-around time are vital characteristics in the fight against infectious diseases. Decentralizing diagnostic tests to the doctors' office, specialist clinics or hospital ER can improve response time and increase test coverage of the population. In this presentation, attendees will gain an understanding of recent developments in decentralized diagnostics and what aspects of the system specification will drive clinical uptake.

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10:15 Manufacturing Innovation for POC Devices

Erol Harvey, Ph.D., CEO, miniFAB

Microfluidics has matured to a point where production volumes reach into the millions per annum, and products are achieving market success. This journey to maturity has included many lessons, such as understanding the division of function between consumable and re-usable components. Dr Harvey's presentation will discuss key design and manufacturing principles that, when considered, optimize the chances of commercial success.

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10:30 Coffee Break in Exhibit Hall with Poster Viewing

» PLENARY KEYNOTE SESSION: See page 3 for details.

12:40 pm Luncheon Presentation: Empowering
In-Office Treatment Decisions with Point-of-Care
Molecular Diagnostic Testing

Shana Kelley, Ph.D., CTO, Xagenic Inc.

Ihor Boszko, Vice President, Business Development, Xagenic Inc.

Point-of-care MDx testing is finally available in 2015, and it unlocks a huge opportunity for improvement of clinical outcomes and reduction of healthcare costs by delivering better diagnostic tools for physicians. Xagenic has developed the enzyme-free, highly multiplexed Xagenic X1™ platform that boasts a time to result of 20 minutes with a low cost of adoption. Our strategy will bring to market a menu of infectious disease tests with greatest utility for clinical decision-making during the initial patient visit.

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1:10 Close of Enabling Point-of-Care Diagnostics

Pushing Discovery to Advance Clinical Translation

RECOMMENDED PRE-CONFERENCE SHORT COURSES*

SC4: Biomarkers for Cancer Immunotherapy

SC8: Detection and Characterization of Circulating Biomarkers

*Separate registration required, please see page 3 for details

TUESDAY, AUGUST 18

7:30 am Main Conference Registration & Morning Coffee

IDENTIFYING AND PRIORITIZING MARKERS

8:30 Chairperson's Opening Remarks

Jennifer Morrisette, Ph.D., Scientific Director, Clinical Cytogenetics Laboratory;
Clinical Director, Center for Personalized Diagnostics (CPD), University of
Pennsylvania Perelman School of Medicine

8:40 Phylomics®: From Omics to Personalized Medicine

Hakima Amri, Ph.D., Associate Professor; Vice President, Phylomics LLC; Co-
Director, Physiology and CAM Graduate Programs, Biochemistry and Cellular and
Molecular Biology, Georgetown University School of Medicine.

9:10 Ranking Omics Data to Discover Biomarkers

Corrado Priami, Ph.D., President & CEO, The Microsoft Research and University of
Trento Centre for Computational and Systems Biology

An approach based on ranking of measurements is presented to identify patient
signatures. The signature can be used to define biomarkers with respect to
diseases, stratification of patients with respect to interventions or even toxicology
of drugs with respect to doses and number of deliveries. I will present the
approach and I'll show examples of its application.

9:40 Databases and Case Review: An In-House Developed Program
for a Mid-Sized Academic Laboratory

Jennifer Morrisette, Ph.D., Scientific Director, Clinical Cytogenetics Laboratory;
Clinical Director, Center for Personalized Diagnostics (CPD), University of
Pennsylvania Perelman School of Medicine

Laboratories are increasingly moving into next generation sequencing (NGS) as
the costs have decreased and the technologies have become more robust. There
are many choices of how to process and analyze data coming off the machine,
some sequencer-specific analysis tools, commercial entities and in-house
solutions. This talk will describe a laboratory developed LIMS system, covering
sample management, analysis and reporting developed for identification of
abnormalities in DNA and RNA used in a clinical laboratory setting.

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

CIRCULATING BIOMARKERS

10:55 Chairperson's Remarks

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

11:00 Circulating MicroRNAs and Other Nucleic Acids in Treatment
Monitoring

Anton Wellstein, M.D., Ph.D., Professor, Oncology, Georgetown University

This talk will describe the methodology of microRNA analysis from the circulation
and application to treatment monitoring. Potential pathway specific findings will
also be discussed.

11:30 Detection and Analysis of DNA/RNA Biomarkers from
Hematological Cancer, Solid Tumors and TBI Patient Samples

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

Fluorescent detection of ccf-DNA/RNA biomarkers from CLL, solid tumor and TBI
patient blood and plasma samples (20-100ul) is achieved in 10-15 minutes using an
AC dielectrophoretic (DEP) microarray. For CLL, PCR and sequencing results are
comparable to "gold standard" procedures. Fragment size analysis is being carried
to determine apoptotic and necrotic origins of CLL and solid tumor ccf-DNA,
which may ultimately have important diagnostic value.

12:00 pm NGS of Circulating
Tumor Cells from the CELLSEARCH® System

Charles Saginario, Ph.D., Scientist, CRS Labs, Janssen Diagnostics

Sponsored by



CLINICAL ANALYSIS OF NGS SAMPLES

12:30 Epigenetic Profiling of DNA Methylation to Categorize Breast
Tumor Aggressiveness

Adam Marsh, Ph.D., Associate Professor, Bioinformatics and Computational
Biology, University of Delaware

Women with triple-negative genotypes for the 3 common marker mutations for
breast cancer are still at significant risk for this disease. We identify a suite of
differentially methylated CpG sites between Normal and Tumor breast tissues that
indicate a high degree of epigenetic conservation among different triple-negative
patients who have developed aggressive breast tumors. Subtle epigenetic shifts in
methylation status may provide a key line of evidence for assessing tumor risk and
deciding between surgery or therapy.

1:00 Luncheon Presentation: Targeted NGS
Analyses of Clinical Samples for SNPs, CNVs, Gene
Fusions and More

Joe Don Heath, Ph.D., Vice President, Market Development Diagnostics, NuGEN

A novel approach for custom targeted sequencing of both DNA and RNA will
be described. Sensitive variant detection in genomic DNA derived from fresh
and FFPE tissues will be demonstrated as well as utilization of the enrichment
technology as a rapid, cost-effective tool for the discovery of novel gene fusions
and the detection of known, clinically-relevant gene fusions using a 500+ cancer
gene screening panel.

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Pushing Discovery to Advance Clinical Translation

1:30 Refreshment Break in the Exhibit Hall with Poster Viewing

PATIENT STRATIFICATION USING NGS DATA

2:00 Chairperson's Remarks

Louis Fiore, M.D., Executive Director, MAVERIC, Boston VA Healthcare System

2:05 The Department of Veterans Affairs Precision Oncology Program

Louis Fiore, M.D., Executive Director, MAVERIC, Boston VA Healthcare System

The VA Precision Oncology Program systematically genotypes cancer patients and enrolls them into a cohort so that they can be matched to biomarker-driven clinical trials. This talk presents a collaborative model for integration of research and clinical care. The program addresses important issues such as bringing clinical trials to patients, identification of cases across a network of hospitals, sharing of clinical data with research partners and collection of patient-centered and patient-reported outcomes.

2:35 NGS for Patient Screening and Treatment Selection for NCI's MPACT and Match Trials

P. Mickey Williams, Ph.D., Director, Molecular Characterization Laboratory (MoCha), Frederick National Laboratory for Cancer Research

3:05 Predictive Biomarkers for Targeted Cancer Therapy

Baolin Zhang, Ph.D., Senior Investigator, Office of Biotechnology Products, Center for Drug Evaluation and Research, Food and Drug Administration

The ability to identify the subsets of patients with molecularly defined cancers could significantly improve patient outcome. This presentation will discuss the major challenges in the discovery, qualification and regulatory review of predictive cancer biomarkers. Emphasis will be placed on the recent efforts of the US Food and Drug Administration in facilitating the joint development of therapeutic products and *in vitro* companion diagnostic devices (IVDs) that are essential for the safe and effective use of the corresponding therapeutic products.

3:35 Automated Multimodal, High-Multiplex, Quantitative Molecular Platform Solution for Complicated Companion Diagnostics

Lily Kong, Senior Director, Assay Development, Qiagen

Clinicians across multiple disciplines are asking complex questions for tailored therapies. Automated multimodal, high-multiplex, quantitative PCR is the ideal next generation of MDx. Modaplex provides precise, robust and simple solutions to meet the needs of next generation cancer diagnostics and therapeutic modalities. We will discuss how our "All in One Tube" technology makes it possible to develop unique, highly multiplexed, multimodal, quantitative and qualitative IVDs to interrogate dozens of biomarkers in one tube. Using this, drug developers can capture the full value of their therapies.

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3:50 Driver-Map™ Panels: Quantitative, Multiplex PCR, Target Enrichment Based NGS for Drug Target Discovery

Gus Frangou, Ph.D., Director, Clinical Diagnostics, Cellecta Inc.

Driver-Map™ Biomarker Discovery Panels offer a novel high-throughput PCR based sequence enrichment platform to comprehensively assess the genomic landscape for both solid tumors and hematologic malignancies from archived FFPE, blood and bone marrow aspirate samples. Specifically, Driver-Map analyzes common genomic "hot spot" regions that are frequently mutated in 250 genes related to cancer treatment, prognosis and diagnosis. In addition, simultaneous quantitative target gene expression analysis using competitive multiplex-PCR amplicons for ~3000 genes and computational network modeling, facilitates the rapid identification of cancer driver genes or gene models, pathway analysis to identify commonalities across tumor type(s), and supporting pharmacogenetic information. The talk will provide insight into how this functional genomics pipeline can be used to expediently identify novel biomarkers and therapeutic targets for cancer *en masse*.

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CELLECTA

4:05 Refreshment Break in the Exhibit Hall with Poster Viewing

CHALLENGES AND SOLUTIONS FOR NGS LABS

4:50 PANEL DISCUSSION:

Moderator: Robert D. Daber, Ph.D., Director, Research and Development and Sequencing Operations, Bio-Reference Laboratories

Panelists: Avni B. Santani, Ph.D., Assistant Professor, Clinical Pathology, University of Pennsylvania School of Medicine; Scientific Director, Molecular Genetics Laboratory, The Children's Hospital of Philadelphia

Helen Fernandes, Ph.D., Director, Molecular Pathology, Pathology & Laboratory Medicine, Weill Cornell Medical College

- Selecting genes for new panels
- Informatics and analysis
- Building clinical infrastructure ensure action on mutations

5:50 Wine & Cheese Pairing Welcome Reception in the Exhibit Hall with Poster Viewing

6:50 Close of Day

Pushing Discovery to Advance Clinical Translation

WEDNESDAY, AUGUST 19

7:15 am Registration

7:30 – 8:25 Problem-Solving Breakout Discussions
with Continental Breakfast

TRANSLATIONAL STRATEGIES AND CASE STUDIES

8:25 Chairperson's Opening Remarks

Robert D. Daber, Ph.D., Director, Research and Development and Sequencing Operations, Bio-Reference Laboratories

8:30 Utility of Implementing Clinical NGS Assays as Standard of
Care in Oncology

Helen Fernandes, Ph.D., Director, Molecular Pathology, Pathology & Laboratory Medicine, Weill Cornell Medical College

The presentation will address the practical processes that need to be adopted for a NGS-based assay to be run in a routine clinical laboratory. The topics will address specific challenges encountered from the preanalytical to the analytical and postanalytical phases of the process. Details on achieving libraries with optimal quality from various types of specimens will be discussed. Factors that affect the implementation of the analytical process and the variability encountered in the interpretation of variants will be highlighted. Strategies for recognizing and dealing with the barriers will be included.

9:00 Development and Implementation of Clinical NGS Testing:
Assay Development and Informatic Challenges

Robert D. Daber, Ph.D., Director, Research and Development and Sequencing Operations, Bio-Reference Laboratories

As genomic technologies continue to advance and new bio-markers emerge, rapid NGS assay development becomes critical in the age of Precision Diagnostics. Here we will discuss emerging methods to capture important biological markers and their associated informatic challenges during both the development and implementation phases.

9:30 Implementation of Clinical Exome Sequencing

Avni B. Santani, Ph.D., Assistant Professor, Clinical Pathology, University of Pennsylvania School of Medicine; Scientific Director, Molecular Genetics Laboratory, The Children's Hospital of Philadelphia

With the advent of next generation sequencing (NGS), diagnostic laboratories are faced with unprecedented challenges in incorporating this technology in the clinical setting. This presentation will provide a comprehensive overview on the key considerations for implementation of clinical exome sequencing including resource allocation, assay development, compliance, bioinformatics, data management, analysis and interpretation of data.

10:00 Qualitative and Quantitative Tools for
Performance Monitoring in of NGS Tumor Profiling
Assays

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Russell Garlick, Ph.D., CSO, SeraCare Life Sciences

Biosynthetic mutation mixes for NGS assays are a powerful way to monitor the daily run performance—tracking both qualitative and quantitative measures. Unlike cell lines, biosynthetic mutation mixes offer a means to cover wide varieties of mutations and the ability to 'tune' them to specific allelic frequencies to evaluate the assay sensitivity and specificity. An overview of their development and use in a clinical setting will be discussed.

10:15 Sponsored Presentation (Opportunity Available)

10:30 Coffee Break in Exhibit Hall with Poster Viewing

» **PLENARY KEYNOTE SESSION:** See page 3 for details.

1:25 Refreshment Break in the Exhibit Hall with Poster Viewing

1:50 Chairperson's Opening Remarks

» **2:00 KEYNOTE PRESENTATION: Monitoring the Cancer
Genome in Plasma Using Circulating Tumor DNA**

Nitzan Rosenfeld, Ph.D., Senior Group Leader, CRUK-CI, University of Cambridge; CSO, Inivata, Ltd.

Circulating cell-free tumor DNA (ctDNA) can be used to probe cancer genome dynamics via plasma samples. When a biopsy is unavailable, ctDNA can be used as a 'liquid biopsy' to assess sensitivity and resistance to targeted therapies. Quantification of ctDNA is informative for cancer prognosis, response or relapse. If cancer progresses, cancer evolution can be studied noninvasively by genome-wide analysis of ctDNA in plasma.

3:00 Close of Predictive Cancer Biomarkers

Strategy, Partnerships, Technology and Adoption

RECOMMENDED SHORT COURSES*

SC9: Regulatory Compliance in Molecular Diagnostics**SC12: Regulatory and Reimbursement Considerations with NGS
and Other Multiplex Assays**

*Separate registration required, please see page 3 for details

TUESDAY, AUGUST 18

7:30 am Main Conference Registration & Morning Coffee

FROM BIOMARKERS TO DIAGNOSTICS

8:20 Chairperson's Opening Remarks

Kenneth Emancipator, M.D., Executive Medical Director, Molecular Biomarkers and Diagnostics, Merck Research Laboratories» 8:30 Extracting Added Value from Clinical Trials
through Systematic Pharmacogenomic Research*Kenneth Emancipator, M.D., Executive Medical Director, Molecular Biomarkers and Diagnostics, Merck Research Laboratories**Rebecca Blanchard, Ph.D., Executive Director, Genetics and Pharmacogenomics, Head, of Clinical Pharmacogenomics, Merck & Co., Inc.*

Clinical development activities provide drug companies with opportunities to identify genomic variants associated with disease, pharmacological mechanisms and biomarkers predictive of drug response. This genomic information can be leveraged to identify new drug targets, optimize drug leads, determine patients most likely to benefit from drug treatment, and to develop companion diagnostics. This presentation will focus on a systematic approach to identifying predictive biomarkers of drug response, possible impact of such findings on drug development strategy, and ultimate development of companion diagnostics.

