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Setting the stage for the great minds of diagnostics to advance medicine together

August 23-26, 2016
Grand Hyatt, Washington, DC

EIGHTH ANNUAL

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EVENT-AT-A-GLANCE

Tuesday - Wednesday AM August 23-24 **PART A CONFERENCES**	Wednesday PM - Thursday August 24-25 **PART B CONFERENCES**	Friday August 26 **PART C SYMPOSIA**
Enabling Point-of-Care Diagnostics	Molecular Diagnostics for Infectious Disease	Advances in Microbiome Diagnostics ***NEW***
Circulating Tumor Cells	Clinical Application of Cell-Free DNA	Predictive Cancer Biomarkers
Companion Diagnostics: Strategy & Partnerships	Diagnostics to Guide Cancer Immunotherapy	Non-Invasive Prenatal Testing ***NEW***
Coverage and Reimbursement of Advanced Diagnostics	Commercialization of Molecular Diagnostics	Health and Wellness Genomic Screening ***NEW***
DNA Forensics ***NEW***	Leveraging Pharmacies for Rapid Diagnostics	The Business of Telemedicine ***NEW***
Clinical NGS Assays	NGS Diagnostics: Data Considerations, Annotation and Interpretation	Digital PCR ***NEW***
Hospital Laboratory Design and Renovation ***NEW***		

SHORT COURSES Monday, August 22	DINNER SHORT COURSES Wednesday, August 24	DINNER SHORT COURSES Thursday, August 25

ABOUT THE SUMMIT

Next Generation Dx Summit convenes more than 1,000 international diagnostic professionals for valuable networking and comprehensive programming spanning from clinical diagnostics to business strategy. Now in its eighth year, the event has grown to include novel immunotherapy biomarkers, cell-free DNA, companion diagnostics, infectious disease, point-of-care, pharmacy-based diagnostics, commercialization, and reimbursement. New programming in 2016 includes prenatal testing, circulating tumor cells, forensics, telemedicine and microbiome sequencing. The Next Generation Dx Summit is a must-attend event with complete coverage of the most timely and important issues for the industry.

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 22, 2016

- 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

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PLENARY KEYNOTE SESSIONS | Wednesday, August 24

11:15 am Moderator's Remarks

11:20 KEYNOTE PRESENTATION: Implementing President Obama's Precision Medicine Plan at the FDA, and Changing the Current Paradigm to Make Use of Targeted Studies Involving a Patient's Specific Genetics, Health History and Lifestyle

Elizabeth A. Mansfield, Ph.D., Director, Personalized Medicine, Office of In Vitro Diagnostics & Radiological Health, FDA CDRH

GET CONNECTED #NGDx16

11:50 Disruptive Innovation in Laboratory Medicine: Game-Changing Technologies and Approaches

Co-organized with AMP Association for Molecular Pathology

Moderator: Ted E. Schutzbank, Ph.D., D(ABMM), Technical Director, Specialized Testing and Microbiology, Laboratory Services, St. John Providence Health System

Disruptive innovation is a new, emerging technology or approach that unexpectedly displaces an established one. Examples in laboratory medicine include next-generation sequencing, early cancer detection, direct-to-consumer testing, point-of-care assays and liquid biopsies. Scenarios incorporating such disruptive innovations will be presented by the moderator to a panel of experts to provoke discussion on the impact on laboratory medicine.

Session Objectives:

- Identify how the development of novel diagnostic technologies and approaches are changing traditional laboratory business models
- Analyze scenarios that propose emerging strategies and models for enhancing patient care
- Propose how the field of laboratory medicine can embrace these novel technologies and strategies

Panelists:

Rebecca McClure, M.D., Senior Scientist, Pathology, Health Sciences North/Horizon Santé-Nord

Dan Snyder, President & CEO, Molecular MD

Steven Kafka, Ph.D., President, Foundation Medicine

Charles Mathews, Vice President, Boston Healthcare

TESTIMONIALS

"Great conference! Most up to date data. Perfect amalgamation between industry, labs, clinicians and regulatory bodies. Highly recommended!"
Clinical Microbiology Fellow, NIH

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

"The Next Generation Dx Summit brings together key players from all facets of diagnostic development. Its format is very conducive to networking and learning from the leaders in the field. This is a great meeting for anyone who is serious about pursuing diagnostic technologies anywhere from research to commercialization."
Program Director, Fluxion Biosciences

"A concentrated event with more KOLs in attendance than any other conference I have been to."
CEO, Raindance Technologies

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SHORT COURSES*

MONDAY MORNING, AUGUST 22

9:00 am - 12:00 pm

SC1: NGS Diagnostics: Technology, Regulation and Reimbursement
Jason Lih, Ph.D., Principal Scientist, Molecular Characterization & Clinical Assay Development Laboratory (MoCha), Frederick National Laboratory for Cancer Research
Aaron J. Schetter, Ph.D., MPH, Senior Staff Fellow, Division of Molecular Genetics and Pathology/OIR, Center for Devices and Radiological Health, U.S. Food and Drug Administration
Katherine Tynan, Ph.D., President, Tynan Consulting LLC
Barbara A. Conley, M.D., Associate Director, Cancer Diagnosis Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute, (tentative)
P. Mickey Williams, Ph.D., Director, Molecular Characterization & Clinical Assay Development Laboratory (MoCha), Frederick National Laboratory for Cancer Research

SC2: Method Validation According to CLSI Guidelines
Shuguang Huang, Ph.D., Associate Vice President, Biostatistics, Helomics

SC3: Translating CTCs for Clinical Use
Scott M. Berry, Ph.D., Associate Scientist, Biomedical Engineering, University of Wisconsin, Madison
Joshua M. Lang, M.D., MS, Assistant Professor of Medicine, Carbone Cancer Center, University of Wisconsin
Michael Haffner, M.D., Carbone Cancer Center, University of Wisconsin

SC4: Overcoming Challenges to Commercial Success in Molecular Diagnostics
Harry Glorikian, Healthcare Consultant

MONDAY AFTERNOON, AUGUST 22

2:00 - 5:00 pm

SC5: Establishing the Value of Diagnostic Tests
Lawrence J. Worden, Vice President and Senior Partner, Market Diagnostics International

SC6: NGS Assay Development and Validation
Jamie Platt, Ph.D., Vice President, Genomic Solutions, Molecular Pathology Laboratory Network, Inc.
Jennifer Morrissette, Ph.D., Scientific Director, Clinical Cytogenetics Laboratory, Clinical Director, Center for Personalized Diagnostics (CPD), University of Pennsylvania School of Medicine

SC7: Digital PCR: A Technology Primer
Alexandra Whale, Ph.D., Senior Researcher, Molecular and Cell Biology Team, Science and Innovation Division, LGC Group

SC8: Detection and Characterization of Circulating Biomarkers
Sonya Parpart-Li, Ph.D., Associate Scientist, Personal Genome Diagnostics
Alison L Allan, Ph.D., Senior Oncology Scientist & Assoc Professor, Oncology & Anatomy & Cell Biology, London Regional Cancer Center

MONDAY EVENING, AUGUST 22

5:30 - 8:30 pm DINNER SHORT COURSE

SC9: 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

SC10: Regulatory Compliance in Advanced Diagnostics
Melina Cimler, Ph.D., Senior Vice President, Quality & Regulatory, Adaptive Biotechnologies
Pamela Swatkowski, Director, Global Regulatory Affairs, Abbott Molecular
Abraham Tzou, M.D., Medical Officer, Center for Devices and Radiological Health, Food and Drug Adminstration

WEDNESDAY EVENING, AUGUST 24

6:30 - 8:30 pm DINNER SHORT COURSES

SC11: Regulatory and Reimbursement Issues with NGS and Multiplex Assays
Živana 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 (MolDX)

SC12: NGS for Infectious Disease Diagnostics
Sneha Somasekar, Staff Research Associate, Viral Diagnostics and Discovery Center, Laboratory Medicine, University of California San Francisco

SC13: Use of CLIA-Waived Point-of-Care 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

SC14: Liquid Biopsy: Clinical Applications and Business Considerations
Theresa Zhang, Ph.D., Vice President, Research Services, Personal Genome Diagnostics
Divyaa Ravishankar, MS, Senior Consultant, Life Sciences, Frost & Sullivan

THURSDAY EVENING, AUGUST 25

5:00 - 8:00 pm SYMPOSIA DINNER SHORT COURSE

SC15: Preimplantation Genetic Screening and Diagnostics: A Technology Overview
Mark Umbarger, Ph.D., Director, Research and Development, Good Start Genetics
Nathan Treff, Director, Molecular Biology Research, Reproductive Medicine Associates of New Jersey; Associate Professor, Department of Obstetrics, Gynecology, and Reproductive Sciences, Rutgers-Robert Wood Johnson Medical School; Adjunct Faculty Member, Department of Genetics, Rutgers-The State University of New Jersey
Svetlana Rechitsky, Ph.D., Laboratory Director, Reproductive Genetics Innovations

**Separate registration required for Short Courses.*

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Advances in Microbiome Diagnostics

The Human Microbiome Project has spurred a large amount of research to understand the complex interactions and impact of microorganisms in health. This research is providing new insights towards the development of diagnostics, as well as prophylactics and therapeutics. The latest frontier of microbiome research is developing diagnostic methods and tests that provide accurate assessment of the taxonomic compositions of microbiomes associated with complex samples. Although this area of research is rapidly expanding, it has not yet resulted in a multitude of clinically validated tests approved by the regulatory agencies. The Advances in Microbiome Diagnostics symposium will bring together researchers, thought leaders, and laboratory professionals to present and examine the latest research on the microbiome in regards to diagnostic tests. Special attention will be paid to the antimicrobial biomarker discovery, coinfection of viral and bacterial pathogens, and cutting edge technologies used in microbiome research, their benefits, and their limitations. FDA regulation, guidelines, and policies will also be discussed. Join your colleagues and peers to examine a variety of microbiomes found in the human body and significant contributions to the field of microbiome diagnostics.

VIEW DETAILS

Predictive Cancer Biomarkers

Predictive cancer biomarkers hold the promise of early cancer detection, personalized treatment, and accurate patient monitoring. The Predictive Cancer Biomarkers symposium will focus on current research regarding tumor pathways and biomarker discovery, the progress toward clinical applications such as early detection and therapy monitoring, and case studies focusing on clinical utility and actionability, how many patients benefit from these assays, the role of genetic counselors, and practicality of funding and reimbursement. FDA validation will also be discussed. Join top cancer researchers and your peers to examine discoveries, best practices, and future directions.

VIEW DETAILS

Non-Invasive Prenatal Testing

Next-generation sequencing has enabled a new era of prenatal testing, that of non-invasive prenatal testing (NIPT), by sequencing cell-free DNA from maternal blood. While there has been a push to expand the range of genetic conditions reported from NIPT as well as to use it beyond high-risk pregnancies, there are still a number of challenges this type of testing faces. Cell-based diagnostic methods are being developed in this area to provide a more concrete non-invasive diagnostic in addition to a non-invasive screening. The Non-Invasive Prenatal Testing symposium will discuss non-invasive testing technologies and cell-retrieval methods, current progress in developing accurate and affordable tests in both cell-free and cell-based areas, and updates on and comparisons to current invasive diagnostic methods and outcomes. Special attention will be paid to carrier screening and how this type of testing provides a basis for prenatal diagnostics.

VIEW DETAILS

Health and Wellness Genomic Screening

Due to dramatic reduction in the cost of next generation sequencing (NGS) and breakthroughs in NGS data analysis, the idea of harnessing the power of NGS to inform health and wellness decisions is rapidly moving towards becoming mainstream. Risk prediction, genetic etiology of diseases, customized nutrition, exercise recommendations and more can be deduced from personal genomic testing. To take full advantage of personal genomic testing we need to develop a system that would include well-validated and reliable assays, comprehensive reports, specific promotional channels, reimbursement, ethical considerations, and more. The Health and Wellness Genomic Screening symposium is designed to discuss these issues and to search for their solutions by bringing together all the stakeholders of this exciting healthcare overhaul including sequencing experts and companies, nutritionists, wellness experts, physicians, patients, regulators and other interested parties.

VIEW DETAILS

The Business of Telemedicine

Telemedicine is not a new field, but advances in technology and a changing healthcare landscape are elevating it to new heights. With smart devices more prevalent and more consistent connectivity, healthcare access can now be in the palm of a patient's hand. And with point-of-care technologies becoming more readily accessible to consumers, there is an added layer of dimensionality to telehealth visits. Finally, a shift in how dollars are being spent on healthcare, both by consumers and employers, is helping to push this field ahead at a rapid pace. The Business of Telemedicine symposium will provide a crash course in the most pressing topics in telehealth. Technology selection, business models, and reimbursement will be a primary focus, with additional coverage on HIPAA compliance, patient engagement, and care coordination. This symposium is ideal for those who are new to the field or those looking to improve their existing telehealth platform or program.

VIEW DETAILS

Digital PCR

Digital PCR continues to be an important addition in diagnostic labs, with more and more groups adding this technology to their catalogue of detection and quantification tools. The Digital PCR symposium will discuss technological aspects of dPCR tools and technologies, including validation and accuracy for dPCR data, how dPCR integrates with NGS, and current and future applications of the technology, from single-cell analysis and diagnostics to environmental monitoring. Hear from researchers, test developers, and platform users on their experiences with and the limitations and benefits of dPCR, with a special focus on clinical applications.

VIEW DETAILS

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Improving Outcomes and Individualizing Treatment

RECOMMENDED PRE-CONFERENCE SHORT COURSES*
SC2: Method Validation According to CLSI Guidelines
SC5: Establishing the Value of Diagnostic Tests
**Separate registration required, please see page 5 for details*

TUESDAY, AUGUST 23

7:30 am Main Conference Registration & Morning Coffee

GLOBAL TRENDS IN INFECTIOUS DISEASE TESTING AT THE POINT-OF-CARE

8:30 Chairperson's Opening Remarks
Gyorgy Abel, M.D., Ph.D., Director, Molecular Diagnostics, Immunology & Clinical Chemistry, Laboratory Medicine, Lahey Hospital & Medical Center

» 8:40 KEYNOTE PRESENTATION: Global Challenge of AMR and Importance of POC in the Fight
Rosanna Peeling, Ph.D., Professor and Chair, Diagnostics Research, Clinical Research, ITD, London School of Hygiene & Tropical Medicine
Diagnostics play a critical role in clinical decision making and disease control. Novel point-of-care (POC) tests that are highly accurate, easy to use and equipped with data transmission capacities can soon be deployed across all health care settings. In a digital age, linkage of data from diagnostic laboratories and POC testing sites can provide timely information on testing coverage, disease trends, and early warning of infectious disease outbreaks, thus increasing the efficiency of health care systems, and improving patient outcomes.

9:40 Global Perspective on Infectious Disease Testing with Point-of-Care Diagnostics
Gyorgy Abel, M.D., Ph.D., Director, Molecular Diagnostics, Immunology & Clinical Chemistry, Laboratory Medicine, Lahey Hospital & Medical Center
Innovative point-of-care molecular diagnostic platforms enable rapid and accurate identification of infectious disease pathogens, even in remote areas and resource-poor settings. Threatening, potentially global epidemics by the Ebola, MERS, Zika, Dengue and Chikungunya viruses, and the emergence of multi-drug-resistant "superbugs" world-wide demand for simple rapid molecular tests that can help determine optimal treatment, curb the spread of infections, and assist with allocation of resources. The presentation reviews clinical applications in diverse geographic and economic settings and discusses the related technologies.

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

11:00 Meeting the Challenge: Global Technological Advances to Tackle Antimicrobial Resistance by Point-of-Care Testing
Till T. Bachmann, Ph.D., Reader, Personalized Medicine in Infectious Disease; Deputy Head, Division of Infection and Pathway Medicine, College of Medicine and Veterinary Medicine, University of Edinburgh
Antimicrobial resistance (AMR) is one the greatest healthcare challenges associated with infectious diseases. Rapid diagnostics, ideally done at point-of-care, are needed to curtail AMR, in particular to determine if and which antibiotics are needed. The presentation will review the recent developments to overcome technical challenges such as short detection time, low detection limits, and constantly evolving pathogens in a changing policy and economic landscape.

11:30 Using Informatics Solutions to Enable Appropriate and Compliant POC Testing
David McClintock, M.D., Medical Director, Pathology Informatics, Pathology, The University of Chicago Medicine
Point-of-care testing has traditionally been a manual, labor intensive process characterized by single use tests that do not readily interface with hospital and clinic information systems. Reliance on physicians, PAs, nurses, and other staff to accurately document the necessary order, result, quality control, and regulatory information required for each test can lead to patient safety, compliance, and billing errors. This talk will cover the current laboratory and regulatory challenges faced in point-of-care testing and how informatics solutions, both current and future, can help in hospital and clinic based practices.

12:00 pm Enabling Molecular POCT - Beyond the Technology Driving Outcome
Sponsored by GenePOC™
Patrice Allibert, Ph.D., CEO, Management, GenePOC
The need for actionable results has never been that expressed as today. The challenges healthcare providers are facing and the constant strive for increased efficiencies creates next to centralised non urgent (>4h TAT) Diagnostic testing a whole space for decentralised actionable (~ 1h TAT) diagnostic testing delivering actionable results at place of care impacting directly patient management.

12:30 Presentation to be Announced
Sponsored by episterm

1:00 Luncheon Presentation: Why IVD Product Development Needs to Become Agile
Sponsored by Invetech
Ludovic Labat, Ph.D., Global Vice President Sales, Diagnostics, Invetech
The IVD industry is increasingly challenged to deliver new instruments to market, while dealing with project delays, shrinking budgets and resource constraints. Learn how companies are adopting a new development paradigm to help teams respond to project unpredictability and result in reduced development costs and time to market.

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

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Improving Outcomes and Individualizing Treatment

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2:00 Chairperson's Remarks
Eric van Gieson, Ph.D., Chief Technology Officer and Director of Research Strategy, National Strategic Research Institute

2:10 Building the Healthcare Internet of Things
Matthew Quinn, MBA, East Coast Managing Director, Healthcare and Life Sciences, Intel Corporation
Some estimate that by 2020, there will be 50B smart devices with 212B sensors generating 44 ZB of data. The Internet of Things or IoT holds great promise in transforming the way that we work and live. This presentation will describe the steps and challenges in building the broader IoT and how we can leverage it to support the creation of an interconnected collection of diagnostic platforms.

2:30 Wearable and Home-Based Sensors: Can They Improve Patient Outcomes?
Steve Steinhubl, M.D., Director, Digital Medicine, Scripps Translational Science Institute; Cardiologist, Scripps Clinic
Remarkable advances in miniaturized computing power and connectivity over the last several decades have changed nearly every aspect of our lives, but they have yet to make a substantial impact on healthcare. However, mobile health (mHealth) technologies currently being developed are capable of enabling unprecedented changes in the manner and quality of clinical care available to the growing majority of the world's population with mobile connectivity.

2:50 Challenges in Developing the Next Generation of Diagnostics: The Role of Prizes
Erik Viirre, M.D., Ph.D., Adjunct Professor, UCSD Departments of Neurosciences, Surgery and Cognitive Sciences, Arthur C. Clarke Center and XPRIZE Foundation
The wide range of diagnostic sensors and analysis systems demands that the next generation will be integrated systems. The Qualcomm Tricorder XPRIZE was designed to spur the development of such integrated systems, with the demand that they be useable by consumers. The competition shows the great promise of these systems, but also the challenges to overcome for products that will actually be used. In this presentation the competition design will be used, some lessons learned from operation of the competition and what the future of sensor development, clinical trials, massive data management and regulatory review will look like.

3:10 Highly Versatile POC Diagnostic Devices
David J. Ecker, Ph.D., Divisional Vice President and Carlsbad Site General Manager, Ibis Biosciences Inc., an Abbott Company
With increasing pressure on healthcare costs, point-of-care diagnostic devices need to deliver increasing value. No matter how hard you try, there is a minimum cost of materials to conduct a point-of-care molecular test, so absent a major breakthrough in technology we must look towards increasing the value of the result. I will describe a strategy for doing this.

3:35 Sample Collection Solutions for Successful Microfluidic PoC Diagnostics
Sponsored by miniFAB
Erol Harvey, Ph.D., CEO, MiniFAB
Quantitative Point-of-Care diagnostics usually require precise sample volumes, from nanoliters to microliters, and often need to be performed without skilled user input. Microfluidic structures can simplify sample collection and clean-up making the process more accurate and less prone to user error.

3:50 Reimagining the Future of CLIA-Waivable Point-of-Care Molecular Diagnostics for Infectious Diseases
Sponsored by LucigenDx
Dipankar Manna, Ph.D., Principal Scientist, LucigenDx
LucigenDx will update on the development of a point-of-care MDx platform designed for CLIA-waiver. The platform consists of an instrument and test cartridge allowing sample extraction, amplification and detection. Data will be presented on the planned *C. difficile* clinical trial.

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

4:50 PANEL DISCUSSION: Guiding Treatment with Instantaneous Diagnostic Results
- Harnessing the "Internet of Things" movement to bring better connectivity between health care decisions and diagnostic results
- Providing instantaneous diagnostic data to the care provider through the use of wearable diagnostics in settings where diagnostics were not available
- Creating entirely new care bundles and protocols for sepsis and other acute diseases where instantaneous medical diagnostic data can have significant impacts on patient outcome

5:20 Innovative Point-of-Need Tools
Sponsored by QIAGEN
Roberto Spricigo, Manager, Strategic Alliances & OEM, PON, QIAGEN Lake Constance
The point-of-care (POC) market is overloaded with instruments that are almost equivalent in their use, yet offer a very limited test menu. The presentation will highlight the need for a new universal open platform for a broad range of rapid tests.

5:35 Emerging Technologies for Next-Generation Microfluidics
Sponsored by BIODOT
Tom Tisone, CEO, BioDot, Inc.
Microfluidics are increasingly more complex and focused on miniaturization. Fabrication of these devices requires reagent-dispensing approaches capable of delivering picoliter to microliter volumes. These systems must be compatible with a wide range of reagent classes and capable of producing millions of dispenses with a high level of precision and accuracy.

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

6:50 Close of Day

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WEDNESDAY, AUGUST 24

7:15 am Registration

7:30 Problem-Solving Breakout Discussions with Continental Breakfast

CELL-BASED ASSAYS AND METHODS FOR DIAGNOSTICS

8:25 Chairperson's Remarks
Holger Becker, Ph.D., Founder & CSO, microfluidic ChipShop GmbH

8:30 3D-Printed Microfluidics for Point-of-Care Medicine
Albert Folch, Ph.D., Associate Professor, Bioengineering, University of Washington
Present technology for microfluidic device fabrication is based on plastic molding. However, molded devices are inherently limited by layered 2D designs, cannot be quickly disseminated from laboratory to bedside, and cannot be easily personalized to each patient. We are developing 3D-printing approaches that allow for custom fabrication of transparent, biocompatible 3D microfluidic devices. This microfluidic technology will be readily available via the web to biomedical scientists at very low cost.

9:00 Micro Flow Cytometry: Automated Sample Prep Enabling A Broad POC Menu
Dan McPeak, Ph.D., Director, Microfluidics, Ativa Medical
The clinical value of high-volume tests, such as CBC, is enhanced when coupled with commonly co-ordered, lower-volume assays. With a broad menu of tests available, POC practitioners would be better equipped to complete a diagnosis within the span of patient contact. This presentation discusses how Ativa Medical's CBC technology creates opportunities for lower-volume, high-value cytometry assays at the point-of-care.

9:30 High Performance Lateral Flow Assays
Bernard H. Weigl, Ph.D., Principal Investigator, Flow Based Diagnostics, Intellectual Ventures Management LLC
Immunochromatographic (or lateral flow) assays have long been the workhorse of diagnostics in global health settings. They are extremely low cost, easy to use, can be manufactured easily, and are available for the diagnosis of a number of infectious diseases that are common in developing countries. However, the format suffers from relatively low sensitivity, dynamic range, and generally is mostly used to provide qualitative answers. We present our work that aims to improve the platform across the board by making the format much more sensitive, quantitative, and usable for a much wider range of diagnostic analytes.

10:00 Finally, a Point-of-Care Molecular System for the Physician's Office
Sponsored by mesabiotech™
Emily Winn-Deen, Ph.D., Chief Strategy Officer, Mesa Biotech, Inc.
Rapid and accurate identification of respiratory viruses is extremely important for accurate treatment of patients in outpatient physician office practices. Current CLIA-waived POC diagnostics either lack adequate sensitivity and/or specificity, or require relatively expensive instrument systems. Mesa Biotech has developed a rapid, easy-to-use, CLIA-waivable molecular diagnostic platform comprised of an inexpensive palm-sized, reusable dock and disposable test cartridges which together form a user-friendly system for use in the physician's office and the urgent care clinic.

10:30 Coffee Break in Exhibit Hall with Poster Viewing

11:15 PLENARY KEYNOTE SESSION
Please see page 3 for details.

12:40 pm Luncheon Presentation: Point-of-Care Molecular Diagnostics Enable Better Testing Compliance and Immediate Patient Management Decisions
Sponsored by Xagenic
Shana Kelley, Founder & CTO, Xagenic Inc.
Ihor Boszko, Vice President, Business Development, Xagenic Inc.
Recent availability of CLIA-waived molecular diagnostic tests has enabled improved patient care at a lower cost to the healthcare system. Xagenic is entering this rapidly growing market by commercializing a combination chlamydia/gonorrhea test, allowing better compliance with USPSTF and CDC screening recommendations. The Xagenic X1™ platform will permit in-office molecular testing in <20 minutes using non-refrigerated cartridges. We will produce a menu of multiplexed infectious disease tests with greatest utility during first clinical presentation.

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

1:25 Ice Cream and Cookie Break in the Exhibit Hall with Poster Viewing

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Circulating Tumor Cells

Current Challenges and New Directions for Liquid Biopsy

RECOMMENDED PRE-CONFERENCE SHORT COURSES*
SC3: Translating CTCs for Clinical Use
SC8: Detection and Characterization of Circulating Biomarkers
**Separate registration required, please see page 5 for details*

TUESDAY, AUGUST 23

7:30 am Main Conference Registration & Morning Coffee

BEYOND ENUMERATION: PREDICTIVE AND PROGNOSTIC BIOMARKERS

8:30 Chairperson's Opening Remarks
Joshua M. Lang, M.D., MS, Assistant Professor, Medicine, Carbone Cancer Center, University of Wisconsin

8:40 Predictive and Pharmacodynamic Biomarkers for Prostate Cancer Clinical Trials
Joshua M. Lang, M.D., MS, Assistant Professor, Medicine, Carbone Cancer Center, University of Wisconsin
New technology has been developed for integrated capture and molecular analysis of circulating tumor cells, focused on the androgen receptor signaling pathway. This presentation will discuss technology development, analytic validation and clinical trial results for these new biomarkers in patients with prostate cancer.

9:10 The Role of CTCs in the Development of Predictive Molecular Biomarkers
Tilak K. Sundaresan, Instructor, Medicine, Massachusetts General Hospital Cancer Center
Individual tumor biopsies may provide an incomplete window into the heterogenous nature of acquired drug resistance. It has been suggested that blood-based methods, including the genetic analysis of circulating tumor cells and circulating tumor DNA, may provide a more comprehensive survey of resistance mechanisms to help guide the selection of therapy. Ultimately, however, the clinical utility of blood-based analyses will be determined by their ability to predict clinical responses to drugs. More studies evaluating this premise will be necessary for the field of blood-based diagnostics genetics to fully mature.

9:40 Microfluidic Approaches to CTC Phenotypic Profiling
Shana Kelley, Ph.D., Professor, Biochemistry, University of Toronto
Circulating tumor cells can be highly heterogeneous, and resolving their phenotypic properties is very important to understand their role in cancer progression. We are developing high-throughput microfluidic approaches that can report on CTC phenotypes at the single-cell level. These tools allow dynamic CTC phenotypes to be tracked in patients and animal models of cancer.

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

10:55 Chairperson's Remarks
Laura Elnitski, Ph.D., Principal Investigator, Translational and Functional Genomics Branch, National Human Genome Research Institute

11:00 Robust Detection of DNA Hypermethylation of ZNF154 as a Pan-Cancer Locus with *in silico* Modeling for Blood-Based Diagnostic Development
Laura Elnitski, Ph.D., Principal Investigator, Translational and Functional Genomics Branch, National Human Genome Research Institute
Aberrant DNA methylation in cancer represents a potential biomarker for screening and diagnostics. We identified hypermethylation at the ZNF154 CpG island in 15 solid epithelial tumor types from 13 different organs. We further assessed the magnitude and pattern of differential methylation across colon, lung, breast, stomach, and endometrial tumors using next generation bisulfite amplicon sequencing. Our findings strongly support this epigenetic signature as a relevant biomarker for circulating tumor DNA.

VALIDATING FOR CLINICAL USE

11:30 The Analytical Validation of a Blood-Based Biomarker Predictive of Drug Sensitivity for Patients with Prostate Cancer
Daniel Danila, M.D., Genitourinary Oncology Service, Medicine, Memorial Sloan-Kettering Cancer Center
Novel biomarkers hold the promise of stratifying treatments based on the presence of putative targets. Given the effort and cost to develop new biomarkers, it is essential to abide to strict performance metrics when qualifying a promising assay in the context of use.

12:00 pm Development of Reference Materials for the Measurements of Circulating Cell-Free Tumor DNA
Hua-Jun He, Ph.D., Research Biologist, Biosystems and Biomaterials Division, National Institute of Standards and Technology
NIST, in collaboration with the Early Detection Research Network, is developing reference materials for ctDNA. The synthesized plasmid containing 7 gene alteration in cancer was spiked into a background of wild-type genomic DNA at different concentrations. The reference materials were quantified by digital PCR, and will be evaluated by NGS. The ctDNA reference materials will improve the reliability and confidence of the measurement of cell-free DNA biomarkers that show great promise for early cancer detection.

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AUGUST
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Cambridge Healthtech Institute's Inaugural

Circulating Tumor Cells

Current Challenges and New Directions for Liquid Biopsy

12:30 Enrichment of Circulating Tumor Cells Using a Novel Microfluidic System

Sponsored by ANGLE

Robert Zeillinger, Ph.D., Assoc Professor, Molecular Oncology Group, Medical University of Vienna

The Parsortix microfluidic technology is capable of providing a CTC sample of high purity, which is pre-requisite for applying qPCR to study gene expression levels in CTCs or ddPCR to detect tumor-specific mutations. Based on the enrichment by size and rigidity, the technology is flexible both in regards to the input sample volume and critical step size. We have shown that the efficient reduction of contaminating leukocytes allows the detection of CTC-related transcripts using qPCR at both high sensitivity and specificity.