9:10 Creating and Managing the Multiple Interfaces of Drug/
Diagnostic Co-Development*George A. Green IV, Ph.D., Group Director, Pharmacodiagnostic Center of Excellence, Bristol-Myers Squibb**Andrea H. Lauber, Ph.D., Executive Director, Business Development, Clinical Biomarkers and Pharmacodiagnosics, Bristol-Myers Squibb*

BMS works closely with external partners to co-develop diagnostic products for our pipeline therapies. The pharmacodiagnostic strategy for each therapeutic asset is developed based on medical need, biomarker science, assay performance and value creation. Partnering facilitates access to the diverse capabilities needed to execute on this strategy. Key partner capabilities considered include biomarkers, technologies, manufacturing and commercialization expertise, and up-to-date regulatory and reimbursement policies; aimed at providing benefits of companion products to clinical practice. We will explore some of challenges and benefits that Rx/Dx collaborations bring to the industry.

9:40 Successful Co-Commercialization of Companion Diagnostics: A
Conversation between Pharma & Diagnostics*Cecilia Schott, Head, Personalized Healthcare, Corporate Development & Ventures, AstraZeneca**Sushma Selvarajan, Head, Business Development & Strategy, Roche Diagnostics*

Roche AstraZeneca (AZ) and Roche Diagnostics have a broad agreement to develop and commercialize companion diagnostics (CoDx) for AZ drugs. The speakers will share key learnings related to pre-commercial planning to enable the successful combined launch of a drug with its CoDx test, including early discussions around product requirements, target customers, educational efforts, reimbursement and co-promotion. The key message is to align early around shared commercial objectives to ensure long-term success.

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

EARLY VS. LATE STAGE DRUG/DIAGNOSTICS CO-
DEVELOPMENT

10:55 Chairperson's Remarks

*William Pignato, Founder and Principal, W.J. Pignato & Associates, LLC*11:00 Challenges with Early Co-Development of Rx/CDx: A
Companion Diagnostics Perspective – From a Large Pharma Point of
View*Peggy Carter, Ph.D., Global Head, Drug Regulatory Affairs, Novartis Companion Diagnostics*

In the ideal situation, the therapy and the companion diagnostic would be co-developed starting as early in the development process as possible; but there are challenges. I will discuss some of these challenges and some strategies that have been employed to overcome them.

11:20 Strategic Considerations of Which Clinical Development Stage
To Start Selecting Patients*Jocelyn A. Holash, Ph.D., Vice President, Translational Sciences, BioClin Therapeutics, Inc.*

I will discuss the pros and cons of implementing patient selection strategies early or late in the drug development process, how this decision will affect the development of a CDx and why small companies might make different decisions than larger companies.

11:40 pm PANEL DISCUSSION: Challenges and Opportunities in
Drug/CDX Co-Development: Early vs. Late Stage Development*Moderator: William Pignato, W.J. Pignato & Associates, LLC*

- Designing Co-Development Strategy in Early Stages
- Coordinating Drug and Diagnostics Development throughout the Process
- Working with Regulators
- Planning Out Market Access Strategies

*Panelists:**Peggy Carter, Ph.D., Novartis Companion Diagnostics**Jocelyn A. Holash, Ph.D., BioClin Therapeutics, Inc.**Mark Monane, M.D., Chief Medical Officer, CardioDx, Inc.*

Strategy, Partnerships, Technology and Adoption

12:10 Next Generation Sequencing in CDx Development

Leeona Galligan, Ph.D., Head, Laboratory Operations, Almac Diagnostics

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The presentation will examine the potential use of NGS as a companion diagnostic and cover the development, validation and CLIA commercial delivery of a NGS based assay. A case study will be presented focusing on the development of a P53 sequencing assay.

12:30 Universal Testing for Actionable Genomic Variants in Cancer: A Paradigm Shift in Precision Oncology

Karen Gutekunst, Ph.D., Vice President, Diagnostic Development, Illumina

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Dr. Gutekunst's presentation will focus on the potential of Next Generation Sequencing to impact cancer care and will describe Illumina's activities to enable broad adoption of the technology.

1:00 Luncheon Presentation: Accelerating NGS-based Diagnostic Development Using Strategic Science: Leveraging FDA's Expedited Access Pathway Program

Kennon Daniels, Ph.D., Senior Consultant, In Vitro Diagnostics Regulatory Affairs, Precision for Medicine

Judi Smith, Vice President, In Vitro Diagnostics Regulatory and Quality, Precision for Medicine

The FDA's Expedited Access Pathway (EAP) program presents a unique opportunity for companies developing innovative NGS-based diagnostics to accelerate market access. Successfully navigating the EAP requires an integrated, multi-disciplinary effort with expert knowledge in technology, science, regulatory and analytics to offer next-generation solutions. Using "Strategic Science" and leveraging the regulatory strategy from the Data Development Plan, companies can more easily link pre- to post-market clinical trial data leading to more efficient clinical trials – ultimately saving time and money.

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1:30 Refreshment Break in the Exhibit Hall with Poster Viewing**KEYNOTE SESSION: COMPANION DIAGNOSTICS
IN THE CLINIC****1:55 Chairperson's Remarks**

Mitch Raponi, Ph.D., Senior Director, Molecular Diagnostics, Clovis Oncology

2:00 Testing for Cancer Heterogeneity

Marc Ladanyi, M.D., Chair, Molecular Oncology, Memorial Sloan-Kettering Cancer Center
NGS offers a powerful tool for assessment of molecular defects found in cancer. The utilization of NGS is becoming common practice in clinical laboratories. This complex technology requires a new level of analytical performance testing and validation. This discussion will focus on approaches used for analytical validation of the NGS clinical assay used for treatment selection in the NCI-MPACT Study.

2:30 Liquid Biopsies for Cancer Detection and Characterization

Victor E. Velculescu, M.D., Ph.D., Professor, Oncology; Co-Director, Cancer Biology, Johns Hopkins Kimmel Cancer Center

Analyses of cancer genomes have revealed mechanisms underlying tumorigenesis and new avenues for therapeutic intervention. In this presentation, I will discuss lessons learned through the characterization of cancer genome landscapes, challenges in translating these analyses to the clinic, and new technologies that have emerged to analyze molecular alterations in the circulation of cancer patients as cell-free tumor DNA. These approaches have important implications for non-invasive detection and monitoring of human cancer, therapeutic stratification, and identification of mechanisms of resistance to targeted therapies.

**CO-DEVELOPMENT OF DRUGS AND MULTIPLEX
COMPANION DIAGNOSTICS****3:00 Evolution of a Therapeutic and Its Companion Diagnostic: The Search For Improved Patient Outcomes Through Better Predictive Tests, A Case Study**

Catherine Lofton-Day, Ph.D., Principal Scientist, Amgen

Predictive biomarkers are difficult to identify during the course of drug development but can provide great improvements in patient outcomes. Maintaining an active biomarker program after drug approval can further define patient response and provide data to support new therapeutic indications and more effective diagnostics. Monoclonal antibody therapies targeting EGFR and associated RAS biomarkers will be discussed as a case study for biomarker evolution and global management of drug/diagnostic pairs.

3:30 Companion Diagnostic Assay Development: A Perspective from a Global IVD Company

Chris Moriarty, Global Manager, Randox Pharma Sciences, Business Development, Randox Biosciences

The majority of IVD cleared diagnostics currently in routine clinical use utilize automated clinical chemistry or immunoassay platforms as they offer ease of use, low cost per test and widespread adoption in clinical labs...key features for any CDx. With this in mind the speaker will present an overview on technical considerations, regulatory pathway and platform solutions for CDx assay development.

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3:45 Positioning Your Companion Program for Global Success

Gary Gustavsen, Vice President, Personalized Medicine Practice, Health Advances LLC

Based on experiences from recent companion programs, it is clear that a "one size fits all" approach is insufficient when commercializing a companion diagnostic worldwide. This dynamic field fundamentally requires complete drug-companion diagnostic commercialization strategies and this session will analyze several key methods to optimize your strategy.

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4:15 Refreshment Break in the Exhibit Hall with Poster Viewing**4:45 Development and Application of a NGS-Based Companion Diagnostic for Prospective Identification of Ovarian Cancer Patients Likely to Respond to Rucaparib**

Mitch Raponi, Ph.D., Senior Director, Molecular Diagnostics, Clovis Oncology

A uniquely integrated translational-clinical program (Assessment of rucaparib in ovarian cancer trials; ARIEL) is ongoing to identify endometrioid and HGSOc patients who may benefit from rucaparib treatment. A test for HRD that identifies both BRCA

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defects and genome-wide loss of heterozygosity (LOH), or "BRCAness," has been developed in collaboration with Foundation Medicine and is being prospectively tested in the ARIEL2 study. The ARIEL program was developed to enable prospective validation of a novel NGS-based companion diagnostic for rucaparib in both the treatment (ARIEL2) and maintenance (ARIEL3) settings. This presentation will discuss the development of the HRD test and results from the ARIEL2 study.

5:15 IncellPrep™, Liquid-Biopsy Technology Generates a Cell Suspension Sample Out of Fresh or FFPE Tissue

Bruce Patterson, M.D., CEO, Incell Dx, Inc.

IncellPrep™ creates a cell suspension from fresh or FFPE tissue that can then be used with IncellDx's Cellular Multiplex™, a quantitative, flow cytometric diagnostic approach, that allows multiplexing of proteins using antibodies, mRNA by in situ hybridization, and DNA cell cycle. Morphologic measurements can be determined as well providing a multiparameter, quantitative alternative to IHC.

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5:30 NGS-Based Companion Diagnostics Assays – FDA Perspective

Abraham Tzou, M.D., Medical Officer, Center for Devices and Radiological Health, Food and Drug Administration

The advent of next generation sequencing (NGS) has introduced new challenges to the existing regulatory paradigm for companion diagnostic devices in oncology. To date, all of the approved DNA-based companion diagnostics are single gene tests for specific indications. In contrast, NGS-based tests can identify variants, which may or may not be pre-specified, in numerous genomic regions for the therapeutic management of patients. To enable appropriate oversight of NGS tests in oncology, FDA is exploring new regulatory approaches.

5:50 Wine & Cheese Pairing Welcome Reception in the Exhibit Hall with Poster Viewing**6:50 Close of Day****WEDNESDAY, AUGUST 19****7:15 am Registration****7:30 – 8:25 Problem-Solving Breakout Discussions with Continental Breakfast****FROM CO-DEVELOPMENT TO CO-COMMERCIALIZATION****8:25 Chairperson's Opening Remarks**

Peter Collins, Chief Commercial Officer, Prematha Health

8:30 Foundation Medicine & Roche: Joining Forces to Transform the Field of Molecular Information in Oncology

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

9:00 Understanding The Challenges in Companion Diagnostic Development

Ron Mazumder, Ph.D., MBA, Global Head, R&D and Operations, Janssen Diagnostics, Janssen Pharmaceutical Companies of Johnson & Johnson

Choosing the right sample type, platform, and partner and synchronizing companion diagnostic development are critical for enabling precision medicine. I will present various learnings gained from executing on our companion diagnostics programs. The incorporation of diagnostics into proof of concept studies and immuno-oncology studies will also be discussed.

9:30 A Unified Approach to NGS-Based Oncology Companion Diagnostics Development

Dan Rhodes, Ph.D., Head, Oncology Strategy, Thermo Fisher Scientific

There is significant interest for the development of a multi-marker companion diagnostic product to support the increasing number of potential targeted therapeutic candidates. Discussion will cover the development of a next-generation sequencing approach to change the paradigm from one test for one drug to one test for many targeted therapies in the future.

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10:00 PANEL DISCUSSION: Co-Commercialization of Drugs and Diagnostics

Moderator: Peter Collins, Chief Commercial Officer, Prematha Health

- What is pharma looking for in a commercialisation partner for Dx
- What are the critical issues in making a Dx product globally available
- How to overcome the challenges of operating in a Parallel universes

Panelists:

Jonathan Pan, Ph.D., Head, Oncology Companion Diagnostic and Disease Strategy, Novartis Pharmaceuticals Corporation

Matthew J. Hawryluk, Ph.D., Foundation Medicine, Inc.

Ron Mazumder, Ph.D., MBA, Janssen

Panelist to be Announced, Thermo Fisher Scientific

10:30 Coffee Break in Exhibit Hall with Poster Viewing**» PLENARY KEYNOTE SESSION
See page 3 for details.****12:40 pm Luncheon Presentation: Rapid DNA Testing for Companion Diagnostics: Accelerating Clinical Trials and Expanding Markets**

Paul Lem, CEO and Founder, Spartan Bioscience Inc.

To fulfill its promise, personalized medicine will require rapid, inexpensive genetic tests for companion diagnostics. For clinical trials, these tests could improve study outcomes and speed up patient enrolment. Following drug approval, rapid genetic testing would make it faster and easier for patients to be prescribed the right drug for their genotypes. Currently, it takes days to weeks to get genetic results from central labs. Rapid genetic testing is a new advance, and one of the leaders is Spartan Bioscience. Spartan's on-demand DNA testing platform goes from sample to result in less than 1 hour. This presentation will discuss the benefits for patients, clinicians, and companies involved in drug commercialization.

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1:10 Close of Companion Diagnostics

Establishing Clinical Utility and Working with Payers

RECOMMENDED SHORT COURSES*

SC6: Establishing the Value of Diagnostic Tests**SC12: Regulatory and Reimbursement Considerations with NGS and Other Multiplex Assays**

*Separate registration required, please see page 3 for details

TUESDAY, AUGUST 18

7:30 am Main Conference Registration & Morning Coffee

FROM TECHNOLOGY CENTERED TO PATIENT
CENTERED ASSESSMENT

8:30 Chairperson's Opening Remarks

Lon Castle, M.D., CMO, Molecular Genetics and Personalized Medicine,
CareCore National» 8:40 KEYNOTE PRESENTATION: Advanced Diagnostics:
From Technology Centered to Patient Centered
AssessmentNaomi Aronson, Ph.D., Executive Director, Technology Evaluation Center (TEC),
Blue Cross Blue Shield Association

The classic model for assessing a genetic test begins with analytic validity, to clinical validity to clinical utility. How would a patient centered approach differ? First, begin assessment with clinical utility. What is the clinical decision at hand? What performance characteristics are needed to support decision-making? Second, make assessment comparative. What are the results of various testing strategies? Third, recognize that cost is a patient-centered outcome. What is the impact on value, affordability and access?

9:10 Long Day's Journey into Night - The Quest for Clinical Utility

Steven Gutman, M.D., Myraqa Strategic Advisor, Illumina, Inc.

Over the past ten years there has been an explosive increase in the number of biomarker assays available for the study and evaluation of human disease. To ensure stakeholders are able to use this growing menu of tests responsibly, there is a compelling need to understand the clinical utility of these assays. Unfortunately a surprising number of tests are plagued by inadequate information on clinical utility. This talk will focus on obstacles, challenges and opportunities for addressing this problem

9:40 Technology Assessment Best Practices: The Palmetto
GBA Perspective

Girish Putcha, M.D., Ph.D., Director, Laboratory Science, Palmetto GBA (MoIDX)

Palmetto's MoIDX is a pilot program launched in 2011 that attempts to make more transparent, consistent and robust the mechanisms by which molecular tests are coded, covered and reimbursed. During this presentation, we will briefly review the technical assessment process at MoIDX.

10:05 The Final Frontier: Securing Reimbursement from Payers

John Fox, M.D., Associate Vice President, Medical Affairs, Priority Health

Commercial payers are often the final hurdle in the reimbursement journey for new molecular tests. The type of information payers require in order to provide coverage—including what they are looking for in clinical utility studies—will be discussed. Attendees will also hear about how the opinions of technology assessment organizations, guidelines and specialty societies might influence payer decisions.

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

10:55 Chairperson's Remarks

11:00 Integrating Evidence into Practice: NCCN's Approach to
Guidelines Development

Joan S. McClure, Senior Vice President for Clinical Information and Publications, NCCN

Inclusion in guidelines frequently expedites payers' acceptance of new molecular technologies. Integrating effectiveness, risk, characteristics of supporting evidence, and cost permits selection of interventions based on the values of the patient and the clinician. Attendees will also find out about the nuances of balancing expert opinion with the information available in the published literature and how each can contribute to the final decision.