1:00 Luncheon Presentation: An Automated, Sensitive Microfluidic Device for Capturing and Characterizing CTCs from Whole Blood Samples

Sponsored by Celsee Diagnostics

Yixin Wang, Ph.D., CSO, Celsee Diagnostics

Current technologies for isolating and analyzing circulating tumor cells (CTCs) are hindered by sub-optimal sensitivity and specificity of devices or assays as well as lack of the capability to characterize CTCs with clinical biomarkers. The Celsee Diagnostics' novel microfluidic technology captures and characterizes CTCs from metastatic cancer patients' whole blood samples based on size and deformability. The design enables downstream characterization of CTCs, including immunohistochemistry, DNA FISH, RNA FISH, PCR and NGS.

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

UNDERSTANDING HETEROGENEITY – WHICH CELLS REALLY MATTER?

2:00 Chairperson's Remarks

Catherine Alix-Panabières, Ph.D., Director, Laboratory of Rare Human, Circulating Cells (LCCRH), Cellular and Tissular Biopathology of Cancers, University Medical Center of Montpellier

2:05 Establishment and Characterization of a Cell Line from Human Circulating Colon Cancer Cells

Catherine Alix-Panabières, Ph.D., Director, Laboratory of Rare Human Circulating Cells (LCCRH), Cellular and Tissular Biopathology of Cancers, University Medical Center of Montpellier

For the first time, the establishment of a permanent cell line from CTCs of one colon cancer patient has been possible (CTC-MCC-41). In culture for three years, these cells have been characterized at the genome, transcriptome, proteome and secretome levels. CTC-MCC-41 cells resemble characteristics of the original tumor cells in the colon cancer patient and display a stable phenotype characterized by an intermediate epithelial/mesenchymal phenotype, stem-cell like properties and an osteomimetic signature indicating a bone marrow origin.

2:35 Heterogeneity and Dynamics of Circulating Tumor Cells

Anders Carlsson, Ph.D., David and Dana Dornsife, College of Letters, Arts and Sciences, University of Southern California

The HD-SCA assay is capable of identifying and characterizing rare events, like CTCs, in blood and bone marrow aspirates of cancer patients, using an enrichment-free, "no cells left behind" imaging based approach. Subsequent next generation single cell sequencing of candidate cells has been applied longitudinally in several cancer diseases, revealing the dynamics of tumor cell clonality at different disease stages and treatments.

3:05 Dissecting CTC Phenotypes in Mechanisms of Breast Cancer Dormancy

Dario Marchetti, Ph.D., Director, Center of the Biomarker Research Program, The Methodist Hospital Research Institute

In this talk, we will discuss the isolation and characterization of CTC subsets from peripheral blood of patients diagnosed with or without breast cancer brain metastasis (BCBM). We identified proliferative and invasive properties of 3D CTC tumorspheres distinctive upon uPAR/int β1 combinatorial expression. The molecular characterization of uPAR/int β1 CTC subsets will enhance abilities to prospectively identify patients who may be at high risk of developing BCBM.

3:35 Overcoming the Challenges of Heterogeneous Liquid Biopsies through Precise Image-Based Single-Cell Sorting

Sponsored by MENARINI silicon biosystems

Farideh Bischoff, Ph.D.; Executive Director, Scientific Affairs; Head, Clinical Development Lab, Menarini Silicon Biosystems

Heterogeneity has always limited the effectiveness of molecular analysis for solid tumors, including circulating tumor cells that are derived from these heterogeneous solid tumors. DEPArrayTM is an innovative technology capable of sorting and isolating 100% pure single or pooled cells through a digitally controlled Dielectrophoretic field using a semiconductor chip. A complete workflow for recovery of single or pools of pure circulating tumor cells from enriched blood has been established and will be presented. Furthermore, studies demonstrating utility of this workflow for downstream analysis using NGS will be reviewed.

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

4:50 PANEL DISCUSSION: Circutlating Biomarkers for Early Detection: Promise and Reality

Moderator: Stuart S. Martin, Ph.D., Associate Professor, Physiology, Greenebaum Cancer Center, University of Maryland School of Medicine

Panelists: Joshua M. Lang, M.D., MS, Assistant Professor, Medicine, Carbone Cancer Center, University of Wisconsin

Laura Elnitski, Ph.D., Principal Investigator, Translational and Functional Genomics Branch, National Human Genome Research Institute

- Challenges in getting to early detection?
- Detecting low levels of disease
- Cutting down on false positive testing?
- Correlating results with disease

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

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6:50 Close of Day

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Circulating Tumor Cells

Current Challenges and New Directions for Liquid Biopsy

WEDNESDAY, AUGUST 24

7:15 am Registration

7:30 Problem-Solving Breakout Discussions with Continental Breakfast

NOVEL LIQUID BIOPSY TECHNIQUES

8:25 Chairperson's Remarks

Andrew D. Rhim, M.D., Assistant Professor, Internal Medicine, Division of, Gastroenterology, University of Michigan

8:30 Novel Methods for Eliminating Wild-Type Alleles from Liquid Biopsies

G. Mike Makrigiorgos, Ph.D., Professor, Radiation Oncology, Dana-Farber and Harvard Medical School

We present Nuclease-assisted Mutation Enrichment with Overlapping Probes (NaME-PrO), a simple and powerful technology for eliminating wild-type DNA sequences from CTCs and circulating DNA, in order to focus on clinically relevant DNA alterations. Furthermore, we show that NaME-PrO combines seamlessly with existing technologies such as COLD-PCR, digital PCR, high resolution melting or sequencing.

9:00 Circulating Epithelial Cells as Biopsies of Subclinical Cancer: Novel Technologies for Molecular Analysis

Andrew D. Rhim, M.D., Assistant Professor, Internal Medicine, Division of Gastroenterology, University of Michigan

Our studies in genetic mouse models have shown that dysplastic epithelial cells are shed into the blood stream long before the formation of clinically detectable tumors. Here, we will summarize our efforts in utilizing circulating epithelial cells as a sampling of clinically undetectable dysplastic lesions that may represent the earliest forms of cancer. This discussion will include recent work in the use of novel microfluidic platforms to achieve ultra-sensitive genomic analysis of captured cells by any platform.

9:30 Isolation and Characterization of Biologically Relevant Circulating Tumors Cells (CTCs): The Importance of the CTC Microenvironment

John J. O'Leary, M.D., Ph.D., MSc, MA, FRCPath, FFPathRCPI, Chair, Pathology, Trinity College Dublin; Director, Pathology, Coombe Women and Infants University Hospital; Consultant, Pathologist, St. James's Hospital; Principal Investigator, Biomedical Diagnostics Institute (BDI)

Circulating tumor cells (CTCs) offer a unique biological window on cancer cell metastasis. Sets of unique biological interactions visited upon the CTC produce a pro-survival and pro-invasion phenotype. CTCs demonstrate different physical form states and different biological transitions during the metastatic trafficking process. This talk addresses issues central to CTC physical state analysis, developing CTC molecular classifiers of biological relevance and critically evaluates the microenvironment of CTCs from primary to liquid phase and pre-metastatic niches, in order to fully define those CTCs capable of forming metastases.

Sponsored by sysmex

10:00 Liquid Biopsy in Clinical Practice: Implementation of the OncoBEAM RAS Platform in the Management of mCRC Patients

Vishal Sikri, Vice President, Commercial Operations, Sysmex Inostics

Measurement of ctDNA is being widely studied across different cancer types. The use of ctDNA assays will continue moving forward since they allow for high sensitivity while still maintaining specificity. The OncoBEAMTM platform has been published across cancer types because of its high sensitivity compared to other technologies. The OncoBEAMTM RAS IVD assay was launched in 2016 for therapy selection and resistance detection applications highlighting the current and future value of ctDNA testing in oncology.

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

11:15 PLENARY KEYNOTE SESSION
Please see page 3 for details.

Sponsored by RainDance Technologies

12:40 pm Luncheon Presentation to be Announced

1:20 Close of Circulating Tumor Cells

1:25 Ice Cream and Cookie Break in the Exhibit Hall with Poster Viewing

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AUGUST
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Companion Diagnostics: Strategy and Partnerships

Strategy, Partnership, Technology and Adoption

RECOMMENDED PRE-CONFERENCE SHORT COURSES*

SC5: Establishing the Value of Diagnostic Tests

SC10: Regulatory Compliance in Advanced Diagnostics

**Separate registration required, please see page 5 for details*

TUESDAY, AUGUST 23

7:30 am Main Conference Registration & Morning Coffee

KEYNOTE SESSION: PHARMA VOICE

8:30 Chairperson's Opening Remarks

Andrea H. Lauber, Ph.D., Executive Director, Business Development, Clinical Biomarkers and Pharmacodiagnostics, Bristol-Myers Squibb

8:40 Precision Medicine and Personalized Solutions: Perspectives from a Healthcare Player, Janssen Diagnostics (Johnson & Johnson)

Werner Verbiest, Head of the Companion Diagnostics Center of Excellence, Johnson & Johnson

The global healthcare market, and with it the pharmaceutical industry, is in a significant state of flux and change. Increased innovation and novel healthcare models will drive a new way of addressing global health. At Janssen, we are committed to transforming the way diseases are treated and where possible even prevented or intercepted. In all our therapeutic focus areas, we are passionate to enhance patient outcome by bringing innovative medical solutions to practice. Janssen Diagnostics, an integrated part of Janssen, is focused on enabling precision medicine concepts and heavily relies on external partnerships to bring customized diagnostic solutions. This presentation will highlight our vision and unique business model in addressing current and future opportunities.

9:10 Predictive Biomarkers, Companion Diagnostic & Drug Development: The Past, Present, and Future

J. Carl Barrett, Ph.D., Vice President, Translational Sciences, Onc iMed, AstraZeneca

Selecting the right patient is key to developing successfully targeted therapies. Examples of how this can be achieved will be presented for olaparib and osimertinib. The challenges in developing next generation companion diagnostics including ctDNA and NGS of tumors will be discussed. Lastly, the role of tumor heterogeneity in limiting drug development and the challenges of tumor heterogeneity for the future of CDx development will be discussed.

9:40 Use of Pharmacogenomics for Drug Differentiations In Non-Oncology Areas

Eric Lai, Ph.D., Senior Vice President and Head, Pharmacogenomics, Companion Diagnostics, Takeda Development Centers of America

Pharmacogenomics has been applied successfully in mainly oncology, but not in other therapeutic areas. This presentation will examine some of the factors that are limiting the use of pharmacogenomics in non-oncology areas.

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

HARNESSING THE POWER OF TECHNOLOGY

10:55 Chairperson's Remarks

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

11:00 Platforms and Bridging Studies in the Development of Companion Diagnostics

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

This talk will highlight strengths and weaknesses of common platforms used in patient stratification studies and discuss how these attributes may affect bridging studies.

11:30 Clinical Utility of the Cobas® EGFR Mutation Test V2 from Liquid Biopsy Samples in Patients with NSCLC

Sid Scudder, M.D., Senior Director, Clinical Science, Genomics & Oncology, Roche Molecular Systems

Common challenges to determining EGFR mutation status in non-small cell lung cancer are insufficient tissue, biopsy exhaustion and inability to undergo biopsy. The cobas® EGFR Mutation Test v2 was developed to detect the most common mutations in exons 18-21, including T790M, in both tissue and plasma. Using different cutoffs for sample type, the detection of 42 separate mutations is now possible. While maintaining a high positive predictive value to detect EGFR mutations relative to tissue results, liquid biopsy testing could eventually enable the detection of EGFR mutations at diagnosis, while on treatment and at progression, including the development of acquired resistance mutations during treatment.

11:50 Development and Application of an 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 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.

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Companion Diagnostics: Strategy and Partnerships

Strategy, Partnership, Technology and Adoption

12:10 pm Considerations for the Development of Pathology-Based Multiplexed Assays for Clinical Biomarker Analyses

Victoria Rimkunas, Ph.D., Head, Integrated Diagnostics Lab, Merrimack Pharmaceuticals

During this talk we will review cases where multiplex pathologist centered diagnostics currently being used at Merrimack Pharmaceuticals to support pre-clinical and clinical studies. Our approach to assay development and an overview of the challenges we faced will be covered. One of the considerations that will be reviewed is how to develop digital pathology solutions.

12:30 pm NGS Assay from Ideation to Realization – Translating Ideas into Patient Benefits

Sponsored by Precision for Medicine

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

Rapid advancements in NGS techniques have led to even more rapidly advancing research into the causal genomic and somatic agents of disease and response. One hurdle is the transition from research to an FDA approved commercial product. We will break down the path to commercialization into steps from research through feasibility, investigational trials, to final FDA approval and market access, and explore strategies for the ultimate goal of the most efficient path to patient access.

1:00 Luncheon Presentation: Managing Risk: A Pragmatic Approach for the Successful Co-Development of Drugs and Diagnostics

Sponsored by MolecularMD

Dan Snyder, President & CEO, MolecularMD

A greater biological understanding of disease has been catalyzed by the advent of powerful genomic applications and techniques. Over 800 candidate compounds are in clinical testing for cancer; 73% have the potential to be personalized medicines. Opportunities to improve healthcare outcomes are unprecedented but not without financial constraints and a high degree of uncertainty. Risk mitigation and a pragmatic, strategic approach to managing the clinical trial and commercialization are key to a successful drug-diagnostic approval.

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

MASTERING PARTNERSHIP ACROSS ALL THE STAKEHOLDERS

2:00 Chairperson's Remarks

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

2:05 Rx/Pdx Partnering: What's Next after the Break-Up?

Andrea H. Lauber, Ph.D., Executive Director, Business Development, Clinical Biomarkers and Pharmacodiagnostics, Bristol-Myers Squibb

Salvatore Salamone, Ph.D., President and CEO, Saladax Biomedical, Inc.

BMS works closely with external partners to co-develop diagnostic products for our pipeline therapies.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.

2:25 Challenges in Co-Development for Multiple Programs – A Large Pharma Company Perspective

Patricia Carrigan, Ph.D., Global Head, Translational Assays Technologies, Bayer HealthCare Pharmaceuticals

There are challenges in picking the right technology and partner to ensure that the targeted therapy and the companion diagnostic would be co-developed starting as early in the development process as possible. I will discuss some of these challenges and some strategies in overcoming them for multiple programs in a large company.

2:45 FDA Submission of Laboratory-Developed Companion Diagnostic Tests - ARUP's Experience with HDES Approval in Rare Disease

Karen A. Heichman, Ph.D., Director, PharmaDx Program, VP New Technology Assessment ARUP Laboratories, Adjunct Associate Professor of Pathology University of Utah School of Medicine

In December 2015, ARUP Laboratories, received FDA approval for the first companion diagnostic tests under the Humanitarian Device Exemption (HDE) program for rare diseases. As a part of this endeavor, ARUP established an augmented quality management system that meets FDA requirements for medical devices including a design control program. The discussion will focus on the challenges of integrating a CDx development strategy, within an established CLIA laboratory, to ensure successful FDA approval of companion diagnostics.

3:05 Presentation to be Announced

Sponsored by HEALTH ADVANCES

3:35 IncellDx: Quantitative Cellular Multiplex Technology Foundation for Lung, Breast and Head and Neck Cancer Assays

Sponsored by incellDx

Bruce Patterson, MD, CEO, Executive, IncellDx

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 multi-parameter, quantitative alternative to IHC.

3:20 Sponsored Presentation *(Opportunity Available)*

3:50 Presentation to be Announced

Sponsored by ALMAC

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

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Companion Diagnostics: Strategy and Partnerships

Strategy, Partnership, Technology and Adoption

4:50 Companion Diagnostics: Emerging Regulatory Issues and Opportunities

Soma Ghosh, Ph.D., Regulatory Scientist, Division of Molecular Genetics and Pathology, OIR, CDRH, FDA

Companion diagnostics are an important component of personalized medicine. They are essential for the safe and effective use of therapeutic products and promise to deliver a clearer understanding of disease development at the patient level. The companion diagnostics industry is rapidly evolving and has generated a series of unique regulatory challenges. These developments will be reviewed and the FDA regulatory review process for companion diagnostic devices will be discussed.

5:20 PANEL DISCUSSION: Matching the Evolution of Diagnostic and Therapeutic Development

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

The integration of a successful therapeutic/companion diagnostic co-development strategy begins in the early stages of therapeutic clinical development. When a diagnostic test is central to patient selection in order to establish the drug's safety or efficacy, it is key to initiate coordination of these drug/diagnostic co-development strategies as early as technically feasible. In this session, we will have speakers from the drug and diagnostic industry that have had first-hand experience in addressing early and late stage co-development issues and challenges.

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

Sponsored by SLONE PARTNERS

6:50 Close of Day

WEDNESDAY, AUGUST 24

7:15 am Registration

7:30 Problem-Solving Breakout Discussions with Continental Breakfast

CO-COMMERCIALIZATION OF DRUGS AND DIAGNOSTICS IN THE US AND BEYOND

8:25 Chairperson's Opening Remarks

Peter Collins, CCO, Premaitha Health

8:30 Global CDx Strategy and Challenges

Marisa Dolled-Filhart, Ph.D., Director, Pathology and Companion Diagnostics, Translational Biomarkers, Merck & Co., Inc.

In developing and executing on a global CDx strategy in light of drug approval strategy, there are several important considerations and challenges. This talk will cover considerations of (a) global CDx clinical trial sample analysis strategies, (b) challenges in aligning drug and CDx submission timelines, (c) requirements that differ from U.S. submissions and (d) commercial considerations.

9:00 Creating a Partnership Ecosystem to Overcome Challenges in Co-Development

Myla Lai-Goldman, M.D., CEO, GeneCentric Diagnostics, Inc.

The path of a novel diagnostic from research tool to clinical adoption is paved with well-documented scientific and business challenges. Early development focuses on ensuring an analytically valid, clinically robust assay, while co-development overcomes the greatest barrier, the demonstration of clinical utility, in well-designed prospective pharmaceutical trials. By creating a partnership ecosystem, diagnostic innovators can concentrate efforts and funds to overcome the major obstacles between discovery and the patient.

9:30 PANEL DISCUSSION: Deploying Companion Diagnostics Beyond US

Moderator: Peter Collins, CCO, Premaitha Health

Panelists: Speakers of the Session

Alex Parker, Ph.D., Vice President, Business Development at Foundation Medicine

Jonathan Roy, Vice President Pharma Partnerships, Leica Biosystems

- Registration and Approvals of a CDx beyond the USA
- Strategies to endure testing to get on drug is available and accessible for a global drug launch
- Building sustainable partnerships between Rx and Dx allowing for the variation in individual country approaches to Rx and Dx reimbursement.

10:00 Sponsored Presentation *(Opportunity Available)*

10:15 Sponsored Presentation *(Opportunity Available)*

10:30 Coffee Break in Exhibit Hall with Poster Viewing

11:15 PLENARY KEYNOTE SESSION

Please see page 3 for details.

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

1:20 Close of Companion Diagnostics: Strategy & Partnerships

1:25 Ice Cream and Cookie Break in the Exhibit Hall with Poster Viewing

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Coverage and Reimbursement of Advanced Diagnostics

Establishing Clinical Utility and Working with Payers

RECOMMENDED SHORT COURSES*

SC5: Establishing the Value of Diagnostic Tests

SC11: Regulatory and Reimbursement Issues with NGS and Multiplex Assays

**Separate registration required, please see page 5 for details*

TUESDAY, AUGUST 23

7:30 am Registration & Morning Coffee

VALUE-BASED DIAGNOSTICS AS A PART OF VALUE-BASED HEALTHCARE

8:30 Chairperson's Opening Remarks
Girish Putcha, M.D., Ph.D., Director, Laboratory Science, Palmetto GBA (MolDX)

» 8:40 KEYNOTE PRESENTATION: The Value of Diagnostics in the Changing Healthcare Environment: From Fee-for-Service to Value-Based Payments
Dwight Denham, Vice President, Global Health Economics & Reimbursement, Danaher Corp

The diagnostics industry and the laboratory medicine community are challenged by the ever-changing face of the healthcare systems they serve. In particular, the evolving shift towards value-based payments. This presentation will introduce the forces behind value based payment, and provide some perspectives on health economic methods to address tests/platforms of varying utilities. Perspectives on the broader number of stakeholders involved in adoption, under value based payment models, will be shared.

9:10 Facing Challenges Regarding the Reimbursement Paradigms for Advanced Diagnostics
Lee Hilborne, MD, MPH, Professor, Pathology and Laboratory Medicine, David Geffen School of Medicine UCLA HealthSystem, Senior Medical Director, Medical Affairs, Quest Diagnositics, Health Policy Researcher, Global Health, RAND

Advanced diagnostics are critically important to improving the value of medicine. New and innovative strategies to improve patient care have outpaced current systems to appropriately reimburse providers for the costs of services and the value provided. At the same time, the Institute of Medicine estimates that 30% of U.S. healthcare is duplicative or unnecessary. Inappropriate or over-utilized medical tests account for $250 to $300 billion in U.S. medical expenses annually. Our challenge must be to quickly establish both clinical validity AND clinical utility for new diagnostic services while taking responsibility for effective utilization of both new and existing diagnostic services

9:40 Approaching MolDX for Coverage: May Evidence Be with You
Girish Putcha, M.D., Ph.D., Director, Laboratory Science, Palmetto GBA (MolDX)

This presentation will discussion several key issues such as: review the MolDX technical assessment process and potential coverage outcomes; present case studies to demonstrate varying ways to approach coverage, share lessons learned, and personal observations on what works–and what doesn't.

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

WINNING COVERAGE DECISIONS

10:55 Chairperson's Remarks
Lon Castle, M.D., CMO, Molecular Genetics And Personalized Medicine, Evicore Healthcare

11:00 The Art of Evidence Generation: How to Win Friends and Influence Payers
Daniel Halevy, MD FASN, Medical Director II, Horizon Blue Cross Blue Shield

This presentation will discussion several key issues such as: examine how medical policy committees evaluate your evidence package, recognize what payers look for in a clinical utility study and discover how the pieces all fit together to determine coverage

11:30 Interacting with the AMA: It's Not Just for Doctors Anymore
Lauren Feldman, M.H.A., Senior Terminology and Strategy Consultant, American Medical Association

In this presentation I will review how to work with the AMA to secure a CPT code, assess the types of molecular diagnostic codes available and discuss the new proprietary laboratory analysis codes and examine example use cases

12:00 pm PANEL DISCUSSION: To Pay or Not to Pay, That is the Question: Different Perspectives on the Reimbursement Hurdles for New Technologies
Moderator: Lon Castle, M.D., CMO, Molecular Genetics And Personalized Medicine, Evicore Healthcare

- 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

12:30 2016 and Beyond! Reimbursement: Lessons for Another Year

Sponsored by XIFIN

Rina Wolf, Vice President, Commercialization Strategies, Consulting & Industry Affairs, XIFIN, Inc.
Kyle Fetter, AVP, Advanced Diagnostics Services, 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.

1:00 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

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Establishing Clinical Utility and Working with Payers

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

IMPACTFUL CASE STUDIES AND EVIDENCE GENERATION STRATEGIES

2:00 Chairperson's Remarks
Katherine Tynan, Ph.D., President, Tynan Consulting LLC

2:05 Coverage and Reimbursement Landscape of Genomic Profiling in Oncology
Jerry Conway, Vice President, Payer Relations & Reimbursement, Foundation Medicine, Inc.
As genomic profiling tests pose to assist in the improvement of overall treatment efficacy and patient outcomes, it is crucial for providers of genomic profiling tests to have extensive knowledge regarding drug formulary and coverage trends in the current diagnostic marketplace to ensure future genomic profiling tests will have optimal patient access routes.

2:30 Who Cares, When, and What Can Be Done: Justifying Somatic and Germline NGS Panels
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.

2:55 Successes and Opportunities in Working with Payers for Reimbursement of NGS
Jason L Gillman, MSPH, Director, Cancer Genomics, Intermountain Healthcare
Intermountain Healthcare established its Precision Genomics program in the fall of 2014. Since that time, we have experienced many successes and identified several opportunities regarding payers and reimbursement. This presentation will explore the strategies and pain points in establishing evidence and working with payers for reimbursement.

3:15 Securing Medical Policy Coverage while Eliminating Coverage of Outdated Technology
Vanessa DePalma, Senior Corporate Director, Health Plan and Payer Markets, Meridian Bioscience, Inc
Diagnostic organizations want to offer the most appropriate laboratory tests to payers, providers and patients with the goal of offering best in class technology that promote: early detection, prevention, quality improvement and cost savings to the system. Additionally, if an outdated diagnostic test exists, key elements must be dully presented to demonstrate why the inferior technology should not be utilized or reimbursed. This case study will review this simultaneous approach and lessons learned in the disease management of helicobacter pylori (H. pylori).

3:35 Sponsored Presentation *(Opportunity Available)*

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

4:50 Winning Coverage & Payment for New Genomic Tests: A Large Reference Lab Perspective
Laurie Howard, Vice President, Reimbursement, Labcorp
This presentation will focus on strategies and tactics we have developed to move new complex molecular tests from commercial introduction to payment and coverage. Some case studies and examples will be presented that deal with tactics around evidence dossier development, as well as multilevel appeals to drive policy change.

5:20 Panel Discussion: Establishing Clinical Utility and Cost Effectiveness of Diagnostic Testing
Moderation: Katherine Tynan, President, TynanDx
Panelists: Speakers of the session
Richard S. Cooper, Member, McDonald Hopkins LLC
During this panel we will discuss through examples the state of diagnostic testing as it relates to overcoming reimbursement issues. Some of the topics to be discussed include:
- Becoming an active part of the coverage conversation with payers
- Approaches for communicating product and market differentiation to payers and providers
- Cost effectiveness studies and who to present them to

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

Sponsored by SLONE PARTNERS

6:50 Close of Day

WEDNESDAY, AUGUST 24

7:15 am Registration

7:30 Problem-Solving Breakout Discussions with Continental Breakfast

PAMA REFLECTIONS (Bridging session with Commercialization of Molecular Diagnostics)

8:25 Chairperson's Opening Remarks
Roger Klein, M.D., J.D., Medical Director, Molecular Oncology, Cleveland Clinic Foundation

8:30 Clinical Laboratory Payment Reform: Implementing Provisions of the Protecting Access to Medicare Act
Carol Blackford, Acting Deputy Director, Hospital and Ambulatory Policy Group, Center for Medicare, Centers for Medicare and Medicaid Services
This session will discuss Medicare reform of the Clinical Laboratory Fee Schedule based on private payer prices. Topics will also include Medicare payment for advanced diagnostic laboratory tests, coding and pricing for new clinical diagnostic laboratory tests and more.

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AUGUST
23 - 24

Cambridge Healthtech Institute's Fifth Annual

Coverage and Reimbursement of Advanced Diagnostics

Establishing Clinical Utility and Working with Payers

9:00 PAMA: The Final Rule Is Out – What Does It Mean for Labs?
Roger Klein, M.D., J.D., Medical Director, Molecular Oncology, Cleveland Clinic Foundation
Signed into law on April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) includes the most extensive reform of the Medicare Clinical Laboratory Fee Schedule (CLFS) since it was established in 1984. Section 216 of PAMA creates a new Section 1834A of the Social Security Act, which contains many of the CLFS reforms. Starting on January 1, 2017, most rates on the CLFS will be derived from private payor rates for laboratory services.

9:30 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 is 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.

10:00 Developing and Communicating Evidence of Economic Value

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ANALYSIS GROUP
ECONOMIC, FINANCIAL and STRATEGY CONSULTANTS

Dave Nellesen, Ph.D., Vice President, Analysis Group
Demonstrating clinical utility of a novel advanced diagnostic test is typically necessary for coverage, but may be insufficient for reimbursement. Frequently, evidence of how a new technology can reduce cost—or deliver substantial value for added cost—is necessary to support premium pricing. This presentation will provide strategies for developing an economic value story, including frameworks for generation of economic evidence and best practices in communicating this evidence to payers, hospitals and other key stakeholders.

10:30 Coffee Break in Exhibit Hall with Poster Viewing

11:15 PLENARY KEYNOTE SESSION
Please see page 3 for details.

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

1:20 Close of Coverage and Reimbursement of Advanced Diagnostics

1:25 Ice Cream and Cookie Break in the Exhibit Hall with Poster Viewing

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DNA Forensics

Exploring New Frontiers in Forensic DNA Investigation

RECOMMENDED PRE-CONFERENCE SHORT COURSES*

SC7: Digital PCR: Technologies, Quantification, and Analysis

SC9: Practical Considerations for NGS Data Analysis and Interpretation

**Separate registration required, please see page 5 for details*

TUESDAY, AUGUST 23

7:30 am Main Conference Registration & Morning Coffee

EMERGING TECHNOLOGY IN FORENSIC ANALYSIS: MASSIVELY PARALLEL SEQUENCING

8:30 Chairperson's Opening Remarks

8:40 Library Preparation for Next-Generation Sequencing
Speaker to be Announced

9:10 Interpretational Issues Involving the Use of Massively Parallel DNA Sequencing in Forensic Science
Mark Wilson, Ph.D., Research Leader, Applied Genomics, Battelle Memorial Institute
The advent of massively parallel DNA sequencing into forensic casework requires that some current approaches to the interpretation of DNA data be reevaluated. This presentation will focus on the two major classes of human DNA markers used in forensic typing: short tandem repeats and mitochondrial DNA. The use of whole genome microbial DNA sequencing will also be discussed from the perspective of DNA profile comparisons and their proper interpretation.

9:40 Massively Parallel Sequencing in Forensic Genetics
Niels Morling, Ph.D., Professor, Director, Forensic Medicine, Faculty of Health and Medical Science, University of Copenhagen
Massively Parallel Sequencing (MPS) can sequence the majority of the key forensic genetic systems and new markers in advanced forensic investigations. MPS offers a large amount of information concerning identity, ancestry, physical traits, etc., from minute amounts of DNA in one or a few investigations. Nomenclature of sequenced STRs, data analysis, pitfalls, and an example of ISO 17025 accreditation of MPS SNP typing will be discussed.