11:15 AHRQ Approaches for Diagnostics Technology Assessment and
Case Studies

Elise Berliner, Ph.D., Director, The Technology Assessment Program, AHRQ

The Agency for Healthcare Research and Quality (AHRQ) provides technology assessments to CMS to inform coverage decisions and other policy questions. This session will describe the methods used by AHRQ for technology assessment, particularly methods relevant to the critical appraisal of diagnostic tests.

11:30 pm 2015 and Beyond! Reimbursement
Lessons for Another Year

Kyle Fetter, Vice President, Advanced Diagnostics, XIFIN, Inc.

Rina Wolf, Vice President, Strategic Commercialization, Consulting & Industry
Affairs, XIFIN, Inc.

This session will highlight any updates on PAMA, Medicare and commercial payor trends in coverage and pricing, and what labs should be looking out for this year, and beyond.

12:00 PANEL DISCUSSION: TO PAY OR NOT TO PAY, THAT IS THE
QUESTION: Different Perspectives on the Reimbursement Hurdles
for New TechnologiesModerator: Lon Castle, M.D., CMO, Molecular Genetics and Personalized
Medicine, CareCore National

- Hear what organizations believe are the key elements of clinical utility
- Discover how assessments from CMS and guideline organizations influence payers' decisions
- Understand how payers ultimately decide whether or not to include new tests
- Determine whether their approach will meet these goals—or if they need to refine their tactics

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Establishing Clinical Utility and Working with Payers

Panelists:

Naomi Aronson, Ph.D., Executive Director, Technology Evaluation Center (TEC),
Blue Cross Blue Shield Association

Steven Gutman, M.D., Myraqa Strategic Advisor, Illumina, Inc.

Girish Putcha, M.D., Ph.D., Director, Laboratory Science, Palmetto GBA (MoLDX)

John Fox, M.D., Associate Vice President, Medical Affairs, Priority Health

Joan S. McClure, Senior Vice President for Clinical Information and Publications, NCCN

Elise Berliner, Ph.D., Director, The Technology Assessment Program, AHRQ

**1:00 Luncheon Presentation (Sponsorship Opportunity Available) or
Enjoy Lunch on Your Own****1:30 Refreshment Break in the Exhibit Hall with Poster Viewing**

CHALLENGES AND SOLUTIONS

2:00 Chairperson's Remarks

Speaker to be Announced, XIFIN

2:05 POC Test and PAMA: Challenges to the Industry

Ester Stein, Director, Corporate Reimbursement, Abbott Molecular

Point-of-care testing (POCT) is a small, innovative but growing area of the U.S. healthcare system. The driving concept behind POCT is that it provides convenient and immediate testing to the patient and accelerates the availability of diagnostic test results to enable healthcare professionals to make treatment decisions sooner. Protecting Access to Medicare Act of 2014 is the first major reform to the Clinical Laboratory Fee Schedule since 1984, which will create environmental changes to the laboratory community. This presentation will examine how this new market based system may impact the point of care testing segment.

**2:35 Reimbursement for Multi-Analyte Assays: Different Ways to
Clinical Utility Data and Improved Health Outcome Data, a Case
Study on Prospective Study Design in Molecular Diagnostics**

Bastiaan Van Der Baan, Vice President, Clinical Affairs, Agendia

Clinical utility as it is defined by payers continues to be an ongoing challenge for diagnostic reimbursement professionals as there are often variations in the way that payers view this data. With most diagnostic companies following the ACCE model system for collecting, analyzing and disseminating information, payers still interpret data from clinical utility studies differently, making the review process feel wearisome and somewhat subjective for reimbursement professionals.

**3:05 Whole Exome Sequencing in the Clinic: The Test Reimbursed,
What Have You Done For Me Lately?**

Mark E. Nunes, M.D., Associate Professor, Pediatrics, Division Chief, Medical Genetics, Kaiser Permanente

The majority of clinical whole exome sequencing (WES) return "not positive," creating challenges for the genetic counselor. However, positive WES results create just as many vexing challenges for the ordering specialist. The Diagnostic and Treatment Odyssey continues in most cases, and the mechanisms for accomplishing and paying for this, outside the academic setting, are not established. This gap in Personalized Medicine is discussed, in contrast to targeted next generation sequencing (NGS) panels.

**3:35 Commercializing Advanced Diagnostics:
Challenges, Strategies, and Finding Paths to Success**

Brian Gorin, Managing Principal, Analysis Group

Evidence requirements for coverage, reimbursement and uptake of advanced diagnostics are on an ever increasing trajectory. Developers need to articulate clear value propositions as early in development as possible. These propositions must be supported by well-designed and thoughtful evidence strategies. Even when these activities are well executed, successful commercialization faces significant risk. Upcoming changes to the regulatory and reimbursement processes in the U.S. will better align diagnostic approval and reimbursement with market forces. Hear about how companies are managing these challenges.

4:05 Refreshment Break in the Exhibit Hall with Poster Viewing

POLICIES REVIEW AND WHAT IS AHEAD

4:50 PAYER PANEL DISCUSSION:

Moderator: Andrew C. Fish, Executive Director, AdvaMedDx

- Payer evidence expectations
- Making the case for clinical utility
- Contrasting diagnostics with therapies
- When does cost matter?
- Interplay of Medicare and private payer policies

Panelists:

Arthur Lurvey M.D., Contractor Medical Director, JE Noridian Healthcare Solutions

Tamara Syrek Jensen, Director, Coverage and Analysis Group, CMS (Invited)

John Fox, M.D., Associate Vice President, Medical Affairs, Priority Health

Chris L. Jagmin, M.D., Senior Medical Director, National Medical Policy and Operations, Aetna

Mark E. Nunes, M.D., Division Chief, Medical Genetics, Kaiser Permanente

**5:50 Wine & Cheese Pairing Welcome Reception in the Exhibit Hall
with Poster Viewing****6:50 Close of Day**

WEDNESDAY, AUGUST 19

7:15 am Registration**7:30 – 8:25 Problem-Solving Breakout Discussions with
Continental Breakfast**

CASE STUDIES AND FDA-CMS PARALLEL REVIEW

8:25 Chairperson's Opening Remarks

Yarmela Pavlovic, Partner, Hogan Lovells US LLP

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Establishing Clinical Utility and Working with Payers

8:30 Genomic Testing: A Case Study in Maximizing Value in Hereditary Condition Screening

Chris L. Jagmin, M.D., Senior Medical Director, National Medical Policy and Operations, Aetna

The growing technical scope of genomic testing can allow for additional low penetrance markers to be explored at the same cost as previous testing for a more confined set of markers. How should insurance companies manage this capability? We created a two-tier system to allow for members to receive either the focused or expanded genomic panel at no additional cost to the members.

9:00 Bringing Cologuard to Market: What It Takes to Work Simultaneously with FDA and CMS

John Ridge, Senior Director, Managed Care and Reimbursement, Exact Sciences
Sandra Statz, Vice President, Clinical, Quality & Regulatory, Exact Sciences

9:10 FDA-CMS Parallel Review Pilot – Cologuard™

Joseph Chin, M.D., M.S., Senior Medical Advisor, Acting Deputy Director, Coverage and Analysis Group, Centers for Medicare & Medicaid Services, US Department of Health & Human Services

This presentation will feature the CMS perspective on review of Cologuard™ in the FDA-CMS Parallel Review Pilot Program. It will discuss CMS involvement and specific requirements that needed to be met for CMS to expedite the national coverage determination process.

9:20 FDA-CMS Parallel Review – FDA Perspective

Nina Hunter, Ph.D., Regulatory Scientist, Division of Molecular Genetics and Pathology, Food and Drug Administration (FDA)

On August 11, 2014, FDA approved Cologuard, the first stool-based colorectal screening test. Concurrently, CMS issued a proposed national coverage determination for Cologuard. Cologuard is the first product reviewed through a joint FDA-CMS pilot program known as parallel review where the agencies concurrently review medical devices to help reduce the time between the FDA's approval of a device and Medicare coverage. A description of the program can be found at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm409021.htm>

9:30 PANEL DISCUSSION: Lessons Learned from the Pilot Program

Moderator: Yarmela Pavlovic, Attorney at Law, Hogan Lovells US LLP

The existing FDA-CMS pilot parallel review program is currently slated to continue accepting applicants until December 2015. Hear from participants (FDA, CMS and Exact Sciences) from the one successful case study of parallel review regarding their experiences with the program as they engage in discussion around the benefits and challenges. The panel discussion will cover the following topics:

- Recommendations for companies considering the process, including factors to evaluate in determining whether to apply
- Planning for participation – how to make the most out of the process
- Evolution of the program – any changes to be expected in the future?

Panelists:

John Ridge, Senior Director, Managed Care and Reimbursement, Exact Sciences
Sandra Statz, Vice President, Clinical, Quality & Regulatory, Exact Sciences
Nina Hunter, Ph.D., Regulatory Scientist, Division of Molecular Genetics and Pathology, Food and Drug Administration (FDA)

10:00 Sponsored Presentation (Opportunity Available)

10:30 Coffee Break in Exhibit Hall with Poster Viewing

» PLENARY KEYNOTE SESSION
See page 3 for details.

1:10 Close of Coverage and Reimbursement of Advanced Diagnostics

Exploring Technical Mechanisms and Medical Utility

RECOMMENDED SHORT COURSES*

SC3: Practical Considerations for NGS Data Analysis and Interpretation**SC7: NGS as a Diagnostics Platform****SC12: Regulatory and Reimbursement Considerations with NGS and Other Multiplex Assays****Separate registration required, please see page 3 for details*

TUESDAY, AUGUST 18

7:30 am Main Conference Registration & Morning Coffee

TECHNICAL CONSIDERATIONS FOR
NGS ASSAY DESIGN

8:30 Chairperson's Opening Remarks

8:40 NCI Clinomics Program: Clinical Cancer Panel and Exome Sequencing and Beyond

Jimmy Lin, M.D., Ph.D., MHS, Director, Clinical Genomics, Genetics Branch, Center for Cancer Research, National Cancer Institute (NCI), National Institutes of Health (NIH)

At the NCI Center for Cancer Research, the ClinOmics Program has been established to perform systematic molecular, genomic, transcriptomic, proteomic, metabolomics and other high throughput (³Omics²) profiling on tumor and normal tissues on enrolled patients treated at the CCR and other NCI divisions for the identification of biomarkers and targets for therapy. I will highlight the technical considerations for our validation and design rationale for our assays.

9:10 Considerations for Optimizing Results with Ion Proton Sequencing

Todd E. Arnold, Ph.D., Managing Director, Mount Sinai Genetic Testing Laboratory; Genetics and Genomic Sciences, Icahn Institute for Genomics and Multiscale Biology
The presentation will discuss important elements for sequencing assays run on the Ion Proton Platform. Topics will include assay design parameters, sample preparation, quality metrics, and multiplexing.

9:40 Rapid Turnaround Inherited Disease Panel in the NICU

Rong Mao, M.D., FACMG, Associate Professor, Pathology, University of Utah School of Medicine; Medical Director, Molecular Genetics and Genomics, ARUP Laboratories

Within the 4000 known single gene disorders, a significant fraction manifests symptoms during the newborn period. A rapid diagnosis of newborn diseases could make the difference between life and death and reduce length of stay in the neonatal intensive care unit (NICU). A targeted 4200 known disease causing gene panel has been developed with a short turnaround and a focused interpretation combining genetics etiology with phenotype will provide a comprehensive clinical understanding of disease in NICU.

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

NGS ASSAY VALIDATION AND ANALYSIS

10:55 Chairperson's Remarks

Justin Zook, Ph.D., Researcher, National Institute of Standards and Technology (NIST)

11:00 Genome in a Bottle: You May Have Sequenced, but How Well Did You Do?

Justin Zook, Ph.D., Researcher, National Institute of Standards and Technology (NIST)
Clinical laboratories, research laboratories and technology developers all need DNA samples with reliably known genotypes in order to help validate and improve their methods. The Genome in a Bottle Consortium (www.genomeinabottle.org) has been developing reference DNA standards with high-accuracy whole genome sequences to help support these efforts internationally.

11:30 From Gene Panels to Exome Sequencing - Validation and Implementation of NGS Assays in the Clinic

Matthew Lebo, Ph.D., FACMG, Director, Bioinformatics; Assistant Laboratory Director, Personalized Medicine Laboratory for Molecular Medicine, Partners Healthcare; Instructor, Pathology, Brigham and Women's Hospital, Harvard Medical School

This presentation will give an overview of state of the art clinical NGS and discuss validation, clinical implementation and the migration from gene panels to exome sequencing for inherited disorders with clinical and genetic heterogeneity.

12:00 pm Strategies for the Validation of Next-Generation Sequencing-Based Multi-Gene Panels in Cancer Diagnostics including Copy Number Analysis

Martin P. Powers, M.D., Molecular Genetic Pathologist, Co-Lab Director; NYS Lab Director, InVita

When validating a multi-gene panel including copy number analysis, certain challenges may present themselves especially with regard to accuracy, precision, sample choice and verification of results. Strategies and proposed solutions to said problems will be presented in the framework of validating a multi-gene hereditary cancer panel.

12:30 Molecular Phenotyping Provides a Unique Insight into Health Assessment for Precision Medicine

Sponsored by
 METABOLON*Shaun Lonergan, Ph.D., Vice President, Precision Medicine, Metabolon*

Metabolon has developed a platform technology capitalizing on advances in mass spectrometry, proprietary software and database analysis to provide unprecedented insight into biochemical pathways. This capability can help assess an individual's health status. Along with information provided by whole genome or exome sequencing technologies, metabolite data provides ontology for determining genome wide associations. In precision medicine, this insight is critical to determining penetrance of a gene determinant of interest and relating it to health status.

Exploring Technical Mechanisms and Medical Utility

1:00 Luncheon Presentation: Ashion Analytics - The Process of Moving from a Research to a Commercial Genomics Lab*Michael Demeure, M.D., Executive Vice President and General Manager, Ashion Analytics*

Precision genomic profiling of tumors from patients with rare or refractory cancers offers prospects for improved survival and cost savings by directing patients toward more effective or less toxic chemotherapeutic regimens. Ashion Analytics has performed over 100 large panel (562 genes) somatic germline subtraction tests on Illumina platform with an average coverage of 400x tumor and 180x germline. Actionable targets associated with FDA approved drugs or clinical trials were seen in 88% of patients.

**1:30 Refreshment Break in the Exhibit Hall with Poster Viewing****NGS PLATFORMS FOR TRANSLATIONAL MEDICINE****2:00 Chairperson's Remarks***David I. Smith, Ph.D., Professor, Laboratory Medicine & Pathology, Mayo Clinic***2:05 Exploring Next-Generation Sequencing Data: Targeted vs. Genomic Approaches***Pinar Bayrak-Toydemir, M.D., Ph.D., Medical Director, Molecular Genetics and Genomics Laboratory, ARUP; Associate Professor, Pathology, University of Utah School of Medicine***2:35 Novel Targeted NGS Test for Retinal Dystrophy Empowers Precision Medicine***John Chiang, Ph.D., FACMG, Director, Casey Molecular Diagnostics Laboratory, Oregon Health and Science University*

As molecular diagnosis becomes an integral component of clinical diagnosis of retinal dystrophy, the methods through which clinicians are granted insight into the molecular mechanisms underlying clinical presentation are rapidly evolving. The recent emergence of NGS offers an exciting new avenue for more comprehensive molecular diagnosis of complex inherited conditions like Retinal Dystrophy (RD). To this end we have developed a high quality and cost effective test for patients who present with RD. This clinical offering has been used to interrogate the underlying molecular mechanisms involved in the presentation of RD in over 700 patients up to date. Implementation of this Next Gen Dx has improved our understanding of the genes contributing to RD, is leading to improved patient care and offers certain patients the opportunities to be enrolled in clinical trials.

3:05 Next-Generation Sequencing Platforms: Where We Are and Where We're Going*David I. Smith, Ph.D., Professor, Laboratory Medicine & Pathology, Mayo Clinic*

I will briefly discuss the history of next generation sequencing and the various platforms that were developed using massively parallel sequencing. I will then discuss the current state of next generation sequencing and how these technologies are going to quickly transform clinical practice.

3:35 MyAML™ Next-Generation Sequencing (NGS) Assay Associates with Clinical Outcomes*Brad Patay, M.D., CMO, Genecision*

Demonstrate how Genecision's MyAML CLIA- and CAP-accredited next generation sequencing assay identifies clinically actionable pathogenic mutations in 194 acute myeloid leukemia (AML) genes. Give examples comparing conventional karyotyping and how a NGS assay outperforms standard cytogenetics by detecting novel fusion partners and cryptic translocations. Demonstrate actionability of MyAML assay showing links to clinical trials and druggable targets. Finally, the session will highlight compliance with secondary findings concepts from recent ACMG and AMP recommendations.

4:05 Refreshment Break in the Exhibit Hall with Poster Viewing**CLINICIAN PERSPECTIVE ON THE POTENTIAL FOR NGS****4:50 Using Genome Sequencing in the Clinical Setting***Jason Merker, M.D., Ph.D., Co-Director, Stanford Clinical Genomics Service; Assistant Professor, Pathology, Stanford University School of Medicine*

Health care providers are more frequently using genome and exome sequencing to evaluate patients with unexplained heritable disease. I will describe our experience establishing a clinical genomics service at an academic medical center. I will then discuss our initial efforts to use genome sequencing to identify the molecular etiology in patients with unexplained pediatric syndromes, heritable cardiovascular disease, heritable cancer predisposition, and heritable drug reactions

5:20 The NGS Cost Equation in Cancer Care: Are We at the Tipping Point?*German Pihan, M.D., Staff Pathologist & Director, Hematopathology Lab, Pathology, Beth Israel Deaconess Medical Center*

The cost-effectiveness of exome sequencing (WES) in the diagnosis, risk assessment and, particularly, therapy of cancer remains undetermined. This talk will address this very important issue and propose guidelines for the development of data-driven algorithms predicting cost-effective implementation of WES.

5:50 Wine & Cheese Pairing Welcome Reception in the Exhibit Hall with Poster Viewing**6:50 Close of Day****WEDNESDAY, AUGUST 19****7:15 am Registration****7:30 – 8:25 Problem-Solving Breakout Discussions with Continental Breakfast**

Exploring Technical Mechanisms and Medical Utility

TRANSLATIONAL STRATEGIES AND CASE STUDIES

8:25 Chairperson's Opening Remarks

Robert D. Daber, Ph.D., Director, Research and Development and Sequencing Operations, Bio-Reference Laboratories

8:30 Utility of Implementing Clinical NGS Assays as Standard of Care in Oncology

Helen Fernandes, Ph.D., Director, Molecular Pathology, Pathology & Laboratory Medicine, Weill Cornell Medical College

The presentation will address the practical processes that need to be adopted for a NGS-based assay to be run in a routine clinical laboratory. The topics will address specific challenges encountered from the preanalytical to the analytical and postanalytical phases of the process. Details on achieving libraries with optimal quality from various types of specimens will be discussed. Factors that affect the implementation of the analytical process and the variability encountered in the interpretation of variants will be highlighted. Strategies for recognizing and dealing with the barriers will be included.

9:00 Development and Implementation of Clinical NGS Testing: Assay Development and Informatic Challenges

Robert D. Daber, Ph.D., Director, R&D and Sequencing Operations, Bio-Reference Laboratories

As genomic technologies continue to advance and new bio-markers emerge, rapid NGS assay development becomes critical in the age of Precision Diagnostics. Here we will discuss emerging methods to capture important biological markers and their associated informatic challenges during both the development and implementation phases.

9:30 Implementation of Clinical Exome Sequencing

Avni B. Santani, Ph.D., Assistant Professor, Clinical Pathology, University of Pennsylvania School of Medicine; Scientific Director, Molecular Genetics Laboratory, The Children's Hospital of Philadelphia

With the advent of next generation sequencing (NGS), diagnostic laboratories are faced with unprecedented challenges in incorporating this technology in the clinical setting. This presentation will provide a comprehensive overview on the key considerations for implementation of clinical exome sequencing including resource allocation, assay development, compliance, bioinformatics, data management, analysis and interpretation of data.

10:00 Presentation to be Announced

Sponsored by



10:15 Sponsored Presentation (Opportunity Available)

10:30 Coffee Break in Exhibit Hall
with Poster Viewing

» PLENARY KEYNOTE SESSION
See page 3 for details.

1:10 Close of Clinical NGS Assays

Advancing Microbial Diagnostics Technologies to Improve Detection and Patient Outcome

WEDNESDAY, AUGUST 19

10:30 am Registration

» PLENARY KEYNOTE SESSION
See page 3 for details.12:40 pm Luncheon Presentation: Empowering
In-Office Treatment Decisions with Point-of-Care
Molecular Diagnostic Testing

Shana Kelley, Ph.D., CTO, Xagenic Inc.

Ihor Boszko, Vice President, Business Development, Xagenic Inc.

Point-of-care MDx testing is finally available in 2015, and it unlocks a huge opportunity for improvement of clinical outcomes and reduction of healthcare costs by delivering better diagnostic tools for physicians. Xagenic has developed the enzyme-free, highly multiplexed Xagenic X1™ platform that boasts a time to result of 20 minutes with a low cost of adoption. Our strategy will bring to market a menu of infectious disease tests with greatest utility for clinical decision-making during the initial patient visit.

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Xagenic

1:25 Refreshment Break in the Exhibit Hall with Poster Viewing

MOLECULAR POINT-OF-CARE TESTING FOR ID

1:50 Chairperson's Opening Remarks

Kate Simon, Ph.D., Senior Consultant, Biologics Consulting Group, Inc.

2:00 Point-of-Care Is Invading Microbiology

Nathan A. Ledeboer, Ph.D., D(ABMM), Assistant Professor, Medical Director, Clinical Microbiology, Medical College of Wisconsin

The point-of-care molecular assays being released exhibit variable sensitivity and specificity. This session will explore the utility of various assays for the point-of-care market from the standpoint of outcomes, contribution to value added care, and assay performance.

NEW & IMPROVED MOLECULAR TESTING – CLINICAL
APPLICATION & EVALUATION

2:30 The Impact of Molecular Tests on the Management of Pneumonia

Thomas M. File, Jr., M.D., MSc, MACP, FIDSA, FCCP, Chair, Division of Infectious Disease, Summa Health System; Professor, Internal Medicine, Master Teacher, Chair, Infectious Disease Section, Northeast Ohio Medical University

The utility of standard diagnostic studies to determine the etiologic agents of pneumonia has been controversial in part because of the lack of rapid, accurate, easily performed, and cost-effective methods. Advancements in molecular testing methods have brought forth new potentials for diagnosis which might allow results for most patients at the initial point of service, including in an office setting, and result in better patient outcomes.

3:00 Host Gene Expression Classifiers Diagnose Acute Respiratory
Illness Etiology

Ephraim L. Tsalik, M.D., MHS, Ph.D., Assistant Professor, Medicine, Division of Infectious Diseases, Center for Applied Genomics & Precision Medicine, Medicine, Duke University School of Medicine

Host gene expression changes are specific to the offending pathogen class. Their ability to discriminate common etiologies of respiratory illness is quantifiable and robust. This creates an opportunity to develop and utilize gene expression classifiers as novel diagnostic platforms with broad downstream implications.

3:30 A Molecular Host Response Assay to
Discriminate Between Infection-Positive and Infection-
Negative Systemic Inflammation in Critically Ill Patients

Therese Seldon, Vice President, Operations, Immunexpress

Sponsored by
Immunexpress

Traditional diagnosis of sepsis is based on detecting pathogens from microbial culture. Newer molecular methods of pathogen detection continue to emerge, yet miss an important part of the sepsis diagnostic picture; the ability to trust a negative result. Analysis of the host immune response provides an alternative approach to diagnosing sepsis. SeptiCyte® Lab, a new host response test showed an area under curve >0.9 with better performance than Procalcitonin in a large, prospective, multisite study.

4:00 Refreshment Break in the Exhibit Hall with Poster Viewing

NGS SEQUENCING FOR ID

4:45 NGS Assays for Diagnosis of Infectious Diseases

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

There is great interest and potential in the use of metagenomic next-generation sequencing (NGS) for diagnosis of infectious diseases in clinical settings. We will discuss assay development, clinical validation, bioinformatics analysis, and regulatory considerations involved when developing such NGS-based assays in CLIA-certified laboratories. We will also discuss emerging rapid, point-of-care sequencing technologies and host-based approaches for infectious disease diagnosis.

5:15 Genomic Insights into the Epidemiology of Healthcare-
Associated Infections

Evan Snitkin, Ph.D., Assistant Professor, Microbiology and Immunology, Medicine, Division of Infectious Diseases, University of Michigan Medical School

Whole-genome sequencing provides the ultimate resolution in molecular typing. This resolution is yielding critical insights into the spread of healthcare-associated infections and will have a major impact on the future of infection prevention.

5:45 Regulatory Perspective on Infectious Disease NGS Dx Devices

Heike Sichtig, Ph.D., Medical Countermeasures / Multiplex, Microbiology Devices, Center for Devices (CDRH), FDA

The presentation will outline studies to evaluate the use of NGS-based devices as an aid in Infectious Disease diagnostics, and to gain a better understanding of potential NGS clinical implementation strategies.

6:15 Close of Day

6:00 Dinner Short Course Registration

6:30- 8:30 pm RECOMMENDED DINNER SHORT COURSE*

SC11: NGS for Infectious Disease Diagnostics

*Separate registration required, please see page 3 for details

Advancing Microbial Diagnostics Technologies to Improve Detection and Patient Outcome

THURSDAY, AUGUST 20

7:30 – 8:25 am Problem-Solving Breakout Discussions with
Continental Breakfast

NGS SEQUENCING FOR ID

8:25 Chairperson's Opening Remarks

Reiner Babel, Ph.D., Executive Director, Consulting, RBDC

8:30 Whole Genome Sequencing of Microbes in the Clinical Laboratory

Randall J. Olsen, M.D., Ph.D., Associate Member, Center for Molecular and Translational Human Infectious Diseases Research, Houston Methodist Research Institute

I will discuss how we routinely use whole genome sequencing in our clinical laboratory to assign a taxonomic classification to unknown organisms, assess genetic relationships among epidemiologically linked strains, and identify the molecular basis of severe, unusual or interesting infections.

8:50 Acute Life-Threatening Infections: Sequencing in Emergency

Ivan Brukner, Ph.D., Molecular Diagnostics Lab Director, Medical Diagnostics, Jewish General Hospital

The most common deadly viral, bacterial and fungal infections present in urine, plasma and SCF (cell-free DNA). Antithetical coverage of what can be done now, and which methods to use will be presented as well as a special overview of detecting unknown DNA pathogen and what is needed to cover RNA pathogens.

ANTIMICROBIAL RESISTANCE
– ANTIMICROBIAL STEWARDSHIP9:10 Antibacterial Resistance Leadership Group Master Protocol for
Diagnostic Studies: A Better Path Forward

Ephraim L. Tsalik, M.D., MHS, Ph.D., Assistant Professor, Medicine, Division of Infectious Diseases, Center for Applied Genomics & Precision Medicine, Medicine, Duke University School of Medicine

The Antibacterial Resistance Leadership Group (ARLG) prioritizes, designs, and executes clinical research that will reduce the public health threat of antibacterial resistance. Among the ARLG's pillars is the advancement of diagnostic testing, which in turn can decrease unnecessary antibacterial use, inform antibiotic stewardship, and positively impact on antibacterial resistance. The ARLG has developed a Master Protocol concept driven by the principle that one patient can contribute multiple samples for the simultaneous evaluation of multiple diagnostic platforms.

9:30 Relying on the Most Accurate System to
Diagnose Infections... Your Immune System

Eran Eden, CEO, MeMed

Bacterial and viral infections are often clinically indistinguishable, leading to antibiotic misuse. To address this challenge a pioneering test called ImmunoXpert™ was developed, which accurately distinguishes between bacterial and viral infections based on a patient's immune response. ImmunoXpert™ empowers physicians to make better antibiotic treatment decisions.

Sponsored by
 MeMed

9:45 Sponsored Presentation to be Announced

Sponsored by
 Streck

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

10:50 Utilizing Molecular Diagnostics to Enhance
Antimicrobial Stewardship

Jerod Nagel, Pharm.D., BCPS (AQID), Clinical Specialist, Infectious Diseases, Clinical Assistant Professor, Director Infectious Diseases Residency, University of Michigan Hospital and Health Systems, University of Michigan, College of Pharmacy

Antimicrobial stewardship programs have a dramatic impact on antimicrobial prescribing. Programs that incorporate molecular diagnostics as part of the decision paradigm, can improve timeliness of appropriate antimicrobial prescribing, reduce cost and improve patient outcomes. This presentation will examine the integration of molecular diagnostics within antimicrobial stewardship programs and the impact on antibiotic utilization.

11:10 Antibiotic Stewardship: A National Priority

Jean B. Patel, Ph.D., D(ABMM), Deputy Director, Office of Antimicrobial Resistance, Division of Healthcare Quality Promotion, CDC

As responsible stewards of antibiotics, we need to use antibiotics only when necessary and to use the right antibiotic when one is needed. These strategies not only improve patient outcomes but also prevent transmission of resistant pathogens. Novel diagnostics to identify an infectious agent, to detect resistance mechanisms and to guide definitive therapeutic decisions have the potential to significantly improve antibiotic use. In this presentation, we will discuss efforts to measure antibiotic use and where diagnostics can make the biggest impact.

DIRECT DETECTION FOR SEPSIS – NEXT STEPS

11:30 Novel Approaches to the Laboratory Diagnosis of Sepsis

Jennifer Dien Bard, Ph.D., D(ABMM), FCCM, Assistant Professor, Clinical Pathology, Keck School of Medicine, University of Southern California; Director, Clinical Microbiology Laboratory; Acting Director, Clinical Virology Laboratory, Pathology and Laboratory Medicine, Children's Hospital Los Angeles

Sepsis is associated with high morbidity and mortality. Prompt microbiological workup that guide appropriate antimicrobial therapy is essential for the optimization of patient outcome. Novel, innovative technologies have revolutionized the detection and identification of bloodstream pathogens in the laboratory. This session discusses approaches to rapid diagnosis of sepsis.

11:50 Integrative 'Omics Analysis of Sepsis: Biomarkers for
Improved Patient Management

Raymond J. Langley, Ph.D., Associate Research Scientist, Lovelace Respiratory Research Institute

Infection-induced severe sepsis patients who do not receive early therapy have a high mortality rate (55%). However, current diagnostics are fairly non-specific. We used an integrative 'omics approach to develop a clinico-metabolomic classifier to predict sepsis and the probability of death at the time of presentation.

Advancing Microbial Diagnostics Technologies to Improve Detection and Patient Outcome

**12:20 pm Luminex® ARIES™ and NxTAG™
Platforms—The New Standard for Clinical
Diagnostics***Sherry Dunbar, Ph.D., Director, Scientific Affairs, Luminex Corporation*

Learn the latest in Luminex Technology. ARIES™, the sample-to-answer real-time PCR platform of the future, integrates seamlessly into the molecular diagnostics lab, increasing efficiency and productivity. NxTAG™, our next generation multiplexing technology for MAGPIX®, provides a closed-tube solution for bead-based multiplexing, with streamlined workflow and robust performance. We will share the latest updates on these exciting new platforms, including some preliminary data from clinical sample testing.