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

10:55 Chairperson's Remarks

11:00 Next-Generation Sequencing in Forensic Science: The Legal Path Forward
Ted R. Hunt, Chief Trial Attorney, Prosecuting Attorney's Office, Jackson County (Kansas City, Missouri)
The ability of Next Generation Sequencing to provide usable information from low level, degraded, and mixed samples collected from crime scenes can be a transformative force in forensic science. However, the full potential of this technology will not be realized without a clear legal path forward. This presentation will discuss the current state of the law, possible challenges, and legal strategies for the implementation of Next Generation Sequencing in forensic science and its admissibility in criminal cases.

11:30 PANEL DISCUSSION with Session Speakers

12:30 pm Accelerating Implementation of the NGS MiSeq FGx System
Sponsored by illumina
Meghan Didier, Senior, Forensic Scientist, Illumina
With the advent of next-generation sequencing (NGS) technology in the forensic DNA community, internal validation studies of the MiSeq FGxTM Forensic Genomics System are warranted. Illumina offers flexible levels of internal validation assistance to ease the burden on laboratories as they make the transition to NGS technology. A team of forensic experts provide valuable training and knowledge to accelerate the NGS learning curve, ensure full understanding of system data, and expedite implementation for casework operations.

1:00 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

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

OPTIMIZING DNA EXTRACTION TECHNIQUES

2:00 Chairperson's Remarks

2:05 NGS mtDNA Genome Capture: A Novel Method for Getting DNA from Chemically Modified Forensic Samples
Timothy P. McMahon, Ph.D., Deputy Director of Forensic Services; Contractor; ARP Sciences LLC, a Division of ARP Supporting the Armed Forces Medical Examiner System
The Armed Forces DNA Identification Laboratory, a division of the Armed Forces Medical Examiner, performs DNA testing for the identification of deceased service members. This presentation will discuss the development and optimization of forensic extraction and analysis methods as well as the implementation of a novel mtDNA massively parallel sequencing assay for chemically modified samples, which have increased AFDIL's ability to obtain DNA results from highly degraded samples.

2:35 Life after Death: The Thanatomicrobiome
Gulnaz Javan, Ph.D., Vice-Chair, Institutional Review Board; Assistant Professor, Forensic Science Program, Department of Physical Sciences, Alabama State University

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DNA Forensics

Exploring New Frontiers in Forensic DNA Investigation

Microbial DNA in the internal organs of decaying humans may hold the key to unlock the door to innovative tools for forensic investigators. Dr. Gulnaz Javan, a forensic scientist who studies the human thanatomicrobiome (i.e., thanatos-, Greek for death), will discuss her recent findings that contribute to the Human Postmortem Microbiome Project.

RAPID DNA EVALUATION

3:05 Next Generation Technology under Development for Rapid, Comprehensive DNA Analysis
Bruce R. McCord, Ph.D., Professor, Analytical/Forensic Chemistry, Florida International University

3:35 Sponsored Presentation *(Opportunity Available)*

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

4:50 Rapid DNA Typing: Applications to Human Identification
Erica Romsos, MFS, Forensic Scientist, Biomolecular Measurement Division, Applied Genetics, NIST
Advancements of all of the processes for the forensic DNA typing process is a challenging goal, but has shown to be possible in recent years. Several parallel efforts have been made to develop a device which will incorporate all of the forensic workflow and utilize a simple swab in, answer out process. Rapid DNA typing advancements will be discussed.

5:20 Does Everyone Need Rapid DNA?
Tobias Hampshire, Ph.D., Global Product Manager, ParaDNA, Science & Innovation, LGC
LGC ParaDNA® Instruments provide a rapid, cost effective approach, for non-expert users to guarantee that the most appropriate samples are sent from the crime-scene for laboratory analysis. We aim to clarify why this is not a Rapid-DNA technology and what users in the U.S. are really doing with it, how it functions at a cellular level, and what our latest R&D is telling us about RNA left at scene.

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

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6:50 Close of Day

WEDNESDAY, AUGUST 24

7:15 am Registration

7:30 Problem-Solving Breakout Discussions with Continental Breakfast

DNA ISOLATION AND PROFILING

8:25 Chairperson's Remarks

8:30 Applications of STR DNA Analysis for Forensic Casework: The Wisconsin Way
Vincent M. Purpero, Ph.D., Forensic Scientist and Senior DNA Analyst, Wisconsin State Crime Laboratory, Division of Law Enforcement Services, Wisconsin Department of Justice
The workflow for generating an STR DNA profile at the Wisconsin State Crime Laboratory consists of: screening evidence, extraction, quantification, amplification and capillary electrophoresis. The WSCL has fully automated this process from extraction to DNA profile. The WSCL also utilizes Y-STR DNA technology when a statistically significant autosomal STR DNA profile is not achieved. Some casework examples illustrate different methods applied to generate statistically reliable STR DNA profiles.

9:00 Allelic Dropout and the Impact on Estimating the Number of Contributors of Low-Level, Complex DNA Mixtures
Catherine M. Grgicak, Ph.D., Assistant Professor, Program in Biomedical Forensic Sciences, Boston University School of Medicine
Computing the number of contributors (NOC) that could explain the evidence is common in forensic DNA analysis. Thus, the impact of dropout on estimating the NOC was assessed by varying the probability of dropout (Pr(D)) in simulated mixtures. Results show that estimating the actual NOC using allele counts was unreliable for mixtures with 1) greater than two contributors, or 2) low-template minor contributors. Gross underestimations were regularly observed.

9:30 Mixture Interpretation Software – Implementing Innovative Software Solutions in a Fast-Paced Crime Laboratory Setting
Kenneth Jones, Trace/Biology Unit Supervisor, Forensic Services Division-Forensic Biology Section, Baltimore Police Department
Forensic DNA analysis continues to evolve with the advent of advanced technologies and increased testing sensitivity, creating large amounts of complex data. Laboratories must adjust their processes and procedures to address this data and the resulting interpretation challenges, particularly mixed samples. The implementation of mixture interpretation software helps address these challenges. The use of TrueAllele, a probabilistic genotyping software, is reviewed, as well as the impact on laboratory operations.

10:00 Probabilistic Genotyping
Speaker to be Announced

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

11:15 PLENARY KEYNOTE SESSION
Please see page 3 for details.

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

1:20 Close of DNA Forensics

1:25 Ice Cream and Cookie Break in the Exhibit Hall with Poster Viewing

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Clinical NGS Assays

Addressing Validation, Standards, and Clinical Relevance for Improved Outcomes

RECOMMENDED PRE-CONFERENCE SHORT COURSES*

SC1: NGS Diagnostics: Technology, Regulation, and Reimbursement

SC6: NGS Assay Development and Validation

SC9: Practical Considerations for NGS Data Analysis and Interpretation

**Separate registration required, please see page 5 for details*

TUESDAY, AUGUST 23

7:30 am Main Conference Registration & Morning Coffee

ASSAY VALIDATION AND ANALYSIS

8:30 Chairperson's Opening Remarks
Kent Lohman, Ph.D., MRIGlobal

8:40 Best Practices for Using Genome in a Bottle Reference Materials to Benchmark Variant Calls
Justin Zook, National Institute of Standards and Technology
NIST has hosted the Genome in a Bottle Consortium to develop well-characterized human genomes to enable benchmarking of variant calls. We also are working with the Global Alliance for Genomics and Health Benchmarking Team to develop tools to calculate standardized performance metrics when comparing variant calls to our benchmark samples. I will discuss our well-characterized genomes and how to use them to benchmark variant call accuracy, and important considerations for clinical laboratories.

9:10 NGS in Clinical Diagnosis: Aspects of Quality Management
Pinar Bayrak-Toydemir, M.D., Ph.D., FACMG, Associate Professor, Pathology, University of Utah; Medical Director, Molecular Genetics and Genomics, ARUP Laboratories
Next-generation sequencing (NGS) technologies continue to be improved in clinical laboratories, enabling rapid transformations in genomic medicine. NGS could be an extensive process both at the wet bench and bioinformatics levels. Quality assurance steps including how to detect sample switch, alignment and variant calling algorithms for in-dels, and necessity for Sanger sequencing confirmation will be discussed using interesting clinical cases.

9:40 Thorough Validation and Implementation of Preimplantation Genetic Screening for Aneuploidy by NGS
Rebekah Zimmerman, Ph.D., Laboratory Director, Clinical Genetics, Foundation for Embryonic Competence
We have developed and validated a targeted NGS assay for whole chromosome aneuploidy that has comparable accuracy to qPCR, while improving cost and throughput limitations. Also of critical interest, we have explored limits of detection for mosaicism and segmental aneuploidy, which are two areas of major concern among the IVF community.

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

EXOME INTERPRETATION CHALLENGES

10:55 Chairperson's Remarks
Avni B. Santani, Ph.D., The Children's Hospital of Philadelphia

11:00 Are We There Yet? The Odyssey of Exome Analysis and Interpretation
Avni B. Santani, Ph.D., Director, Genomic Diagnostics, Pathology and Lab Medicine, The Children's Hospital of Philadelphia
The comprehensive analysis of complex genomic data such as exome sequencing presents several challenges to a clinical laboratory. Factors including phenotyping, use of public and internal databases and balancing sensitivity with a rapid return of results are critical. Using several cases as examples, the critical areas during the exome interpretation process will be highlighted.

11:30 Challenges in Exome Interpretation: Intronic Variants
Rong Mao, M.D., Associate Professor, Pathology, University of Utah; Medical Director, Molecular Genetics and Genomics, ARUP Laboratories
Exome sequencing, the targeted sequencing of the subset of the human genome that is protein coding, is a powerful and cost-effective new tool for dissecting the genetic basis of diseases and provide a diagnostic odyssey for undiagnostic rare and complex conditions. Interpretations of variants detected by exome sequencing, determination of the pathogenicity and clinical significant of the variants are big challenge. Hereby I present the intonic variants detection and interpretation by exome sequencing

12:00 pm Exome Sequencing: Case Studies of Diagnostic and Ethical Challenges
Lora J. H. Bean, Ph.D., Assistant Professor, Human Genetics, Emory University
Exome sequencing in the age of variant databases and data sharing is a powerful tool in genetic diagnostics; however, analysis of variants across the entire exome presents interpretative and ethical challenges. Cases will be presented demonstrating the challenge of diagnosing a newly described syndrome and making a dual diagnosis, as well as cases exemplifying the challenges of technical limitations, specifically the inability to detect deletions or sequence genes with pseudogenes.

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Clinical NGS Assays

Addressing Validation, Standards, and Clinical Relevance for Improved Outcomes

12:30 Sponsored Presentation *(Opportunity Available)*

1:00 Luncheon Presentation *(Sponsorship Opportunity Available)*
or Enjoy Lunch on Your Own

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

ESTABLISHING STANDARDS

2:00 Chairperson's Remarks
Karl V. Voelkerding, M.D., ARUP Laboratories

2:05 Assessing the Feasibility of Establishing Performance Standards for Next Generation Sequencing Based Genetic Testing
Karl V. Voelkerding, M.D., Professor, Pathology, University of Utah; Medical Director for Genomics and Bioinformatics, ARUP Laboratories
In this presentation, the concepts of validation and establishment of performance characteristics for NGS tests will be discussed in relation to CAP accreditation requirements. Results from the CAP methods based proficiency testing program for detection of germline variants launched in 2015 will be presented in the context of a discussion of the feasibility of establishing performance standards for germline NGS testing.

2:35 Clinical Cancer Genomics-Driving Precision Medicine
Shashi Kulkarni, MS, Ph.D., Vice Chairman, Research, Molecular and Human Genetics, Baylor College of Medicine Houston Texas; Chief Scientific Officer, Baylor Miraca Genetics Laboratory
Next-generation DNA sequencing technology is revolutionizing clinical cancer genomic diagnostics by enabling precision cancer medicine by directing molecularly targeted therapies. Adoption of NGS brings 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 next-generation sequencing including resource allocation, assay development, compliance, bioinformatics, data management, analysis and interpretation of data in a CAP/CLIA environment.

3:05 NGS Harmonization Manifold: From Data to Ontologies, from Computations to Knowledge
Vahan Simonyan, Ph.D., Lead Scientist, Director, Bioinformatics; Principal Investigator, HIVE, Food and Drug Administration (FDA)
Multiple aspects of data and computation standardizations will be discussed from research and regulatory perspectives. Brief description of FDA's NGS harmonization efforts in the form of High-performance Integrated Virtual Environment (HIVE) will be outlined and biocompute object database for harmonized computational protocols will be described.

3:35 An NGS Inter-Laboratory Study to Assess Performance and QC
Sponsored by seracare
Andrea Ferreira-Gonzalez, Ph.D., Chair, Molecular Diagnostics Division, Pathology, Virginia Commonwealth University Medical School
Russell Garlick, CSO, SeraCare Life Sciences

NGS assays that accurately detect somatic mutations in tumor tissue are crucial to precision medicine. Laboratory-developed test procedures need to be accurate, precise, clinically relevant, and monitored for continued quality performance. However, the technical performance between laboratories has been difficult to assess because there are no widely accepted standards. This presentation describes an inter-laboratory study using Seraseq™ biosynthetic reference materials to assess different platforms, assays, and pipelines for routine QC use.

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

4:50 PANEL DISCUSSION: Gene Panel vs. Whole Exome vs. Whole Genome
Moderator to be Announced
Panelists: John Chiang, Ph.D., Director, Casey Eye Institute, Oregon Health & Science University
Avni B. Santani, Ph.D., Director, Genomic Diagnostics, Pathology and Lab Medicine, The Children's Hospital of Philadelphia
Justin Zook, Ph.D., Researcher, National Institute of Standards and Technology (NIST)
- Depth of coverage
- Increasing speed
- Impediments to WGS and WES becoming routine practice
- What do clinicians want?
- Reimbursement and coding

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

6:50 Close of Day

WEDNESDAY, AUGUST 24

7:15 am Registration

7:30 Problem-Solving Breakout Discussions with Continental Breakfast

DETERMINING CLINICAL SIGNIFICANCE AND RETURNING RESULTS

8:25 Chairperson's Opening Remarks
Helen Fernandes, Ph.D., Weill Cornell Medical College

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8:30 Applications of Clinical NGS Data for Translational Studies
Helen Fernandes, Ph.D., Pathology & Laboratory Medicine, Weill Cornell Medical College
This presentation will discuss how clinical NGS data obtained from formalin fixed paraffin embedded (FFPE) and Fine Needle Aspirate (FNA) derived tumor DNA is used for translational studies.

9:00 NGS-Based Tests: Understanding Performance, Sharing Data, and Providing Transparency
Živana Težak, Ph.D., Associate Director, Science and Technology, Office of In Vitro Diagnostics and Radiological Health (OIR), CDRH/FDA
As a part of the White House's Precision Medicine Initiative, FDA was tasked with optimizing regulatory framework for NGS based clinical tests. This presentation will describe FDA's current thinking on the content and possible use of standards in design and performance evaluation of NGS-based tests, crowdsourcing efforts to share and improve bioinformatics tools, and the use of public human genetic variant databases to help assessing clinical relevance of test results. Ultimately, the goal is to accelerate the clinical adoption of precision medicine while ensuring that the tests used are safe and effective.