12:35 Sponsored Presentation (*Opportunity Available*)**12:50 Luncheon Presentation** (*Sponsorship Opportunity Available*) **or
Enjoy Lunch on Your Own****1:20 Session Break****DIRECT DETECTION FOR SEPSIS (CONT'D)****2:00 Chairperson's Remarks***Raymond J. Langley, Ph.D., Associate Research Scientist, Lovelace Respiratory Research Institute***2:05 Utility of the Abbott PCR/ESI-MS (Iridica) in Diagnostic
Microbiology: Results of a Multicenter Trial for the Rapid Diagnosis
of Sepsis**

Mark Wilks, Ph.D., Lead Clinical Scientist, Microbiology, Barts Health NHS Trust
Abbott PLEXiD (now Iridica) is the first commercially available CE marked system for the direct diagnosis of ID directly from the clinical specimen. A Europe wide multicentre trial has recently been concluded and should hopefully be published before the conference.

Sponsored by

Luminex**NOVEL TECHNOLOGIES & APPROACHES****2:35 Biologically-Inspired Engineering of the Human Innate Immune
System for the Diagnosis and Therapy of Infectious Diseases***Michael Super, Ph.D., Senior Staff Scientist, Advanced Technology Team, Wyss Institute, Harvard University*

We have engineered PAMPs-binding proteins (e.g. FcMBL) on solid supports to capture fungi, bacteria, viruses, parasites and toxins from complex media. We use the engineered FcMBL for pathogen identification using molecular and protein analysis and we have successfully treated septic rats and pigs using FcMBL in an extracorporeal dialysis-like-therapy (DLT).

3:05 Rapid Pathogen ID on Existing MALDI-TOF-MS Systems

David R. Goodlett, Ph.D., Issac E. Emerson Professor, Pharmaceutical Sciences, School of Pharmacy; Mass Spectrometry Facility Director, University of Maryland
UMB inventors have developed a lipid-based rapid, accurate and automatable method of pathogen detection that may be deployed on existing MALDI-TOF-MS instruments already becoming popular in diagnostic laboratories for pathogen identification based on high abundance protein profiles.

**3:35 PANEL DISCUSSION: Looking at the Future of Emerging
Technologies for Infectious Disease Detection and Diagnosis***Moderator: Michael Super, Ph.D., Senior Staff Scientist, Advanced Technology Team, Wyss Institute, Harvard University*

Panelists:

*Raymond J. Langley, Ph.D., Associate Research Scientist, Lovelace Respiratory Research Institute**Sherry Dunbar, Ph.D., Director, Scientific Affairs, Luminex Corporation**David R. Goodlett, Ph.D., Issac E. Emerson Professor, Pharmaceutical Sciences, School of Pharmacy; Mass Spectrometry Facility Director, University of Maryland***4:05 Close of Conference**

Enabling Non-Invasive Diagnostics

RECOMMENDED PRE-CONFERENCE SHORT COURSE***SC1: Use of FFPE/Fixed Tissues for Clinical Research**

*Separate registration required, please see page 3 for details

WEDNESDAY, AUGUST 19**10:30 Registration****» PLENARY KEYNOTE SESSION****See page 3 for details.****12:40 pm Luncheon Presentation: Precision-Based
Circulating Tumor DNA Detection in Gynecologic
Cancer Patients**Sponsored by
 RainDance
Technologies*John Martignetti, M.D., Ph.D., Genetics and Genomic Sciences, Pediatrics, Obstetrics/Gynecology & Reproductive Sciences and Oncological Sciences, Icahn School of Medicine at Mount Sinai*

We developed a rapid and efficient approach for variant discovery in gynecologic cancers which couples tumor-specific mutation identification to digital PCR-based ctDNA detection. We generated tumor mutation profiles for each of our ovarian and endometrial cancer patients and tested this pipeline to detect and monitor tumor status. All results were compared against current FDA-approved biomarkers and the known clinical status of the patients, demonstrating the highly sensitive, specific and robust nature of our approach.

1:25 Refreshment Break in the Exhibit Hall with Poster Viewing**OPENING SESSION****1:50 Chairperson's Opening Remarks****» 2:00 KEYNOTE PRESENTATION: Monitoring the Cancer
Genome in Plasma Using Circulating Tumor DNA***Nitzan Rosenfeld, Ph.D., Senior Group Leader, CRUK-CI, University of Cambridge; CSO, Inivata, Ltd.*

Circulating cell-free tumor DNA (ctDNA) can be used to probe cancer genome dynamics via plasma samples. When a biopsy is unavailable, ctDNA can be used as a 'liquid biopsy' to assess sensitivity and resistance to targeted therapies. Quantification of ctDNA is informative for cancer prognosis, response or relapse. If cancer progresses, cancer evolution can be studied noninvasively by genome-wide analysis of ctDNA in plasma.

3:00 Blood-Based Genotyping of Colorectal Cancer Patients*Giulia Siravegna, MSc, Ph.D. Student, Molecular Medicine, Oncology, School of Medicine, University of Torino; IRCCS-Candiolo Cancer Institute*

Liquid biopsy and cfDNA analysis allow genotyping of colorectal cancer (CRC) patients using a blood sample. CRC patients represent a model to assess whether blood analyses could in principle be used to perform diagnosis, to guide clinical decisions and to monitor the efficacy of therapies, establishing proof of principle that genotyping of cancer alleles in the patients' blood allows clinically valuable longitudinal assessment for patients.

**3:30 The Use of Multiplexed ICE COLD-PCR
Coupled to Multiple Downstream Analysis Platforms
for Detection of Low Level Sequence Alterations**Sponsored by
 Transgenomic®
Advancing Personalized Medicine*Katherine Richardson, Ph.D., Vice President, Research & Development, Transgenomic, Inc.*

The use of "liquid biopsies", where limited or no tumor tissue is available, is increasingly important for molecular demographics, diagnostics and pharmacodynamic monitoring of patients during therapy. The combination of MX-ICP with many different downstream analysis platforms means that efficient detection of alterations at $\leq 0.01\%$ in samples is feasible for most laboratories. Increased sensitivity using less DNA enables monitoring and detection of alterations in the low volumes of liquid biopsies for patient treatment, monitoring and surveillance.

4:00 Refreshment Break in the Exhibit Hall with Poster Viewing**NOVEL CLINICAL APPLICATIONS OF RARE MUTATION
DETECTION TECHNOLOGY****4:35 Chairperson's Introduction: PAP Smear Diagnostics for
Endometrial and Ovarian Cancers***Luis A. Diaz, M.D., Associate Professor, Oncology, Johns Hopkins Sidney Kimmel Comprehensive Cancer Center*

Dr. Diaz will introduce the topic and speakers of this session on novel clinical applications of rare mutation detection technology. He will also review findings from a study that demonstrates that DNA from most endometrial and a fraction of ovarian cancers can be detected in a standard liquid-based Pap smear specimen obtained during a routine pelvic examination.

**4:45 Circulating Cell-Free DNA and Circulating Tumor Cells as
Complementary Sources of Liquid Biopsy in Cancer Patients***Klaus Pantel, M.D., Professor and Founding Director, Institute of Tumor Biology, University Medical Center Hamburg-Eppendorf*

Circulating cell-free DNA and genomic DNA amplified from single circulating tumor cells harbor complementary information on mutations relevant for the treatment of individual cancer patients. Here the technical challenges and clinical implications of both approaches are discussed in the context of cancer therapy in patients with solid tumors.

5:15 Cell-Free DNA in Transplant Medicine*Kiran K. Khush, M.D., MAS, Assistant Professor, Medicine, Cardiovascular Medicine, Stanford University*

This presentation will review clinical applications of cell-free DNA testing in transplant medicine, specifically focusing on the non-invasive diagnosis of acute rejection, unbiased screening for pathogens, and measurement of overall level of immunosuppression. The focus will be on heart and lung transplantation, with illustrative cases.

Enabling Non-Invasive Diagnostics

5:45 Clonal Hematopoiesis and Blood-Cancer Risk Inferred from Exome Sequencing of Blood-Derived DNA

Giulio Genovese, Ph.D., Computational Biologist, Stanley Center for Psychiatric Research, Broad Institute

Clonal expansion in blood is readily detected from whole-exome sequencing of DNA in peripheral-blood cells, it most frequently involves somatic mutations in genes DNMT3A, ASXL1, and TET2, and is often a precursor in blood malignancies. While uncommon before 50 years of age, we observe it in a cohort of 12,380 subjects in more than 10% of individuals above 65 years of age.

6:15 Close of Day**6:00 Dinner Short Course Registration***

**Please see page 3 for details.*

THURSDAY, AUGUST 20**7:30 – 8:25 am Problem-Solving Breakout Discussions with Continental Breakfast****TECHNOLOGY FOR PROFILING cfDNA****8:25 Chairperson's Opening Remarks**

David S. B. Hoon, MSc, Ph.D., Chief of Scientific Intelligence, Director, Molecular Oncology, Director, JWCI Sequencing Center, John Wayne Cancer Institute

8:30 Whole Genome Sequencing of Plasma DNA in Patients with Cancer

Michael R. Speicher, M.D., Department Chair, Institute of Human Genetics, Medical University of Graz

To scan the tumor genomes of patients with cancer noninvasively we establish a genome-wide copy number profile of the tumor by whole-genome sequencing from plasma at a shallow sequencing depth. In parallel, we sequence a panel of high-interest genes and introns with frequent fusion breakpoints with high coverage. Data of patients with breast, colon, and prostate carcinoma will be presented.

9:00 Diagnostic Applications of Cell-Free DNA in Solid Organ and Bone Marrow Transplantation

Iwijn De Vlaminck, Ph.D., Assistant Professor, Biomedical Engineering, Cornell University

This talk will cover applications of cell-free DNA in the diagnosis of rejection in solid-organ transplantation, and Graft Versus Host Disease in bone marrow transplantation, as well as applications of cell-free DNA monitoring in the broad, hypothesis-free monitoring of infection.

9:30 Urinary Circulating Free DNA Platform for Diagnosis and Cancer Treatment Monitoring

Vlada Melnikova, Ph.D., Vice President, Research and Development, Trovogene Inc.

The concept of liquid biopsies is now expanding to include urine as a specimen type. Using DNA extraction process that isolates systemic cfDNA and PCR-NGS enrichment method for mutation detection, we demonstrate high clinical sensitivity for detection of genomic alterations across different cancer types. Accurate quantitation using validated protocols reveals that longitudinal dynamics of mutational load in urine correlates with disease burden and drug response, thus enabling development of novel algorithms to inform treatment decisions.

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precision cancer monitoring

10:00 Coffee Break in the Exhibit Hall with Poster Viewing**» 10:50 KEYNOTE PRESENTATION: Detection of Somatic Mutations in Biological Fluids in the Management of Cancer**

Nickolas E. Papadopoulos, Ph.D., Professor, Oncology Cancer Biology, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University

Somatic mutations are cancer specific biomarkers. Their detection in circulating free DNA or other biological fluids reveal the presence of cancer. However, their accurate detection can be technically challenging because they are present in a very small number of molecules. Here we discuss our efforts for developing sensitive methods for their detection and clinical applications in the management of cancer.

LIQUID BIOPSY- Comparing and Contrasting Circulating Biomarkers**11:20 PANEL DISCUSSION:**

Nitzan Rosenfeld, Ph.D., Senior Group Leader, CRUK-CI, University of Cambridge; CSO, Inivata, Ltd.

Klaus Pantel, M.D., Professor and Founding Director, Institute of Tumor Biology, University Medical Center Hamburg-Eppendorf

Luis A. Diaz, M.D., Associate Professor, Oncology, Johns Hopkins Sidney Kimmel Comprehensive Cancer Center

David S. B. Hoon, MSc, Ph.D., Chief of Scientific Intelligence, Director, Molecular Oncology, Director, JWCI Sequencing Center, John Wayne Cancer Institute

We will discuss the current challenges and future perspectives of CTCs and circulating nucleic acids (ctDNA, microRNA) as novel biomarkers in clinical oncology.

- Potential and pitfalls of current methods used for liquid biopsy (CTCs, ctDNA, miRNAs)
- Current areas of clinical applications of liquid biopsy (e.g., cancer screening, predicting outcome, monitoring therapies, discovering resistance mechanisms)
- Future developments required to move liquid biopsies into clinical management of cancer patients

12:20 pm Clinical Translation of cfDNA for Solid Organ Transplantation

John J. Sninsky, Ph.D., CSO, CareDx Inc.

For reimbursement, clinical translation of cfDNA for solid organ transplantation requires elevated levels of evidence (LOE). Examples of needed LOE that will be discussed include the rigor of implementation and maintained accuracy and reproducibility of a test in a CLIA laboratory and multi-center prospective trials for clinical validity and utility.

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Personalized Transplant Surveillance

Enabling Non-Invasive Diagnostics

12:35 Quantification of Circulating Biomarkers from Plasma and Serum Using AC Electrokinetics*Raj Krishnan, Ph.D., CEO, Biological Dynamics, Inc.*

Interest in the isolation, quantification, and analysis of cell-free biomarkers directly from blood has grown significantly. Biological Dynamics has developed proprietary platforms for isolating and quantifying large circulating biomarkers from physiological solutions using AC Electrokinetics (ACE). Biomarkers, such as necrotic cell-free DNA (ncfDNA), have been established as indicators of cancer, and the ability to detect and track these biomarkers unlocks a new era in early disease diagnosis and treatment response monitoring.

12:50 Luncheon Presentation: Clinical Experience Using EGFR Mutational Analysis in ctDNA and PDL-1 and c-MET in CTCs in the Treatment of Patients with Lung Adenocarcinoma*Lyle Arnold, Ph.D., Senior Vice President, R&D, CSO, Biocept**Hatim Husain, M.D., Assistant Professor, Medicine, UCSD Moores Cancer Center*

Liquid biopsies offer the opportunity to interrogate a number of different target sample types, including ctDNA and CTCs. At Biocept both ctDNA and CTCs are used for identifying medically actionable biomarkers to assist in the optimal treatment of patients. We will report on the combined use of PDL-1, c-MET, and EGFR mutation status in the treatment selection and monitoring of patients with lung cancer.

1:20 Session Break**CLINICAL APPLICATIONS IN ONCOLOGY****2:00 Chairperson's Remarks***Maximilian Diehn, M.D., Ph.D., Stanford University***2:05 An Ultrasensitive Method for Quantitating Circulating Tumor DNA with Broad Patient Coverage***Maximilian Diehn, M.D., Ph.D., Assistant Professor, Radiation Oncology, Stanford Cancer Institute, Institute for Stem Cell Biology & Regenerative Medicine, Stanford University*

This presentation will review the potential clinical utility of ctDNA analysis using Cancer Personalized Profiling by deep Sequencing (CAPP-Seq), a novel next-generation sequencing-based approach for ultrasensitive ctDNA detection. Applications of CAPP-Seq for the personalization of cancer detection and therapy are discussed.

2:35 Personalized Cancer Patient Monitoring with Plasma DNA Multimarker Analysis*Alain R. Thierry, Ph.D., Senior Investigator, Research Institute in Oncology of Montpellier, INSERM*

Based upon crucial observations on the structure and origins of circulating cell free DNA (cfDNA), we designed a specific method to analyze five different biomarkers on plasma DNA. Point mutation detection was the subject of the first clinical validation of the cfDNA analysis in oncology in a study on KRAS and BRAF mutation testing in metastatic colorectal cancer patient. We demonstrated that quantitative markers such the total cfDNA concentration, the mutant cfDNA concentration, the cfDNA mutation load and a fragmentation index are all strong prognostic factors. Lastly, we showed that point mutations initially at very low allele frequency (<0.1% in cfDNA) may confer resistance under subsequent targeted therapy suggesting the need for highly sensitive methods for theragnostics purpose as well as for patient follow up.

3:05 Circulating Tumor DNA (ctDNA) as a Non-Invasive Substitute to Metastasis Biopsy for Tumor Genotyping and Personalized Medicine in a Prospective Trial across All Tumor Types*Jean-Yves Pierga, M.D., Ph.D., Circulating Cancer Biomarkers Lab, SIRIC, Translational Research and Medical Oncology, Institut Curie and University Paris Descartes*

ctDNA analysis was an alternative to invasive biopsy of metastasis, irrespective of cancer type and metastatic site, for multiplexed mutation detection in a prospective Phase II trial in patients with different tumor types. This could allow selecting appropriate and optimal therapies based on the context of a patient's tumor genetic content.

3:35 Circulating Plasma Tumor DNA as a Biomarker for Individualized Medicine in Early Stage Breast Cancer*Ben H. Park, M.D., Ph.D., Associate Professor, Oncology, Johns Hopkins University*

Circulating plasma tumor DNA (ptDNA) could be used as a marker of minimal residual disease after surgery for early stage breast cancer. Using droplet digital PCR, we demonstrate that ptDNA can be detected preoperatively with 93.3% sensitivity and 100% specificity, and ptDNA can be detected postoperatively in patients without evidence of disease. The ability to use this information for clinical decision-making will be discussed.

4:05 Close of Conference

Ensuring Success of Innovative Tests

RECOMMENDED PRE-CONFERENCE SHORT COURSES*

SC2: Method Validation According to CLSI Guidelines

SC6: Establishing the Value of Diagnostic Tests

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

WEDNESDAY, AUGUST 19

10:30 Registration

» PLENARY KEYNOTE SESSION
See page 3 for details.

1:25 Refreshment Break in the Exhibit Hall with Poster Viewing

KEYNOTE SESSION

1:50 Chairperson's Opening Remarks

Scott M. Kahn, Ph.D., CSO, Oncostem Biotherapeutics, LLC.; Adjunct Associate Research Scientist, Urology, Columbia University; Chairman, Biomarkers Council, International Cancer Advocacy Network

» 2:00 KEYNOTE PRESENTATION: Precision Medicine for Adult Volunteers

C. Thomas Caskey, M.D., FACP, FACMG, FRSC, Professor, Molecular & Human Genetics, Baylor College of Medicine

Forty-five physicians and eighty-five Young Presidents' Organization members volunteered to participate in an educational program studying utility of whole genome sequencing. The study matched a molecular diagnosis to their medical history in 29% of volunteers. The utility and acceptance will be illustrated.

REVIEW OF THE STUDY OF MOLECULAR
TESTING ASSESSMENT

2:30 Private Payer Evaluation of Diagnostic Tests – A Survey of 50 Medical Directors and an Insider's Perspective on the Health Technology Assessment Process

John W. Hanna, MBA, Vice President, Endocrinology, Veracyte, Inc.

Melissa K. Bennett, MS, CGC, Clinical Director, Laboratory Management Program, CareCore National

This session presents results of a published study surveying 50 payer medical directors and evaluating their perceptions of the value of molecular diagnostics, understanding of diagnostic test evidence including clinical utility, and use of standardized health technology assessment (HTA) processes. CareCore will also discuss their standard processes for molecular test evaluation and the growing interest among private payers to outsource HTAs.

- Perception of the value molecular diagnostic
- Understanding of diagnostic study design

- Understanding of diagnostic test evidence evaluation, and in particular clinical utility
- The use of standard tech assessment groups like Hayes, etc. in evaluating products

3:30 Capture and Molecular Characterization of Viable Circulating Tumor Cells using a Novel Epitope Independent Micro-Fluidic Platform

Shane Booth, Ph.D., CTO, Research and Development, ANGLE plc

Sponsored by



4:00 Refreshment Break in the Exhibit Hall with Poster Viewing

CHALLENGES AND PROSPECTS AHEAD FOR LDTs

4:45 Regulatory Panel:

Moderator: Andrew C. Fish, Executive Director, AdvaMedDx

This session will review current issues related to FDA oversight of laboratory developed tests (LDTs) and offer perspectives from key stakeholders, including regulators, laboratories, manufacturers, and clinicians. The panel will discuss topics including the status and content of FDA proposed guidance on LDT oversight, any legislative and policy updates, evidence expectations regarding analytical and clinical validity, and compliance challenges.

Panelists:

Elizabeth A. Mansfield, Ph.D., Director, Personalized Medicine, FDA CDRH

Elissa Passiment, Executive Vice President, American Society for Clinical Laboratory Science (ASCLS)

Roger D. Klein, M.D., J.D., Pathologist, Molecular Pathology, Cleveland Clinic Foundation

Richard L. Schilsky, M.D., FACP, FASCO, CMO, American Society of Clinical Oncology

6:15 Close of Day

6:00 Dinner Short Course Registration

RECOMMENDED DINNER SHORT COURSE*

SC9: Regulatory and Reimbursement Considerations with NGS and Other Multiplex Assays

*Separate registration required, please see page 3 for details

Ensuring Success of Innovative Tests

THURSDAY, AUGUST 20

7:30 – 8:25 am Problem-Solving Breakout Discussions with
Continental BreakfastACCESS AND VALUE OF NGS DATA: DRIVING CLINICAL
DECISION MAKING ACROSS DISEASE AREAS

8:25 Chairperson's Opening Remarks

Harry Glorikian, Healthcare Consultant

8:30 A New Business Model in Laboratory Testing – Sharing Data

*Carl Morrison, M.D., DVM, Executive Director, Center for Personalized Medicine;
Director, Roswell Park Cancer Institute*

Prior models of revenue streams for laboratories have been almost exclusively from 3rd party payers for laboratory services provided. As laboratories move from traditional single analyte testing to comprehensive multi-analyte platforms the ability to generate 2nd and 3rd uses of this data has the ability to generate additional revenue streams. Dr. Morrison will present how his group is using this new business model to achieve new avenues of commercialization for laboratory testing through the OmniSeq program.

8:45 NGS: Filling in the Gaps

Erynn Gordon, MS, LCGC, Medical Marketing Director, 23andme

The use of Sanger sequencing and array based testing over the past few decades has made genetic testing available to patients with clear Mendelian disorders. However, the cost and time involved has been a burden to patients and many have been left without answers. NGS has shifted the genetic testing paradigm allowing many, if not all, genes to be queried at once.

9:00 New Knowledge from NGS and Big Data

Felix W. Frueh, Ph.D., CSO, Human Longevity, Inc.

The ability to integrate NGS in larger contexts of diverse health care data provides the opportunity to interpret the human genome at increased precision. Such interpretation creates the foundation for new knowledge (e.g. associations between genome-level data and clinical manifestations) that will drive clinical decision making in molecular medicine.

9:15 Improve Cancer Treatments by Incorporating the NGS Data of
Tumor Samples*Han Liang, Ph.D., Associate Professor and Deputy Chair, Bioinformatics and
Computational Biology, R. Lee Clark Fellow, The University of Texas MD Anderson
Cancer Center*

An important task in cancer research is how to accurately identify biomarkers and use them to predict the prognosis or drug responses of cancer patients. Using the genomic data from large-patient cohorts, we evaluated the power of diverse types of molecular data in predicting patient survivals and annotated the functional effects of mutational hotspots in clinically actionable genes across tumor types.

9:30 Cross-Industry Partnerships to Foster
Innovation and Decrease Manufacturing Time
to Market in the Biomedical Business*Ali Tinazli, Ph. D., Vice President, Head, Business Development & Sales, Sony
DADC Biosciences*

Smart Consumables based on polymer materials with microscale or supreme optical features are prerequisites for emerging applications in the biomedical markets as in *in vitro* diagnostics. The increasing complexity of such new product, including CMOS hybrid consumables, requires new manufacturing technologies.

9:45 Sponsored Presentation (Opportunity Available)

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

ACCESS AND VALUE OF NGS DATA

10:50 PANEL DISCUSSION:

Moderator: Harry Glorikian, Healthcare Consultant

- What are the value creation points for the data? How does the data make a difference in how someone is treated?
- Ensuring access to and organizing and managing data
- How are partnering deals structured? What are some key issues?
- How do you monetize the value of the data?
- Is the data more valuable than the technology that creates it?

*Panelists:**Carl Morrison, M.D., DVM, Center for Personalized Medicine; Roswell Park Cancer
Institute**Erynn Gordon, MS, LCGC, 23andme**Felix W. Frueh, Ph.D., Human Longevity, Inc.**Han Liang, Ph.D., The University of Texas MD Anderson Cancer Center*

12:20 pm Sponsored Presentation (Opportunity Available)

12:50 Luncheon Presentation (Sponsorship Opportunity Available) or
Enjoy Lunch on Your Own

1:20 Session Break

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Ensuring Success of Innovative Tests

SO YOU HAVE YOUR DIAGNOSTIC- NOW WHAT?

2:00 PANEL DISCUSSION: Clinical Informatics Needed to Ensure Implementation of Your Test

Moderator: Julie Lynch, Ph.D., MBA, RN, Principal Investigator, Veterans Health Administration

- How do you meet informatics requirements for your test
- Linking test results to pharmacy and EHR
- Guidelines for HIPAA compliance of your test with requirements
- How do you ensure utilization of test?

Panelists:

Terah B. Collins, Genomics Strategist, Cerner Corporation

Valentina I. Petkov, M.D., MPH, Health Scientist/Program Officer, Surveillance Research Pro-gram, Division of Cancer Control and Population Sciences National Cancer Institute

Danielle Chun, MPH, Genomics Informaticist, VINCI Services, VA

Scott Kulich, M.D., Ph.D., Associate Professor, Pathology, Division of Pathology and Division of Neuropathology, VA Pittsburgh Healthcare System (VAPHS)

3:30 Chairperson's Remarks

Ali Tinazli, Ph.D., Vice President, Head, Business Development & Sales, Sony DADC Biosciences

» 3:35 CLOSING KEYNOTE: Commercializing Personalized Medicine: It's All About the Value Proposition

Daryl Pritchard, Ph.D., Vice President, Science Policy, Personalized Medicine Coalition

A key barrier to the commercialization of personalized medicine products involves an unclear value proposition. Many factors are involved in value assessments, but determining what are the most important value drivers depends on who you are asking.

4:05 Close of Conference



Present a Poster & Save!

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 materials, your abstract must be submitted, approved and your registration paid in full by July 17, 2015

- Your research will be seen by leaders from top diagnostic technology developers and academic and government institutes
- Your poster abstract will be published in the conference materials
- Receive \$50 off your registration fee

Characterizing Tumor, Host and Tumor-Host Interaction

RECOMMENDED SHORT COURSES*

SC4: Biomarkers for Cancer Immunotherapy**SC12: Regulatory and Reimbursement Considerations with NGS and Other Multiplex Assays**

*Separate registration required, please see page 3 for details

WEDNESDAY, AUGUST 19

10:30 am Registration

» **PLENARY KEYNOTE SESSION**
See page 3 for details.

1:25 Refreshment Break in the Exhibit Hall with Poster Viewing

**DIAGNOSTICS TO GUIDE IMMUNOTHERAPY
BEYOND GENOMICS****1:50 Chairperson's Opening Remarks***Stephen Johnston, Ph.D., Co-Director, The Biodesign Institute, Innovations in Medicine, Professor, College of Liberal Arts and Sciences, School of Life Sciences, Arizona State University*» **2:00 KEYNOTE PRESENTATION: Diagnostics to Guide Immunotherapy Beyond Genomics***Sam M. Hanash, M.D., Ph.D., Professor, Molecular Pathology, Division of Pathology/Lab Medicine, The University of Texas MD Anderson Cancer Center*

Understanding the mechanisms of immune evasion exhibited by tumor cells is essential for effective immunotherapy. Defining these mechanisms extends beyond genomic characterization of tumors and requires elucidation of dynamic processes of altered metabolism and altered protein expression, localization, processing and presentation of antigens, leading to diagnostics to guide immunotherapy.

2:30 Deciphering The Diagnostic Landscape for PD-1/PD-L1 Checkpoint Inhibitors*Marcin Kowanetz, Ph.D., Biomarker Lead for Atezolizumab (anti-PDL1), Oncology Biomarker Development, Genentech, Inc*

Cancer immunotherapies provide long lasting and durable responses in patients. To identify patients who best respond to these therapies, development of diagnostic strategies become important particularly as more drugs enter clinical trials over the next decade. Emerging clinical data on PD-L1 as a predictive marker of monotherapy checkpoint inhibitors in NSCLC and UBC will be presented. Lastly, biomarkers that aid the rational development of combination strategies will be reviewed.

3:00 Biomarkers as Guide Posts in Patient Selection and Process Development of Chimeric Antigen Receptor-Directed T Cell Therapy*J. Joseph Melenhorst, Ph.D., Director, Product Development & Correlative Sciences Labs, Translational Research Program, Pathology and Laboratory**Medicine; Adjunct Associate Professor, Abramson Family Cancer Research Institute, Perelman School of Medicine, University of Pennsylvania*

T cells equipped with chimeric receptors (CAR) targeting tumors have evolved rapidly from a basic scientific tool to a new way in which we induce remission in patients with very poor risk cancer. The synergy between basic and translational science continues to further boost the utility of immunotherapy and enhance its potency in various forms of cancer. In my talk I will highlight recent developments in the field and conclude with how correlative studies may contribute to the success of this therapy.

3:30 Sponsored Presentation (Opportunity Available)**4:00 Refreshment Break in the Exhibit Hall with Poster Viewing****4:45 Development of an Immunohistochemistry Test for "Programmed Cell Death 1 Ligand" (PD-L1) as a Companion Diagnostic for Pembrolizumab***Marisa Dolled-Filhart, Ph.D., Director, Pathology and Companion Diagnostics, Molecular Biomarkers and Diagnostics, Clinical Flow Cytometry and Molecular Pathology, Merck & Co., Inc.*

Tumors express PD-L1 to contribute to escape from immunosurveillance. Pembrolizumab blocks this escape mechanism and thus effectively treats a number of cancers. The rapid clinical development of pembrolizumab required rapid development of an immunohistochemistry assay for PD-L1. Merck developed the assay initially to determine whether or not PD-L1 is a predictive biomarker, then to enrich clinical trials, and ultimately partnered with a diagnostics company to develop the assay as a companion diagnostic

5:15 Companion Diagnostics for Immune-Based Treatments of Cancer: The Role of Immunohistochemical Methods*Clive R. Taylor, M.D., Ph.D., Professor, Chairman of the Department of Pathology, USC Keck School of Medicine, Los Angeles*

Personalized medicine demands personalized pathology. Molecular, genomic and immunohistochemical (IHC) techniques have demonstrated the value of Companion Diagnostics' in classifying patients as 'responders' or 'non-responders' for targeted therapies, including immune based therapies. Many of the targets for immunotherapy are proteins and IHC is, in theory, the ideal method for their detection and measurement. This presentation addresses challenges that growing demand for quantitative Companion Diagnostics present for IHC.

5:45 Immunosignatures to Detect and Treat Cancer Early*Stephen Johnston, Ph.D., Co-Director, The Biodesign Institute, Innovations in Medicine, Professor College of Liberal Arts and Sciences, School of Life Sciences, Arizona State University*

Immunosignatures is a simple method to profile the antibodies in an individual. This platform diagnostic may be useful for diagnosing any disease, including cancer. It could be applied to stratify potential recipients of ICIs or to follow the course of response to treatment. We have also examined the ability of IMS to detect cancer at early stages. We will present data from mouse model on combining early detection with early ICI treatment.