9:30 Genetic Counseling in the Era of Genomic Medicine
Sarah Scollon, MS, C.G.C., Instructor, Pediatrics-Oncology, Baylor College of Medicine
As NGS has been incorporated into clinical care, genetic counselors have played critical roles in translating this new technology to patients. This presentation will share genetic counseling experiences from the NHGRI/NCI supported Clinical Sequencing Exploratory Research Consortium including the BASIC3 study at Baylor College of Medicine. Topics will include lessons learned consenting patients and communicating genomic test results and future challenges and opportunities in the era of genomic medicine.

10:00 Presentation to be Announced

Sponsored by IDT INTEGRATED DNA TECHNOLOGIES

10:15 Sponsored Presentation *(Opportunity Available)*

10:30 Coffee Break in Exhibit Hall with Poster Viewing

11:15 PLENARY KEYNOTE SESSION
Please see page 3 for details.

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

1:20 Close of Clinical NGS Assays

1:25 Ice Cream and Cookie Break in the Exhibit Hall with Poster Viewing

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Hospital Laboratory Design and Renovation

Bringing Together Designers, IVD Manufacturers and Laboratory Directors

RECOMMENDED PRE-CONFERENCE SHORT COURSES*
SC2: Method Validation According to CLSI Guidelines
SC5: Establishing the Value of Diagnostic Tests
**Separate registration required, please see page 5 for details*

TUESDAY, AUGUST 23

7:30 am Main Conference Registration & Morning Coffee

NEW GENERATION CLINICAL LAB: INTEGRATING TOOLS & PROCESSES

8:30 Chairperson's Opening Remarks
Per Skoglund, Change Manager, Karolinska University Laboratory, Karolinska University Hospital

8:40 Planning, Building and Moving into a New Laboratory
Myra L. Wilkerson, M.D., Vice Chair, Laboratory Medicine Service Line, Geisinger Health System
Administration has agreed to fund a new laboratory building. How do you start such a big project? How do you choose an architect? Who helps you choose everything from paint colors to laboratory casework? How do you move without disruption of services? This session focuses on the recent experience of building a new core laboratory facility for the Geisinger Health System, providing guidance for others considering a laboratory building project.

9:25 Laboratory of the Future - Lean Redesign Case Study
Patricia Macholan, Executive Director, Laboratory Technical Operations Excellence, Quest Diagnostics
Since the future role of Laboratory Medicine is strongly and equally challenged by economic and new technological pressures, it is essential to take a broad view of the discipline and present to the administrators and other decision-makers the full spectrum of activities and benefits Laboratory Medicine can provide. In particular, the importance and the true impact of Laboratory Medicine can only be achieved by adding value to laboratory tests, represented by their effectiveness in influencing the management of patients and related clinical outcomes.

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

HOW DESIGN FIRMS CAN HELP

10:55 Chairperson's Remarks
Patricia Macholan, Executive Director, Laboratory Technical Operations Excellence, Quest Diagnostics

11:00 Planning Clinical Laboratories: Adventures in Space and Time
Barbara A. Spitz, AIA, HERA Lab Planners
Joshua Evans, HERA Lab Planners
If you have ever done a renovation project, you probably have some idea of planning in three dimensions. Clinical labs, however, must also recognize the importance of the fourth dimension, time. Planning a clinical lab is more akin to planning a trip on a large sailboat: both are fast moving machines run by a crew with different skills, navigating a variety of constantly changing conditions. Because of hospital demands, clinical lab operations must adhere to turn-around-time targets. Planning three dimensional space becomes a complex exercise when this fourth dimension of time is introduced. We will describe tools used to enable the team to address automation, specimen volume, efficient flow and staffing needed in a clinical lab. We will discuss the various drivers in the planning of a clinical lab and help you understand not only the three dimensions of space but also the impact of the fourth dimension of time.

11:45 am Optimal Efficiency: New Approaches to Lab Consolidation and Centralization
Manuel Hernandez, M.D., Principal & Health Practice Leader, CannonDesign
Can lab consolidation or centralization help reduce hospital costs and mitigate risks? Showcasing case studies from around the nation, this session highlights how hospital lab consolidation and centralization can help hospitals achieve significant efficiencies that lead to substantial cost savings and support more robust operational protocols. Strategies that optimize workflow and staff utilization; improve throughput and accuracy in sample testing; and ease access to test results will be discussed.

12:30 pm Mobile Labs: Bringing Labs to the Point of Need
Sponsored by positiveID
Lyle Probst, President, E-N-G Mobile Systems Inc., PositiveID Corporation
E-N-G, a leader in mobile laboratory design/production, has delivered over 400 MobiLab™ Mobile Laboratories. The field-proven line is available in a range of platforms including vans, truck-based systems, shipping containers, and trailers up to 53 feet. Applications range from general-purpose and chemistry labs to BSL3-ready and full CBRNE threat detection/analysis.

12:45 Sponsored Presentation *(Opportunity Available)*

1:00 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

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

CASE STUDIES

2:00 Chairperson's Remarks
Joseph M. Campos, Ph.D., George Washington University Medical Center

2:05 Karolinska University Laboratory – Experiences, Benefits and Challenges in Adapting the New Operating Model to Value-Based Healthcare
Per Skoglund, Change Manager, Karolinska University Laboratory, Karolinska University Hospital
Niklas Bark, Ph. D, Specialist, Karolinska Institute
Elisabeth Gustavsson, Chemist, University of Gothenburg

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Bringing Together Designers, IVD Manufacturers and Laboratory Directors

The Karolinska University Laboratory is the largest supplier of laboratory services in Sweden, offering a complete laboratory service, including highly specialized and standardized diagnostics, consultation, point-of-care analysis etc. to the Stockholm County. Our single largest customer is the Karolinska University Hospital. The hospital in collaboration with Karolinska Institute is currently changing the operating model by replacing the classical divisions and clinics with an implementation of patient centered value-based healthcare. The main change is to align all responsibility and resources to identified patient flows. This means that the Karolinska University Laboratory has a unique opportunity to adapt the new operating model and optimize quality and efficiency from a value-based healthcare perspective and to identify and evaluate the change in laboratory needs. We will present our strategies and processes to meet the opportunities and challenges that the change process implies for the laboratory service.

2:35 New Generation Laboratory Management: Technologies and Solutions

David Layton, Improvement Engineering and Operations Leader, ARUP Laboratories

Identify the sources of waste and non-value added activities associated with current lab processes, and understand where opportunities for improvement lie. With a vision and documentation of the current processes and improvement opportunities; Value Stream Mapping, Standard Work, Work Flow Analysis, Flexible systems and the other tools of Lean are used to design and engineer an efficient future state laboratory

3:05 LEAN Cost Accounting in the Laboratory

Stephen S. "Sky" Soom, Associate Vice President, Performance & Innovation, PAML

In today's era of rapidly changing reimbursement models, test methods and payer shifts, laboratories need a way to monitor these changes in near real time to respond accordingly. PAML has developed software capabilities and a supporting Business Intelligence platform to meet the dynamics of today's challenges of remaining on the proactive side of the cost of testing.

3:35 "Best Test First?"

Sponsored by The HudsonAlpha CLINICAL SERVICES LAB

Andy Crouse, Ph.D., Director, Business Development, HudsonAlpha Clinical Services Lab, LLC

The diagnostic odyssey for patients with rare and undiagnosed disease is approximately 7 years long, >$100,000 and can result in inappropriate and/or harmful treatment regimens. Whole genome sequencing produces a diagnosis in ~40% of cases; those diagnoses often impact medical management. Integrating whole genome sequencing into the clinic will positively impact patient care and medical costs.

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

4:50 PANEL DISCUSSION: Open Discussion on Other Lab Issues- Silos, Personnel and Metrics

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

Panelists: Speakers of the Day

Topics to be discussed include but are not limited to:

- Breaking down laboratory silos
- Using laboratory metrics to optimize lab workflow
- Personnel issues for the future- designing labs that focus on employee well-being and engagement

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

Sponsored by SLONE PARTNERS

6:50 Close of Day

WEDNESDAY, AUGUST 24

7:15 am Registration

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

A DESIGN WITH THE FUTURE IN MIND

8:25 Chairperson's Opening Remarks

Jeff Shulkin, M.S., Principal, Morph Design, Inc.

8:30 Designing the Microbiology Laboratory of Tomorrow and Beyond

Anne Beall, Director, U.S. Clinical Marketing; Microbiology & Molecular Solutions, BioMerieux Inc.

For decades, clinical microbiology labs has been doing the same thing the same way. Lab design is only one of the drivers to improve performance. A combination of the right design, optimization of people resources, processes and technology can help drive microbiology laboratory efficiency.

9:15 Creating the Evolving Laboratory

Jeff Shulkin, M.S., Principal, Morph Design, Inc.

The Incongruence - Traditional approaches to Laboratory Design often result in 'fixed' facilities requiring frequent, expensive, disruptive, impractical, minimally effective and, oft, non-fundable serial remodels. In contrast, the testing requirements of Pathology, Clinical Laboratory, Research and R&D labs best reflect the characteristics of dynamic Living Systems. Quoting Frank Lloyd Wright, "Form follows function – that has been misunderstood. Form and function should be one." The Congruence – Integrate the anatomy, physiology and mutability of Living Systems in the design of Living Laboratories.

10:00 Sponsored Presentation *(Opportunity Available)*

10:30 Coffee Break in Exhibit Hall with Poster Viewing

11:15 PLENARY KEYNOTE SESSION
Please see page 3 for details.

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

1:20 Close of Hospital Laboratory Design and Renovation

1:25 Ice Cream and Cookie Break in the Exhibit Hall with Poster Viewing

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Molecular Diagnostics for Infectious Disease

RECOMMENDED PRE-CONFERENCE SHORT COURSES*

SC1: NGS Diagnostics: Technology, Regulation and Reimbursement

SC6: NGS Assay Development and Validation

SC9: Practical Considerations for NGS Data Analysis and Interpretation

**Separate registration required, please see page 5 for details*

WEDNESDAY, AUGUST 24

10:30 Registration

11:15 PLENARY KEYNOTE SESSION
Please see page 3 for details.

12:40 pm Luncheon Presentation: Point-of-Care Molecular Diagnostics Enable Better Testing Compliance and Immediate Patient Management Decisions

Sponsored by Xagenic

Shana Kelley, Founder & CTO, Xagenic Inc.

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

Recent availability of CLIA waived molecular diagnostic tests has enabled improved patient care at a lower cost to the healthcare system. Xagenic is entering this rapidly growing market by commercializing a combination chlamydia/gonorrhea test, allowing better compliance with USPSTF and CDC screening recommendations. The Xagenic X1™ platform will permit in-office molecular testing in <20 minutes using non-refrigerated cartridges. We will produce a menu of multiplexed infectious disease tests with greatest utility during first clinical presentation.

1:25 Ice Cream and Cookie Break in the Exhibit Hall with Poster Viewing

EMERGING TECHNOLOGIES & NGS SEQUENCING FOR ID

1:50 Chairperson's Opening Remarks

Gerrit van Roekel, MSc, MBA, Senior Program Officer, Life Science Partnerships, The Bill and Melinda Gates Foundation

2:00 Establishing FDA-ARGOS for Regulation of Sequencing-Based Diagnostics for Infectious Diseases

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

The presentation will outline studies to evaluate the use of sequencing-based devices as an aid in infectious disease diagnostics, and to gain a better understanding of potential HTS clinical implementation strategies. Regulatory use case scenarios utilizing the FDA-ARGOS database resource will be showcased. The information contained in the presentation concerning possible approaches for validation are suggested approaches open for feedback.

2:30 Emerging Assays for Infectious Diseases in Diagnosis and Outbreak Surveillance

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

Advances in technology, genomics, and bioinformatics and the vast increases in the size of reference databases has made comprehensive diagnosis of infectious diseases practical. Here we will discuss the promise, challenges, and experience with clinical validation and implementation of a metagenomic next-generation sequencing (mNGS) assay for identification of pathogens in hospitalized patients. We will also discuss the use of new technologies, including nanopore sequencing and transcriptome profiling, for surveillance of epidemics such as the 2015-2016 Zika virus outbreak in the Americas.

3:00 Viral Hemorrhagic Fever Detection: Challenges of Translating Research into Actionable Diagnostics

Timothy D. Minogue, Ph.D., Chief, Molecular Diagnostics Department, Diagnostic Systems Division, USAMRIID

The current Ebola outbreak highlights the need for effective/ rapid diagnostics in an outbreak situation. However, several highly pathogenic organisms present with similar pathology are endemic to similar regions and co-circulate with Ebola. Our group strives to provide research and development of diagnostics to affect time-to-answer, assay sensitivity, and ease of use to help diagnosis these types of diseases.

3:30 Quantitative Molecular Diagnostics in Less Than 12 Minutes for Point of Care and Decentralized Settings

Sponsored by KMC Systems

Robert Juncosa, CEO, Thermal Gradient, Inc.

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

Thermal Gradient's POC CLIA-Waivable instrument and cartridge perform molecular diagnostic testing in under 12 minutes. Learn the fundamentals of enabling rapid PCR technology, the basis for the Flash MDx platform, which is portable and fully automated, and how the Flash platform addresses the need for rapid molecular POC solutions.

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3:45 20-minute Multiplex PCR Detection of Antibiotic-Resistant Gram-Negative Bacteria: Utility of a Novel Random-Access Real-Time PCR System

Sponsored by Streck

Chris Connelly, Ph.D., Research & Development Scientific Manager, Molecular Technology, Streck, Inc.

Rapid testing strategies are needed to characterize antibiotic resistant organisms and improve antimicrobial stewardship programs. The Streck Zulu RT™ instrument, in combination with the ARM-D® line of real-time PCR kits, can screen samples for the presence of genes that mediate resistance in 20 minutes using 4 randomly accessible modules.

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

4:45 Challenges and Approaches for Assuring the Quality of Next-Generation Sequencing in Clinical Laboratories Sequencing Human or Pathogen DNA

Ira M. Lubin, Ph.D., FACMG , Branch Chief (acting); Team Lead, Genetics, Laboratory Research and Evaluation Branch, Division of Laboratory Systems/CSELS, Office of Public Health Scientific Service, Centers for Disease Control and Prevention

The Centers for Disease Control and Prevention published practice recommendations developed by multidisciplinary workgroups for the integration of next-generation sequencing into clinical laboratory settings. Although targeted at the analysis of human genomic DNA, general principles were identified relevant to the analysis of pathogens. Common challenges and approaches faced by laboratories, whether sequencing human or pathogen DNA will be discussed.

5:05 NGS for Diagnosis and Molecular Epidemiology in Clinical Laboratories: Experience and Challenges

Guiqing Wang, M.D., Ph.D., Chief of Labs, Pathology and Clinical Laboratories, Westchester Medical Center & New York Medical College

NGS has great potential for diagnosis of infectious diseases directly from primary clinical specimens and for molecular epidemiology in hospitals and public health setting. For diagnostic microbiology, various sample and library preparations and bioinformatics tools were explored for different types of clinical specimens. Also NGS was used to replace PFGE and MLST in hospital outbreak and nosocomial transmission investigations for improving infection control practice. Experience and challenges in the implementation and routine use of NGS in clinical laboratories will be addressed.