6:15 Close of Day**6:00 Dinner Short Course Registration**

Characterizing Tumor, Host and Tumor-Host Interaction

6:30 - 8:30 pm RECOMMENDED DINNER SHORT COURSE***SC12: Regulatory and Reimbursement Considerations with NGS and Other Multiplex Assays**

*Separate registration required, please see page 3 for details

THURSDAY, AUGUST 20**7:30 – 8:25 am Problem-Solving Breakout Discussions with Continental Breakfast****PROGRAMMED CELL DEATH 1 LIGAND AND BEYOND****8:25 Chairperson's Opening Remarks**

David L. Rimm, M.D., Ph.D., Yale University

8:30 Measuring Immune Checkpoint Targets

David L. Rimm, M.D., Ph.D., Professor, Pathology, Executive Director, Translational Pathology, Director, Yale Pathology Tissue Services, Yale University

Immune checkpoint therapies, specifically PD-L1 axis drugs, are extremely promising showing durable response in high stage patients. However, they are effective on only a small percentage of the population; about 10-30% depending on tumor type. The assays to identify these patients has been challenging. Here we describe antibodies and assays that have been used to measure PD-L1 expression and also examine other variables that may help to predict response to therapy.

9:00 Adaptive Immune Resistance by Tumor: Biomarker Implications

Janis Taube, M.D., Assistant Professor, Departments of Dermatology and Pathology, Johns Hopkins School of Medicine

Immune resistance by tumor may have both adaptive and constitutive components, and both have mechanistic and biomarker implications. This talk will discuss our ongoing efforts to characterize further the local tumor microenvironment with the aim of improving patient selection and developing rational treatment combinations to overcome adaptive immune resistance.

9:30 Sponsored Presentation (Opportunity Available)**10:00 Coffee Break in the Exhibit Hall with Poster Viewing****10:50 PD-L1 Assays in Lung Cancer**

Fred R. Hirsch, M.D., Ph.D., Professor, Medicine and Pathology, University of Colorado Cancer Center; CEO, International Association for the Study of Lung Cancer (IASLC)

Immunotherapy for patients with advanced NSCLC has emerged as a very promising therapeutic avenue. Clinical studies indicate that patients with PDL-1 expressing tumors have a better response than those with PDL-1 negative tumors.

Several companies are pursuing PDL-1 assays, but they all seem to be different in terms of defining a PDL-1 positive tumor. The International Association for the Study of Lung Cancer (IASLC) is planning an international characterization study of the PDL-1 assays in order to get a better understanding of the comparability between the assays and their performance on different types of specimens (large specimens, small biopsies, cytology) and different platforms.

11:20 Principles of Checkpoint Blockade in Gastrointestinal Malignancies

Robert Albert Anders, M.D., Ph.D., Associate Professor, Pathology, Johns Hopkins School of Medicine

Patient tissue has been tied to patient prognosis since Cuthbert Duke's famous 1932 classification of colorectal cancer. The American Joint Committee on Cancer Tumor/Nodes/Metastases system refined and replaced the Dukes classification of colorectal cancers. Current efforts based upon the quality, quantity and location of the immune response to malignancy may provide more prognostic information. The development of immune check point inhibitors will be discussed in the setting of gastrointestinal cancers.

11:50 MDSC Clinical Assay as a New Diagnostic for Cancer

Alan L. Epstein, M.D., Ph.D., Professor, Pathology, University of Southern California, Keck School of Medicine

Myeloid derived suppressor cells have been found to correlate with tumor burden in thyroid and prostate cancer and may offer clinicians a new assay to assess tumor growth in patients undergoing treatment. The assay consists of a panel of three monoclonal antibodies used with flow cytometry on blood samples taken at the time of diagnosis or during therapy. Additional clinical trials in renal, bladder, and breast cancer are in progress.

12:20 pm Sponsored Presentation (Opportunity Available)**12:50 Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own****1:20 Session Break****2:00 Chairperson's Remarks**

Sriram Sathy, Ph.D., Director, Target and Biomarker Discovery, Jounce Therapeutics

Characterizing Tumor, Host and Tumor-Host Interaction

2:05 Developing a Multi-Parametric Approach For Biomarkers And Patient Enrichment Strategies In Immune-Oncology*Sriram Sathy, Ph.D., Director, Target and Biomarker Discovery, Jounce Therapeutics*

Clinical proof of concept has been demonstrated with agents such as anti-CTLA-4 and anti-PD-1. This success was facilitated by greater understanding of the mechanisms of the immune mediated tumor escape, including the role that T cell checkpoint inhibitors play in this process. Jounce is focused on developing cancer immunotherapies that are geared to provide durable clinical responses through identification of optimal targets for specific indications and for certain subsets, patients within those indications. Towards this goal we have developed a robust translational platform that allows for both target identification as well as patient/indication selection in an unbiased fashion. This approach relies on the fundamental principle of defining the immune system content and characteristics via a comprehensive multiple parameters approach. The talk will focus on multiple biomarkers that needs to be examined in the clinic to associate with response and explore available methodologies to address these biomarkers in the clinic.

2:35 Prediction of PD-1 Blockade Response by Adaptive Immune Resistance*Paul Tumeh, Ph.D., CSO, Dermatology, Acteris, Inc.*

Measurement of pre-existing CD8+ T cells distinctly located at the invasive tumor margin have been shown to reliably predict response to therapies targeting the PD-1/PD-L1 immune inhibitory axis. Moreover, tumor regression after therapeutic PD-1 blockade requires pre-existing CD8+ T-cells that are negatively regulated by PD-1/PD-L1-mediated adaptive immune resistance. This presentation will review the clinical analysis of patients with metastatic melanoma obtained before and during anti-PD-1 therapy (pembrolizumab) using quantitative immunohistochemistry and quantitative multiplex immunofluorescence.

3:05 Uncovering Rational Candidates for Novel Immuno-Oncological Therapies*Scott Rodig M.D., Ph.D., Pathology, Brigham & Women's Hospital and Dana-Farber Cancer Institute, Associate Professor, Pathology, Harvard Medical School*

PD1 blockade using human antibodies elicits potent anti-tumor immunity in a subset of patients with cancer. Novel agents targeting a broad array of additional immuno-modulatory proteins are now in early stage clinical trials for patients with advanced disease. We will describe the development and application of novel quantitative methods to identify and quantify critical immunological markers in tissue biopsy samples that serve to facilitate the selection of tumor types and patient populations that are most likely to benefit from specific, targeted immuno-therapies.

3:35 PANEL DISCUSSION: Enabling Immune Checkpoint Inhibitors Therapy*Moderator: David L. Rimm, M.D., Ph.D., Professor, Pathology; Executive Director, Translational Pathology, Director, Yale Pathology Tissue Services, Yale University*

- Discover novel immune checkpoints as antibody targets for cancer immunotherapy
- Validate predictive biomarkers
- Design and validate clinical assay

4:05 Close of Conference

Harnessing the Power of Genomic Information

WEDNESDAY, AUGUST 19

10:30 am Registration

» PLENARY KEYNOTE SESSION
See page 3 for details.

1:25 Refreshment Break in the Exhibit Hall with Poster Viewing

TACKLING INTERPRETATION AND
ANNOTATION CHALLENGES

1:50 Chairperson's Opening Remarks

Wayne W. Grody, M.D., Ph.D., UCLA School of Medicine

2:00 Annotation and Interpretation of Clinical Exome Sequencing

Wayne W. Grody, M.D., Ph.D., Professor, Medical Genetics and Molecular Pathology, Pathology & Lab Medicine, Pediatrics, and Human Genetics; Director, Molecular Diagnostic Laboratories and Clinical Genomics Center, UCLA School of Medicine

Our center has been performing clinical-grade whole-exome sequencing (WES) for the diagnosis of rare Mendelian disorders since January 2012. In addition to our in-house bioinformatics pipeline and externally available databases and algorithms, all mutations and variants are interpreted by a unique "Clinical Genomics Board" comprised of lab directors, technologists, bioinformaticists, genetic counselors, medical geneticists, and the ordering clinicians. We find that this approach provides the most "value-added" clinical insight for proper annotation and reporting of variants. As a result, definitive pathogenic variants were identified and reported in 27% of all cases, and likely pathogenic variants were detected in an additional 28%, producing an aggregate diagnostic yield of up to 55%.

2:30 Precision Medicine – Challenges Associated with Annotation and Interpretation of Somatic Mutation Data

Gregory J. Tsongalis, Ph.D., Director, Molecular Pathology; Professor, Pathology, Geisel School of Medicine, Dartmouth University

The past several years have seen a significant increase in the demand for somatic mutation testing in human cancers in order to specifically tailor therapeutic management strategies to specific patients. Many laboratories have begun testing for various numbers of mutations in large numbers of genes using massively parallel sequencing to provide genomic profiles that would direct therapeutic selection. This lecture will discuss the challenges associated with data analysis from the perspective of annotation and interpretation for routine clinical practice.

3:00 Interpretation of Exome Sequencing: Opening the Floodgates

Karen Weck, M.D., Professor of Pathology & Laboratory Medicine and Genetics, University of North Carolina, Chapel Hill

Massively parallel sequencing is an attractive modality for the diagnosis of genetic disorders. However, a major challenge with implementation in the clinical setting is interpretation of the huge numbers of genomic variants identified in an individual patient. The NCGENES (North Carolina Clinical Genomic Evaluation by Next-generation Exome Sequencing) project is evaluating the use of whole exome sequencing (WES) as a diagnostic tool in patients with a variety of suspected genetic conditions. We have established a priori diagnostic gene lists tailored to clinical phenotypes in order to streamline interpretation of genomic variants and increase the positive predictive value of WES. In this talk, I will define several categories of "uncertain" results that may be generated by WES and discuss strategies employed to adjudicate WES results. Defining the pathogenicity of individual variants is important, but it is also necessary to consider the phenotype to assess the overall diagnostic yield of such testing. Results of sequencing >400 patients indicate that diagnostic yield of WES is strongly influenced by the clinical indication for testing.

3:30 Sponsored Presentation (Opportunity Available)

4:00 Refreshment Break in the Exhibit Hall with Poster Viewing

CHALLENGES AND PROSPECTS AHEAD FOR LDTs

4:45 REGULATORY PANEL:

Moderator: Andrew C. Fish, Executive Director, AdvaMedDx

This session will review current issues related to FDA oversight of laboratory developed tests (LDTs) and offer perspectives from key stakeholders, including regulators, laboratories, manufacturers, and clinicians. The panel will discuss topics including the status and content of FDA proposed guidance on LDT oversight, any legislative and policy updates, evidence expectations regarding analytical and clinical validity, and compliance challenges.

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Roger D. Klein, M.D., J.D., Pathologist, Molecular Pathology, Cleveland Clinic Foundation

Richard L. Schilsky, M.D., FACP, FASCO, CMO, American Society of Clinical Oncology

6:15 Close of Day

6:00 Dinner Short Course Registration*

*Please see Page 3 for details

Harnessing the Power of Genomic Information

THURSDAY, AUGUST 20

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8:25 Chairperson's Opening Remarks

Harry Glorikian, Healthcare Consultant

8:30 A New Business Model in Laboratory Testing – Sharing Data

*Carl Morrison, M.D., DVM, Executive Director, Center for Personalized Medicine;
Director, Roswell Park Cancer Institute*

Prior models of revenue streams for laboratories have been almost exclusively from 3rd party payers for laboratory services provided. As laboratories move from traditional single analyte testing to comprehensive multi-analyte platforms the ability to generate 2nd and 3rd uses of this data has the ability to generate additional revenue streams. Dr. Morrison will present how his group is using this new business model to achieve new avenues of commercialization for laboratory testing through the OmniSeq program.

8:45 NGS: Filling in the Gaps

Erynn Gordon, MS, LCGC, Medical Marketing Director, 23andme

The use of Sanger sequencing and array based testing over the past few decades has made genetic testing available to patients with clear Mendelian disorders. However, the cost and time involved has been a burden to patients and many have been left without answers. NGS has shifted the genetic testing paradigm allowing many, if not all, genes to be queried at once.

9:00 New Knowledge from NGS and Big Data

Felix W. Frueh, Ph.D., CSO, Human Longevity, Inc.

The ability to integrate NGS in larger contexts of diverse health care data provides the opportunity to interpret the human genome at increased precision. Such interpretation creates the foundation for new knowledge (e.g. associations between genome-level data and clinical manifestations) that will drive clinical decision making in molecular medicine.

9:15 Improve Cancer Treatments by Incorporating the NGS Data of
Tumor Samples*Han Liang, Ph.D., Associate Professor and Deputy Chair, Bioinformatics and
Computational Biology, R. Lee Clark Fellow, The University of Texas MD Anderson
Cancer Center*

An important task in cancer research is how to accurately identify biomarkers and use them to predict the prognosis or drug responses of cancer patients. Using the genomic data from large-patient cohorts, we evaluated the power of diverse types of molecular data in predicting patient survivals and annotated the functional effects of mutational hotspots in clinically actionable genes across tumor types.

9:30 Cross-Industry Partnerships to Foster
Innovation and Decrease Manufacturing Time to
Market in the Biomedical Business*Ali Tinazli, Ph.D., Vice President, Head, Business Development & Sales, Sony
DADC Biosciences*

Smart Consumables based on polymer materials with microscale or supreme optical features are prerequisites for emerging applications in the biomedical markets as in *in vitro* diagnostics. The increasing complexity of such new product, including CMOS hybrid consumables, requires new manufacturing technologies.

9:45 Sponsored Presentation (Opportunity Available)

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

ACCESS AND VALUE OF NGS DATA

10:50 PANEL DISCUSSION:

Moderator: Harry Glorikian, Healthcare Consultant

- What are the value creation points for the data? How does the data make a difference in how someone is treated?
- Ensuring access to and organizing and managing data
- How are partnering deals structured? What are some key issues?
- How do you monetize the value of the data?
- Is the data more valuable than the technology that creates it?

*Panelists:**Carl Morrison, M.D., DVM, Executive Director, Center for Personalized Medicine;
Director, Roswell Park Cancer Institute**Erynn Gordon, MS, LCGC, Medical Marketing Director, 23andme**Felix W. Frueh, Ph.D., CSO, Human Longevity, Inc.**Han Liang, Ph.D., Associate Professor and Deputy Chair, Bioinformatics and
Computational Biology, R. Lee Clark Fellow, The University of Texas MD Anderson
Cancer Center*

12:20 pm Sponsored Presentation (Opportunity Available)

12:50 Luncheon Presentation (Sponsorship Opportunity Available) or
Enjoy Lunch on Your Own

1:20 Session Break

NGS ANNOTATION IN GENOMICS, GENETICS,
AND RNA-SEQ

2:00 Chairperson's Remarks

*Jamie L. Platt, Ph.D., Vice President, Genomic Solutions, Geneuity**Sponsored by
Sony DADC*

Harnessing the Power of Genomic Information

2:05 The NGS Annotation Landscape for Genomics, Genetics, and RNA-Seq: Current Challenges for Commercial Clinical Labs*Jamie L. Platt, Ph.D., Vice President, Genomic Solutions, Geneuity*

Advanced sequencing technologies are highly dependent on bioinformatics tools and appropriate interpretation. In addition to applying the optimized bioinformatic algorithms with specific, validated thresholds, transforming the data into clinically useful information requires appropriate annotation. The application typically dictates the knowledge base of choice as well as the clinical interpretation. Selecting or building the appropriate bioinformatics, annotation solutions and clinical interpretation are challenges for commercial clinical labs that will be discussed within the context of Genomics, Genetics, and RNA-Seq.

2:35 Joint Presentation: The VA Precision Oncology Program with N-of-One: Optimizing The Use of NGS Results to Enable a Partnership Between Clinical Care and Research*Louis Fiore, M.D., Executive Director, MAVERIC, Boston VA Healthcare System**Jennifer Levin Carter, M.D., CMO & Founder, N-of-One*

The Department of Veterans Affairs New England Healthcare system has recently launched the Precision Oncology Program. The Program offers targeted sequencing to all patients with non-small cell lung cancer and returns annotated results to clinicians for clinical care decision making. A research agenda adds clinical trial matching and data repository creation as value-added components of the Program. This presentation will focus on the process of clinical interpretation of the NGS results by N-of-One and the clinical use of those interpretations in the VA.