5:25 Standards for NGS-Based Microbial Identification and Quantitation

Jason Kralj, Ph.D., Staff Scientist, Complex Microbial Systems Group, Biosystems and Biomaterials Division, Material Measurements Labora, NIST

Increasingly, NGS-based platforms are being used for identifying clinical, environmental, and biothreat samples. As these continue to develop, it is clear that developers and end-users alike need standards to ensure compatibility between platforms, confidence in identification and limits of detection, and for competency testing for regulatory oversight. We explore how simple mixtures of well-characterized DNA materials can inform the process of sample identification, including how sequencing and informatics artifacts can be identified to improve confidence in analysis.

5:45 Clinical Metagenomics: A Next Generation Diagnostics Solution for Infectious Diseases

Nur Hasan, Ph.D., Adjust Faculty, Center for Bioinformatics and Computational Biology, University of Maryland College Park, Leader Science Team, CosmosID

The presentation will describe various aspects of MetaGenID: ease and operational friendliness, data mining efficiency and processing speed, breadth, depth and curation of genome databases to deliver actionable results, flexibility to allow user incorporations of specific metadata and/or genome sequences, and ability to deploy such system in the field. The presentation will further demonstrate some valuable features that make this technology very attractive and powerful for simultaneous detection and characterization of infectious agents.

6:00 Sponsored Presentation *(Opportunity Available)*

6:15 Close of Day

6:00 Dinner Short Course Registration

6:30- 8:30 pm RECOMMENDED DINNER SHORT COURSE*
SC12: NGS for Infectious Disease Diagnostics
**Separate registration required, please see page 5 for details*

THURSDAY, AUGUST 25

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

EMERGING TECHNOLOGIES & AUTOMATION FOR RAPID DETECTION OF INFECTIOUS DISEASE

8:25 Chairperson's Opening Remarks

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

8:30 Automated Plate Reading and Interpretation: Fact or Fiction?

Nathan A. Ledeboer, Ph.D., Associate Professor of Pathology, Medical Director, Clinical Microbiology, Medical College of Wisconsin

Automation in clinical chemistry and hematology laboratories has been widely available for years, but only recently in microbiology. Following development of an automated reading algorithm, we evaluated its performance for identification of MRSA and VRE from chromogenic media and apply performance of the algorithm to recognize and quantitate colonies from a blood agar plates.

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9:00 Axiom MDA – A High-Throughput Pan-Microbial Microarray

Tom Slezak, Distinguished Member of the Technical Staff, Pathogen Bioinformatics, Lawrence Livermore National Laboratory

The Lawrence Livermore Microbial Detection Array (LLMDA) has evolved since 2007 to now be able to identify over 12,000 unique species (all sequenced bacteria, viruses, fungi, archaea, and protozoa as of the design date). It has recently been commercialized on the Affymetrix Axiom platform which processes 24 or 96 samples in parallel, each with 1.4M probes covering the 12,000+ species. We will briefly discuss the history of how the LLMDA has been used on prior platforms and data from the new Axiom MDA format.

9:30 A Multiplexed Platform for Precision Medicine at the Point of Care Applied to Sepsis Diagnostics

Sponsored by m·bio™ DIAGNOSTICS

Chris Myatt, CEO, MBio Diagnostics, Inc.

Optical waveguide sensors combined with fluorescent detection enable sensitive and multiplexed tests for point of care use. We will detail a simple disposable cartridge and portable reader design that enables fast measurements of host response signatures. We detail examples of risk stratification and rapid classification of infection for sepsis.

9:45 Rapid Point-of-Care Molecular Diagnostics for Sexually Transmitted Infections

Sponsored by agl

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

Atlas Genetics is an innovative MDx Company focused on POC testing through its fully-automated, ultra-rapid platform providing lab quality molecular tests. Up to 24 genetic targets can be detected from multiple sample types. CE Mark was awarded January 2016 for a Chlamydia trachomatis test, with CT/NG in the near-term pipeline.

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

Sponsored by Celsee Diagnostics™

10:50 The Host Response as a Diagnostic Target for Infectious Disease

Ephraim L. Tsalik, M.D., Ph.D., Assistant Professor, Medicine, Duke University School of Medicine

Infection represents a maladaptive interaction between pathogen and host. Diagnostics have largely focused on pathogen identification although this approach has limitations. A focus on the host response offers a complementary diagnostic strategy. Biomarkers may derive both from biology-informed candidates as well as unbiased 'omic methodologies. Advances in modeling and technology are now converging, creating new opportunities for host-response diagnostics in infectious diseases.

11:20 Validation and Implementation of the Biofire GI Panel

Julie A. Ribes, M.D., Ph.D., Director, Clinical Microbiology, Associate Director, Hospital Laboratories, UK HealthCare Chandler Hospital

UK HealthCare went live with the FDA-approved Biofire GI FilmArray early in 2015. The intent of this implementation was to replace the 3-4 day routine stool culture with a test that is completed in about an hour. This talk will cover how the film array works, how to validate the panel, and issues encountered with implementation, and 1 year's experience.

SEPSIS DIAGNOSTICS & MANAGEMENT

11:50 Molecular Detection of Pathogens and Mechanisms of Resistance in Patients with Sepsis

Julie A. Ribes, M.D., Ph.D., Director, Clinical Microbiology, Associate Director, Hospital Laboratories, UK HealthCare Chandler Hospital

UK HealthCare implemented the Nanosphere Gram positive and Gram negative Blood culture panels in the fall of 2014, and the Biofire Sepsis panel in 2016. The intent of these implementations was to provide the patient with the right drug at the right time. This talk will discuss the evaluation of Nanosphere and BioFire platforms, their implementation and post-go live experience.

12:20 pm Integrated Sample-Prep and Immunoassay Array Platform for High-Sensitivity, Low-Complexity Multiplexed POC Diagnostics

Sponsored by Paratus DIAGNOSTICS

John C. Carrano, Ph.D., CEO, Paratus Diagnostics

Here we report on a disposable device that utilizes our Specimen Delivery System (Paratus SDS®) and attaches to a smartphone for multiplexed detection of infectious diseases. Operation involves inserting the specimen containing swab directly into the sensing cartridge where the biomarkers elute downstream for subsequent detection through a chemiluminescent immunoassay.

12:35 A Fluidic Card Multiplex Array for Quick Point-Of-Care Detection of Sepsis

Sponsored by RANDOX BIOSCIENCES Discovery | Drug Development | Diagnostics

Claire Huguet, Ph.D., Head, Biomarker Services, Biosciences, Randox Biosciences

Severe sepsis is a leading cause of death worldwide, requiring fast germ identification techniques. We describe a 45-plex, molecular assay using a disposable fluidic biochip format for use with a POC platform at patient bedside. Accurate germ ID is obtained in 2 hours, covering a mix of bacteria's and fungi.

12:50 Luncheon Presentation: Fit-For-Workflow Considerations for Designing Multiplex PCR Assays

Sponsored by Seegene

Young Kim, Ph.D., Lead Application Scientist, Research & Development, Seegene Technologies

Conventional PCR assay development is generally limited to very few targets, and not an ideal companion to NGS. Using examples from BCR-ABL, thrombosis, and HPV, we will discuss novel approaches to multiplex PCR assay development with high-throughput, target complexity, sensitivity and specificity.

1:20 Session Break

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SEPSIS DIAGNOSTICS & MANAGEMENT

2:00 Chairperson's Remarks

Thomas M. File, Jr., M.D., MSc, MACP, FIDSA, FCCP, Chair, Infectious Disease Division Summa Health System Akron; Professor, Internal Medicine, Northeast Ohio Medical University (NEOMED)

2:05 Multi-Cohort Analysis and Robust Host Gene Markers in Diagnosis and Prognosis of Infectious Disease

Timothy E. Sweeney, M.D., Ph.D., Research Associate, Institute for Immunity, Transplantation and Infections, Stanford University

By integrating data from multiple study cohorts, we have found highly robust, parsimonious gene sets for the diagnosis of infectious diseases, such as acute bacterial or viral infections, or pulmonary TB. Similarly, promising work has shown the potential to risk-stratify patients with sepsis based on host biomarkers, potentially enabling a precision medicine approach to the septic patient.

MOLECULAR-BASED TESTING IN ACTION IN THE CLINICAL SETTING

2:35 Mass Spectrometry-Based Multiplexing Assays for Direct Detection and Absolute Quantitation of Flaviviral Proteins - A Tale of Two Flaviviruses: Dengue Virus and Zika Virus

Francois Jean, Ph.D., Associate Professor, Microbiology and Immunology; Scientific Director, Facility for Infectious Disease and Epidemic Research (FINDER), University of British Columbia

My talk will be directed at the critical need for molecular diagnosis of flavivirus infection - in particular with the current challenges associated with the co-infection of Zika virus (ZIKV) and Dengue virus (DENV) in the Americas.

IMPACT OF RAPID DIAGNOSTIC TESTS ON ANTIMICROBIAL STEWARDSHIP AND ANTIBIOTIC USAGE

3:05 Impact of Rapid Diagnostic Tests on Antimicrobial Stewardship

Thomas M. File, Jr., M.D., MSc, MACP, FIDSA, FCCP, Chair, Infectious Disease Division Summa Health System Akron; Professor, Internal Medicine, Northeast Ohio Medical University (NEOMED)

Antimicrobial resistance is a serious health threat that affects the clinical outcome of patients, as well as results in higher rates of adverse events and healthcare costs. Antibiotic misuse is the most important modifiable factor, which leads to antimicrobial resistance. Antimicrobial stewardship programs (ASP) have proven highly successful in improving antibiotic use. The availability of more rapid molecular tests for infectious disease has the potential to enable better pathogen-directed therapy, avoid antimicrobial overuse, and result in improved antimicrobial stewardship.

3:35 The Importance of Rapid Diagnostics in Antimicrobial Stewardship

Debra Goff, Pharm.D., FCCP Infectious Disease Specialist, The Ohio State University Wexner Medical Center

Our work involves a review of clinical applications of rapid diagnostic tests and the practical applications to stewardship, in support of early diagnosis for appropriate antimicrobial therapy.

4:05 Close of Conference

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Clinical Application of Cell-Free DNA

Ensuring Clinical Value of Non-Invasive Diagnostics

RECOMMENDED PRE-CONFERENCE SHORT COURSES*

SC3: Translating CTCs for Clinical Use

SC5: Establishing the Value of Diagnostic Tests

**Separate registration required, please see page 5 for details*

WEDNESDAY, AUGUST 24

10:30 am Registration

11:15 PLENARY KEYNOTE SESSION
Please see page 3 for details.

12:50 pm Luncheon Presentation to be Announced

Sponsored by RainDance Technologies

1:25 Ice Cream and Cookie Break in the Exhibit Hall with Poster Viewing

VALIDATING LIQUID BIOPSIES

1:50 Chairperson's Opening Remarks

Maximilian Diehn, M.D., Ph.D., Assistant Professor, Radiation Oncology, Stanford Cancer Institute, Institute for Stem Cell Biology & Regenerative Medicine, Stanford University

» 2:00 KEYNOTE PRESENTATION: A Regulatory Perspective on Tumor Gene Panels

Eunice Lee, Ph.D., Chief, Office of In Vitro Diagnostics and Radiological Health, Center for Devices and Radiological Health, US Food and Drug Administration

High throughput assays are rapidly being employed for oncology applications in the clinical setting. This has introduced new challenges to the regulatory paradigm for *in vitro* diagnostic devices (IVDs). An overview of the regulatory landscape for IVDs will be provided, including companion and complementary diagnostics. The complexities associated with tumor gene panels intended to evaluate liquid biopsies will also be discussed, highlighting considerations for validating the performance of the assays.

2:30 Multipanel Massive Parallel Sequencing cfDNA in Monitoring Cutaneous Melanoma Progression

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

Analysis of cfDNA gene mutation panel in melanoma patients serial bleeds over several years of follow-up can be very informative on events ongoing during tumor progression. The highly sensitive and approach of multiple gene mutation panel assessment by MPS of cfDNA provides a very comprehensive analysis to allow correlation to real-time clinical events of patients. These retrospective studies demonstrate that cfDNA mutations can arise at different time points during tumor progression. This approach of precision medicine monitoring melanoma progression allows a more accurate real-time assessment of what is transpiring in the patient.

3:00 Monitoring of Circulating Tumor DNA in Diffuse Large B-Cell Lymphoma

Mark Roschewski, M.D., Staff Clinician, Commissioned Corps, United States Public Health Service, Center for Cancer Research, Lymphoid Malignancies Branch, National Cancer Institute, National Institutes of Health

Monitoring treatment response in diffuse large B-cell lymphoma (DLBCL) relies on imaging scans that do not improve survival. Cell-free circulating tumor DNA (ctDNA) can be detected in patients with DLBCL. Next-generation sequencing (NGS)-based assays of ctDNA provide biologic information previously inaccessible and predict early treatment failure and disease relapse prior to CT scans in DLBCL. Will discuss clinical and research applications of ctDNA monitoring in DLBCL.

3:30 Multiplexed ICE COLD PCR Enriches Any Low-Level Mutation Present in DNA Isolated from FFPE and Plasma Samples

Sponsored by Transgenomic® Advancing Personalized Medicine

Ben Legendre, Jr., Vice President, Laboratory Operations, Transgenomic, Inc.

Using Multiplexed ICE COLD-PCR, cancer patients' DNA isolated from FFPE & Plasma was utilized to enrich for any low level mutations present in the samples. The results demonstrated detection of low level mutations in liquid biopsies; thus allowing for disease management with respect to treatment options and/or drug cocktail modifications for cancer patients.

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

VALIDATING LIQUID BIOPSIES (CONT.)

4:40 Chairperson's Opening Remarks

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

4:45 Analysis of cfDNA to Monitor Metastatic CRC Patients and Manage Drug Resistance

Scott Kopetz, M.D., Ph.D., FACP, Associate Professor, Gastrointestinal Medical Oncology, University of Texas MD Anderson Cancer Center

Circulating cell-free DNA provides an opportunity for rapid interrogation of patient responses for metastatic colorectal cancer patients. Mechanisms of resistance and heterogeneity can also be interrogated with this methodology. This lecture will provide illustrative cases and discussion of the opportunities and hurdles for implementation.

5:15 Liquid Biopsy Approaches for Characterizing Cancer Genomes

Victor Velculescu, M.D., Ph.D., Professor, Oncology; Co-Director, Cancer Biology, Johns Hopkins Sidney Kimmel Cancer Center; Co-Founder, Personal Genome Diagnostics

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.

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5:45 Evaluation of Circulating DNA Analysis in Oncology: Multi-Center Clinical Trials in Europe and Efforts to Standardize Collection of Material and Interpretation of Results

Alain R. Thierry, M.D., Director, Research, Research Institute in Oncology of Montpellier, INSERM

Following critical observations in the past 10 years, numerous studies of clinical validation and clinical utility of circulating DNA analysis, especially in oncology, are ongoing. However, no consensus is made in the field toward setting guidelines and better Standard Operating Procedures (SOP). A comprehensive set of rigid criteria outlining the blood collection, handling, plasma preparation, cirDNA extraction and storage conditions are needed. We will discuss our experience in leading various multicenter, prospective, blinded assays.