Sponsored by**3:05 Databases and Case Review: An In-House Developed Program for a Mid-Sized Academic Laboratory***Jennifer Morrisette, Ph.D., Scientific Director, Clinical Cytogenetics Laboratory, Clinical Director, Center for Personalized Diagnostics (CPD), University of Pennsylvania Perelman School of Medicine*

Genomic technologies have revolutionized clinical landscape of oncology, with the ability to detect mutations in many genes at relatively low cost. As more targeted therapies are available, both as FDA cleared treatments and in the clinical trial setting, more clinicians are demanding genomic data on their patient's tumors, looking for a therapy to exploit individualized for the mutations present in the tumor tissue. Laboratories are increasingly moving into next-generation sequencing (NGS) as the costs have decreased and the technologies have become more robust. There are many choices of how to process and analyze data coming off the machine, some sequencer-specific analysis tools, commercial entities and in-house solutions. This talk will describe a laboratory developed LIMS system, covering sample management, analysis and reporting developed for identification of abnormalities in DNA and RNA used in a clinical laboratory setting.

3:35 PANEL DISCUSSION: Annotation Whole Exome Sequencing and Panels: Practical Approaches*Moderator: Jamie L. Platt, Ph.D., Vice President, Genomic Solutions, Geneuity*

- Data analysis approaches and challenges in next-generation sequencing
- User-friendly and accurate databases: do they exist?
- Handling the incidentalome
- New requirements for informed consent

4:05 Close of Conference

Strategies for Implementation of Pharmacy-Based Point-of-Care Diagnostic Testing

WEDNESDAY, AUGUST 19

7:15 am Registration

TRENDS IN POCT - VISION OF THE FUTURE

8:25 Chairperson's Opening Remarks

Gyorgy Abel, M.D., Ph.D., Lahey Hospital & Medical Center

» 8:30 KEYNOTE PRESENTATION: Coming to a Lab Near You: Global Review of POCT

Gyorgy Abel, M.D., Ph.D., Director, Molecular Diagnostics, Immunology & Clinical Chemistry, Laboratory Medicine, Lahey Hospital & Medical Center

Clinical demand, convenience, and technological advancements have contributed to the increasing popularity of point-of-care testing (POCT) world-wide. Yet there are considerable differences in the utilization of POCT depending on the different medical needs, health care delivery and reimbursement systems in various countries. The presentation reviews these differences, the key drivers, challenges, trends, and the attitudes toward POCT by geographic/economic region.

9:00 Use of a Point-of-Care Laboratory to Successfully Manage Ebola Patients

James C. Ritchie, Ph.D., Medical Director & Professor, Pathology & Laboratory Medicine, Emory University

Our hospital has successfully treated 4 Ebola patients. These patients were entirely managed using laboratory values generated by a point-of-care testing laboratory located within the treatment unit. We will discuss the instrumentation used, the staff preparation, and the teamwork needed to make this approach viable. We will also briefly discuss the results for the common chemistry analytes on these patients throughout their treatment course. Finally we will discuss the shipping of specimens and decontamination of equipment and the laboratory after the patients depart.

9:30 Ambulatory Point-of-Care Testing for Ebola, Lassa, Fever and Trace Infections

Mustapha S. Fofana, Ph.D., Associate Professor, Mechanical, Biomedical and Manufacturing Engineering, Worcester Polytechnic Institute

The Ambulatory Point-of-Care Testing (POCT) vehicles are designed for rapid verification of people suspected of Ebola, Lassa, Fever and Trace (ELFT) infections. We will discuss the basic mechanics for POCT, explain engineering innovations of the POCT vehicles, outline new approach of POCT for ELFT infections, discuss safety topics related to renewable standards for evaluating and treating ELFT patients.

10:00 Improving Patient Care through Decentralizing Molecular Diagnostic Tests for Infectious Diseases

Sponsored by



John Clarkson, Ph.D., Chief Executive, Atlas Genetics Ltd

Diagnostic test accuracy and turn-around time are vital characteristics in the fight against infectious diseases. Decentralizing diagnostic tests to the doctors' office, specialist clinics or hospital ER can improve response time and increase test coverage of the population. In this presentation, attendees will gain an understanding of recent developments in decentralized diagnostics and what aspects of the system specification will drive clinical uptake.

10:15 Manufacturing Innovation for POC Devices

Sponsored by



Erol Harvey, Ph.D., CEO, miniFAB

Microfluidics has matured to a point where production volumes reach into the millions per annum, and products are achieving market success. This journey to maturity has included many lessons, such as understanding the division of function between consumable and re-usable components. Dr Harvey's presentation will discuss key design and manufacturing principles that, when considered, optimize the chances of commercial success.

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

THE BUSINESS OF HEALTHCARE: SOCIAL, ECONOMIC, AND LEGAL IMPLICATIONS

10:55 Chairperson's Opening Remarks

Donald G. Klepser, Ph.D., MBA, Associate Professor, Pharmacy Practice, University of Nebraska Medical Center

11:00 Point-of-Care Diagnostics: Business Case and Patient Perceptions

Donald G. Klepser, Ph.D., MBA, Associate Professor, Pharmacy Practice, University of Nebraska Medical Center

This program will focus on the regulatory and statutory issues that may be encountered by pharmacies conducting Point-of-Care Tests or planning to conduct Point-of-Care Tests. It will also be useful to test manufacturers and developers who are looking to enter the community pharmacy market.

11:30 Point-of-Care Diagnostics: Regulatory Perspective

Allison M. Dering-Anderson, BA, Pharm.D., RP, FAAM, Clinical Assistant Professor, Pharmacy, University of Nebraska College of Pharmacy

This program will focus on the regulatory and statutory issues that may be encountered by pharmacies conducting Point-of-Care Tests or planning to conduct Point-of-Care Tests. It will also be useful to test manufacturers and developers who are looking to enter the community pharmacy market.

Strategies for Implementation of Pharmacy-Based Point-of-Care Diagnostic Testing

12:00 pm Reimbursement of Point-of-Care Testing in a Retail Health Clinic Setting*Daniel R. Kerls, MBA, OTR/L, Director, Ambulatory Operations, CVS MinuteClinic*

This presentation will focus on how point of care labs influence overall reimbursement in a retail health setting and provide an overview of current challenges and opportunities, as well as considerations of supplies and control testing.

12:30 Enjoy Lunch on Your Own**1:25 Refreshment Break in the Exhibit Hall with Poster Viewing****CAPABILITIES OF PHARMACIES****1:50 Chairperson's Opening Remarks***Allison M. Dering-Anderson, BA, Pharm.D., RP, FAAIM, Clinical Assistant Professor, Pharmacy, University of Nebraska College of Pharmacy***2:00 Community Pharmacies: The Face of Neighborhood Healthcare***Alex J. Adams, Pharm.D., IOM, Vice President, Pharmacy Programs, National Association of Chain Drug Stores (NACDS)*

Community pharmacists are among the most accessible and trusted healthcare professionals; 95% of all Americans live within 5 miles of a pharmacies. Increasingly the public is turning to pharmacies for expanded services such as immunizations and point-of-care tests. This session will describe the community pharmacy landscape and opportunities to bring tests truly to the point-of-care.

2:30 Utilizing Pharmacists in Point-of-Care Testing: Scope of Practice Opportunities and Barriers*Krystalyn K. Weaver, Pharm.D., RPh, Director, Policy and State Relations, National Alliance of State Pharmacy Associations*

This session will provide information on pharmacists' education and training as it relates to point-of-care testing. An overview will be provided on how state laws and regulations that define pharmacist scope of practice create opportunities and barriers for the implementation of point-of-care testing programs in community pharmacies.

**EXPLORING PHARMACY NEEDS AND
DIAGNOSTIC CAPABILITIES****3:00 Key Informant Interviews: Preliminary Results and Next Steps***Kenneth C. Hohmeier, Pharm.D., Assistant Professor, Clinical Pharmacy; Director, Community Affairs, College of Pharmacy, University of Tennessee*

This session will present preliminary results from key informant interviews of diagnostic test manufacturers and pharmacy leaders. Manufacturers will have an opportunity to ask questions about the pharmacy market and pharmacy representatives will provide insight into the needs of the pharmacy market. The session will also include an opportunity for the audience to inform future interviews.

4:00 Refreshment Break in the Exhibit Hall with Poster Viewing**AVAILABILITY OF DIAGNOSTIC TESTS****4:45 Sponsored Presentation (Opportunity Available)****5:15 The Shifting Landscape of Diagnostic Testing***Harry Glorikian, Senior Executive/Board Director/Healthcare Consultant*

Diagnostic technology is continually evolving to meet changing models of care. This talk will discuss the trends driving the shift of where testing is performed. We will also discuss existing and emerging technologies in relation to diagnostics. We will discuss CLIA-waived tests and rapid tests that don't require extensive processing but also other emerging trends that affect patient care and management. Finally, potential clinical and business opportunities for this market will be addressed.

5:45 What Tests Are Currently Available and Do They Fit into a Community Pharmacy Practice*Michael E. Klepser, Pharm.D., FCCP, Professor, Pharmacy Practice, Ferris State University College of Pharmacy*

The emerging market to use of CLIA-waived POC tests in community pharmacies will be discussed. Existing and developing care models will be explored. A review of test characteristics that would be attractive for pharmacy use will be provided. Opportunities and barriers for implementation of CLIA-waived POC test integrated care models will be explored.

6:15 Close of Day**6:00 Dinner Short Course Registration****6:30 - 8:30 RECOMMENDED DINNER SHORT COURSE*****SC10: Use of CLIA-Waived POC and Rapid Diagnostic Tests in Community Pharmacies****Separate registration required, please see page 3 for details***THURSDAY, AUGUST 20****7:30– 8:25 am Problem-Solving Breakout Discussions with Continental Breakfast****WORKING WITH PARTNERS: OPPORTUNITIES FOR
PHARMACIES AND DIAGNOSTIC COMPANIES****8:25 Chairperson's Opening Remarks***Michael E. Klepser, Pharm.D., FCCP, Professor, Pharmacy Practice, Ferris State University College of Pharmacy*

Strategies for Implementation of Pharmacy-Based Point-of-Care Diagnostic Testing

8:30 PANEL DISCUSSION:

Moderator: Michael E. Klepser, Pharm.D., FCCP, Professor, Pharmacy Practice, Ferris State University College of Pharmacy

Panelists: Daniel R. Kerls, MBA, OTR/L, Director, Ambulatory Operations, CVS MinuteClinic

Casey Kozlowski, Director, Diagnostic Testing, Walgreens

Jesse McCullough, Pharm.D., Clinical Services Manager, Rite Aid Pharmacy

- Using technology to advance clinical services
- Developing an untapped market
- Generating data to support new programs
- Challenges faced by pharmacy
- Challenges faced by diagnostic manufacturers

9:30 What's Holding Back Point-of-Care Diagnostics?

Sponsored by
 TRUE DIAGNOSTICS
FOR POINT OF CARE ANSWERS

Jerry Lee, CEO, True Diagnostics, Inc.

The potential of the POCT Market rests not only on its ability to provide a quick response for providers and patients but also its capacity to deliver more specific results, simpler procedures and improve healthcare economics. True Diagnostics is advancing these competitive advantages to enable opportunities for the POCT Market.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing**DEVELOPMENT AND IMPLEMENTATION OF A
SUSTAINABLE PROGRAM****10:50 Point-of-Care Testing in a Retail Health Clinic Setting**

Alexander Sbordone, J.D., Operations Manager, MinuteClinic, CVS Caremark Corporation

As retail health clinics continue to grow, more patients are using this model for the convenience that it offers. Practitioners in this setting are relying on point-of-care lab testing to assist in the diagnosis and treatment of both acute and chronic disease. This presentation will review the testing utilized at CVS Minute Clinic as well as the laboratory challenges and opportunities found in this setting.

11:20 Shifting the Paradigm: Bringing Lab Services to the Corner Drugstore

Casey L. Kozlowski, R.Ph., MBA, Director, Diagnostic Testing Product Development, Pharmacy Transformation, Walgreens Boots Alliance

Using Theras' innovative technology and Walgreens' nationwide footprint, the two companies have partnered to bring diagnostic testing closer to the patient, and possibly change the way patients think about their pharmacy, pharmacists, and lab testing.

11:50 Late Breaking Presentation**12:20 pm Sponsored Presentation** (Opportunity Available)**12:50 Luncheon Presentation** (Sponsorship Opportunity Available) or
Enjoy Lunch on Your Own**SO YOU HAVE YOUR DIAGNOSTIC- NOW WHAT?****2:00 PANEL DISCUSSION: Clinical Informatics Needed to Ensure Implementation of Your Test**

Moderator: Julie Lynch, Ph.D., MBA, RN, Principal Investigator, Veterans Health Administration

Panelists: Terah B. Collins, Genomics Strategist, Cerner Corporation

Valentina I. Petkov, M.D., MPH, Health Scientist/Program Officer, Surveillance Research Program, Division of Cancer Control and Population Sciences National Cancer Institute

Danielle Chun, MPH, Genomics Informaticist, VINCI Services, VA

Scott Kulich, M.D., Ph.D., Associate Professor, Pathology, Division of Pathology and Division of Neuropathology, VA Pittsburgh Healthcare System (VAPHS)

- How do you meet informatics requirements for your test
- Linking test results to pharmacy and EHR
- Guidelines for HIPAA compliance of your test with requirements
- How do you ensure utilization of test?

3:30 Chairperson's Remarks

Speaker to be Announced, SonyDADC

» 3:35 CLOSING KEYNOTE: Commercializing Personalized Medicine: It's All About the Value Proposition

Daryl Pritchard, Ph.D., Vice President, Science Policy, Personalized Medicine Coalition

A key barrier to the commercialization of personalized medicine products involves an unclear value proposition. Many factors are involved in value assessments, but determining what are the most important value drivers depends on who you are asking.

4:05 Close of Conference

Cover

Conference-at-a-Glance

Plenary Keynote Session

Short Courses

Enabling Point-of-Care Diagnostics

Predictive Cancer Biomarkers

Companion Diagnostics

Coverage and Reimbursement of
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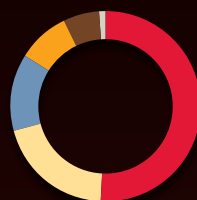
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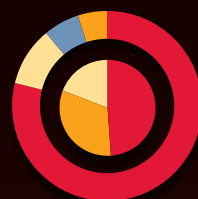
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- Other **1%**



GEOGRAPHIC LOCATION

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Monday, August 17th

SC1: Use of FFPE/Fixed Tissues for Clinical Research
SC2: Method Validation According to CLSI Guidelines
SC3: Practical Considerations for NGS Data Analysis and Interpretation
SC4: Biomarkers for Cancer Immunotherapy
SC5: Microfluidics for Point-of-Care
SC6: Establishing the Value of Diagnostic Tests
SC7: NGS as a Diagnostics Platform
SC8: Detection and Characterization of Circulating Biomarkers
SC9: Dinner Short Course: Regulatory Compliance in Molecular Diagnostics

Wednesday, August 19th

SC10: Dinner Short Course: Use of CLIA-Waived Point-of-Care and Rapid Diagnostic Tests in Community Pharmacies
SC11: NGS for Infectious Disease Diagnostics
SC12: Regulatory and Reimbursement Considerations with NGS and Other Multiplex Assays

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August 18-19

C1: Enabling Point-of-Care Diagnostics
C2: Predictive Cancer Biomarkers
C3: Companion Diagnostics
C4: Coverage & Reimbursement of Advanced Diagnostics
C5: Clinical NGS Assays

August 19-20

C6: Molecular Diagnostics for Infectious Disease
C7: Clinical Application of Cell-Free DNA
C8: Commercialization of Molecular Diagnostics
C9: Diagnostics to Guide Cancer Immunotherapy
C10: NGS Diagnostics
C11: Leveraging Pharmacies for Rapid Diagnostics

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