6:15 Close of Day

6:00 Dinner Short Course Registration

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

SC14: Liquid Biopsy: Clinical Applications and Business Considerations

**Separate registration required, please see page 5 for details*

THURSDAY, AUGUST 25

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

CLINICAL APPLICATIONS IN CANCER

8:10 Chairperson's Opening Remarks

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

8:15 Presentation to be Announced

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8:30 Clinical Applications of Tracking Plasma AR Aberrations in Castration-Resistant Prostate Cancer

Daniel Wetterskog, Ph.D., Senior Scientific Officer, Centre for Evolution and Cancer, Translational Biology of Urological Cancers Team, Institute of Cancer Research

Our group has been using plasma to interrogate resistance in castration-resistant prostate cancer (CRPC) and develop biomarkers for selecting treatment. Using targeted next-generation sequencing of cfDNA from sequential plasma samples we identified AR mutations emerging with resistance to abiraterone. We also identified a strong association between plasma AR aberrations and resistance to abiraterone in heavily-pretreated CRPC patients. Our data support the clinical utility of cfDNA studies in metastatic prostate cancer.

9:00 Genomic Alterations in Cell-Free DNA and Enzalutamide Resistance in Castration-Resistant Prostate Cancer

Alexander W. Wyatt, Ph.D., Senior Research Scientist, Vancouver Prostate Centre, Assistant Professor, University of British Columbia

The molecular landscape underpinning response to the androgen receptor (AR) antagonist enzalutamide in metastatic castration-resistant prostate cancer (mCRPC) patients is undefined. We collected temporal cfDNA samples from 65 mCRPC patients receiving enzalutamide and performed deep sequencing. AR amplification was associated with primary resistance, as was heavily mutated AR. AR mutations exhibited clonal selection during treatment. At progression cfDNA sequencing revealed mutations or copy number changes in all patients tested, including clinically-actionable alterations in DNA damage repair genes and PI3K pathway genes.

9:30 Transitioning from Research to Clinical-Grade Sequencing: Organ Transplant Use Case

Sponsored by CareDx

John Sninsky, Ph.D., CSO, Research & Development, CareDx, Inc.

A significant unmet medical need exists for clinical diagnostic tools to permit surveillance management of transplant patients and improve the long-term outcomes of immunosuppressive therapy. A clinical-grade cfDNA NGS assay was developed to accurately and reproducibly monitor the levels of the "transgenome". Among key elements of the clinical-grade assay that will be discussed are the use of method proficiency testing, independently sourced analytical reference material and best-in-class bioinformatics and laboratory information management.

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

Sponsored by Celsee Diagnostics

10:50 Characterizing Clonal Evolution and Treatment Resistance Using Circulating Tumor DNA Analysis

Muhammed Murtaza, Ph.D., MBBS. Assistant Professor and Co-Director, Center for Noninvasive Diagnostics, Translational Genomics Research Institute

Analysis of circulating tumor DNA is moving rapidly towards clinical applications such as noninvasive tumor genotyping, monitoring of tumor burden and tracking clonal evolution. However, there is little evidence evaluating the extent of tumor heterogeneity that can be captured in plasma DNA. In this presentation, I will share insights gained from extensive comparison between multi-regional tumor biopsies and serial plasma samples in a patient with breast cancer.

11:20 Circulating Cell-Free DNA: A Novel Gateway to the Genome of Hodgkin/Reed-Sternberg Cells in Hodgkin's Lymphoma?

Peter Vandenberghe, M.D., Ph.D., Head, Laboratory for the Cytogenetic and Molecular Diagnosis of Malignant Diseases, Center for Human Genetics, University Hospitals Leuven; Professor, Medicine, Human Genetics, KU Leuven

Non-invasive massive parallel sequencing of ccfDNA allows the identification of genomic imbalances in Hodgkin/Reed-Sternberg (HRS) cells in early and advanced stage classical Hodgkin's lymphoma (cHL). Given the scarcity of HRS cells in cHL biopsies, this observation opens important new perspectives for genetic investigation of cHL, and may facilitate the development of targeted and precision therapy in cHL.

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11:50 Dynamic Changes in Circulating Tumor DNA in Urine after Drug Administration

Hatim Husain, M.D., Physician, Medical Oncology, University of California, San Diego

We have been able to monitor early drug response to anti-EGFR therapy to model tumor lysis. We will be presenting data on pretreatment kinetics and dynamic changes in ctDNA for patients across anti-EGFR therapies and other genotypes in lung cancer. The data presented will be evaluating urine as a modality for monitoring ctDNA.

12:20 pm Liquid Biopsy: Providing Answers that Matter

Sponsored by Biocept
Completing the Answer™

Veena Singh, Medical Director, Biocept

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. Learn more about biomarkers on blood and providing answers that matter.

12:50 Automation Solutions for Cell Free DNA

Sponsored by TECAN

Jon Smith, Manager, Application Sciences, Tecan

Ensuring clean, uncontaminated collection of plasma prior to purification of cfDNA is critical to the success of downstream molecular diagnostic assays. Automation of plasma isolation and collection prior to subsequent downstream processing is key for increasing efficiency and reducing costs due to retesting. Here we demonstrate a suite of automation tools for optimizing plasma isolation and streamlining subsequent downstream sample processing.

1:20 Session Break

1:35 Presentation to be Announced

Sponsored by Biological Dynamics
Rapid answers for clinical treatment

LIQUID BIOPSY: WHO WILL MAKE IT TO THE MARKET?

2:00 Moderator's Remarks

John Beeler, Ph.D., Vice President, Business Development, Inivata

Panelists:

- How much content is valuable? How many genes are necessary or ideal in a gene panel?
- What are oncologists and patients looking for?
- How are Doctors using data to make decision?
- What is the ideal technology to use? Do you need a comprehensive panel upfront? Discussion of technology and utilization
- How does cost factor in?
- How does regulatory approval factor in?

Regulation: *Abraham Tzou, M.D., Medical Officer, FDA*

CLIA New York State: *Stephanie Shulman, M.P.H., M.S., M.T. (ASCP), Director, Clinical Laboratory Evaluation Program, Wadsworth Center, New York State Department of Health*

Policy: *Sean Tunis, CEO, Center for Medical Technology Policy*

Oncologist: Liquid Biopsy: Use in Clinical Trials

Barbara A. Conley, M.D., Associate Director, Cancer Diagnosis Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute (tentative)

Liquid biopsies offer the promise of interrogating a patient's cancer without a biopsy, as well as being able to longitudinally sample the molecular profile. Potential uses for "liquid biopsy" in clinical trials include initial diagnosis, target-finding (predictive marker), pharmacodynamics assays and ascertaining development of resistance. Qualities of a fit for purpose liquid biopsy for use in clinical trials for cancer drug development will be presented.

Payer: *Girish Putcha, M.D., Ph.D., Director, Laboratory Science, Palmetto GBA (MolDX)*

Investor: *Eli Casdin, Managing Member, Casdin Capital*

4:05 Close of Conference

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AUGUST
24 - 25

Cambridge Healthtech Institute's Second Annual

Diagnostics to Guide Cancer Immunotherapy

Biomarkers and Diagnostics to Predict and Monitor Response to Cancer Immunotherapy

RECOMMENDED PRE-CONFERENCE SHORT COURSES*

SC4: Overcoming Challenges to Commercial Success in Molecular Diagnostics

SC10: Regulatory Compliance in Advanced Diagnostics

**Separate registration required, please see page 5 for details*

WEDNESDAY, AUGUST 24

10:30 am Registration

11:15 PLENARY KEYNOTE SESSION
Please see page 3 for details.

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

1:25 Ice Cream and Cookie Break in the Exhibit Hall with Poster Viewing

KEYNOTE SESSION: FROM PREDICTIVE BIOMARKERS TO COMPANION DIAGNOSTICS

1:50 Chairperson's Opening Remarks
Kenneth Emancipator, M.D., Executive Medical Director and Head, Companion Diagnostics, Merck Research Laboratories

2:00 Improving Immunotherapy for Cancer by Core Analysis
James L. Gulley, M.D., Ph.D., Chief, Genitourinary Malignancies Branch, Director, Medical Oncology Service, Center for Cancer Research, NCI, NIH
Immunotherapy has demonstrated rapid, deep, and durable responses across a wide array of different cancers. However these remarkable responses have only been seen in a small subset of patients. Combinations of agents that can initiate an immune response with agents that can render immune cells more functional within the tumor have the potential to further improve outcomes. However key to this is an understanding of immune regulatory influences within the tumor microenvironment.

2:30 Spotlight on the Human Tumor Microenvironment-Biological Lessons Learned from Human Studies with Checkpoint Inhibitors
Priti Hegde, Ph.D., Anti-Angiogenesis and Cancer Immunotherapy Franchises Biomarker Lead, Oncology Biomarkers, Genentech
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.

3:00 The Immunoproteasome is a Key Regulator of Immune Evasion
Sam M. Hanash, M.D., Ph.D., Professor, Molecular Pathology, Division of Pathology/Lab Medicine, The University of Texas MD Anderson Cancer Center
Antigen presentation by tumor cells is largely dependent on the immunoproteasome. Assessment of the status of the immunoproteasome may predict response or resistance to immunotherapeutic modalities.

3:30 A Cost-Effective GMP Platform for the Manufacture of Companion Diagnostic Proteins
Sponsored by C3 CELL CULTURE COMPANY
Scott Waniger, Vice President, BioServices Division, Cell Culture Company
Manufacturing small quantities of GMP biologics for IVDs cost effectively is difficult. One solution is the use of a scalable, single-use perfusion bioreactor. In this presentation, a comparison of bioreactors for production of IVDs will be given. Data will be presented showing scalability and the ability to maintain steady-state production.

3:45 Circulating Stromal Cells for Immunotherapy
Sponsored by CREATV MicroTech
Daniel Adams, Senior Research Scientist, Creatv MicroTech Inc
Circulating Stromal cells and Circulating Tumor cells present in the blood of patients with solid tumors are easily isolated using CellSieveTM microfilters, useful for non-invasive sequential tumor monitoring. With the ability to stain >12 clinically relevant biomarkers, this technique is ideal for targeted drug analysis, combination immunotherapy and companion diagnostics.

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

4:45 Precision Immunotherapy: The Challenge of Converting Complex Predictive Biomarkers into Practical Companion Diagnostics
Kenneth Emancipator, M.D., Executive Medical Director, Head of Companion Diagnostics, Merck Research Laboratories
Early immunotherapies have produced dramatic results for some patients, but future immunotherapies likely need to be guided by diagnostics to benefit more patients. Properly targeting immunotherapy requires incorporating into clinical practice complex diagnostics which can assess host immune response in addition to cancer biology itself. "Precision Immunotherapy" requires discovery of appropriate predictive biomarkers and incorporating them into practical companion diagnostics which will be adopted by practitioners.

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5:15 PANEL DISCUSSION: Companion Diagnostics for Cancer Immunotherapy: Beyond PD-L1

Moderator: Kenneth Emancipator, M.D., Executive Medical Director and Head, Companion Diagnostics, Merck Research Laboratories

- Latest advances in overcoming tumor-induced immune suppression and immune escape
- Standardization of existing assays and approaches
- Clinical trials for cancer immunotherapy: specific features and the role of diagnostics

6:15 Close of Day

6:00 Dinner Short Course Registration*

*Separate registration required, please see page 5 for details

THURSDAY, AUGUST 25

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

NOVEL APPROACHES: NEOANTIGENS, EPIGENETICS AND MORE

8:25 Chairperson's Remarks

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

8:30 Companion Diagnostics for Cancer Immunotherapy

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

Companion diagnostic testing for PD-1 axis immunotherapy has been a challenge. Multiple assays to test for the same variable (PD-L1) and other mechanisms for assessing the immunologic state of the tumor and its environment are all being tested. This session will discuss issues related to both PD-L1 assays and also discuss progress toward prediction of patient benefit from immune therapy, including assays that are not in the drug labels.

9:00 PD-1 Blockade in Tumors with Mismatch-Repair Deficiency

Luis Diaz, M.D., Associate Professor, Oncology & Cancer Biology, Johns Hopkins University

Somatic mutations have the potential to encode "non-self" immunogenic antigens. Tumors with a large number of somatic mutations due to mismatch-repair defects appear to be highly susceptible to immune checkpoint blockade. This presentation will summarize the clinical and genomic data of using mutations as neoantigens.

9:30 Sponsored Presentation *(Opportunity Available)*

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

Sponsored by Celsee Diagnostics™

10:50 Epigenetic Priming for Immunotherapy in Breast Cancer

Pamela N. Munster, M.D., Professor, Medicine; Program Leader, Development Therapeutics; Director, Early Phase Clinical Trials' Program, Helen Diller Cancer Center, University of California, San Francisco

A breakdown in immune tumor surveillance plays a crucial role in the development of metastatic cancer. Targeting the programmed death receptor (PD-1) and its ligand (PD-L1) have been major breakthroughs. In breast cancers however, particularly in hormone-driven breast cancer, immune responses are often absent. In reverse-translating clinical findings, from the patient to preclinical models, we show that epigenetic modulation leads to epigenetic immune priming and enhancement of immune response.

11:20 Cancer Neoantigens and Their Role as Predictive Biomarkers for Cancer Immunotherapy

Nadeem Riaz, M.D., Radiation Oncology, Memorial Sloan Kettering Cancer Center

Ultimately for the adaptive immune system to combat a cancer, it must recognize it as foreign. Pre-clinical work has suggested mutations in a tumor lead to the formation of neo-antigens (novel peptides) that the immune system recognizes as foreign. Increased mutational load in a number of malignancies has been associated with improved response to checkpoint blockade, suggesting that an increase in neo-antigens leads to a stronger likelihood of response. We will review mutational load and neo-antigen-based signatures as predictors of response to checkpoint blockade.

11:50 Inflammatory Signatures as Predictors of Immunotherapy Response

Darrell Borger, Ph.D., Director, MGH Biomarker/Translational Research Laboratory, Cancer Center, Massachusetts General Hospital

There has been much focus on tumor intrinsic mechanisms that promote escape from immune surveillance as correlates of response to immune modulation. However, we have been working to evaluate the other side of the equation and have been investigating signatures that could predict a balance of co-stimulatory and co-inhibitory signals that may provide for favorable T cell response signature. This has been evaluated in a significant cohort of melanoma patients that have been treated with ipilimumab.

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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PD-L1 AND BEYOND

2:00 Chairperson's Remarks
Janis M. Taube, M.D., MSc, Johns Hopkins University School of Medicine

2:05 Hitting the Target: CAR T-Directed EGFRvIII in Glioblastoma
Jennifer Morrissette, Ph.D., Scientific Director, Clinical Cytogenetics Laboratory; Clinical Director, Center for Personalized Diagnostics (CPD), University of Pennsylvania School of Medicine
We initiated a pilot study of autologous T cells re-directed to the EGFR variant III mutation by means of a lentiviral vector encoding a chimeric antigen receptor (CAR). GBM tumors were screened for the presence of the EGFRvIII mutation by a next-generation sequencing based assay with eligible patients enrolled in the study. NGS results of those patients who have had pre- and post-infusion studies will be discussed.

2:35 Combining PD-L1 Status with Additional Predictive Factors for Cancer Immunotherapy Response
Janis M. Taube, M.D., MSc, Director, Dermatopathology; Associate Professor, Dermatology and Pathology, Johns Hopkins University 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.

3:05 Clinical Advances with Anti-PD-1 Inhibition and Combination Immunotherapy Strategies
Geoffrey T. Gibney, M.D., Georgetown-Lombardi Comprehensive Cancer Center
Targeted immunotherapy has achieved long-lasting clinical responses in a subset of patients with a variety of aggressive malignancies. I will discuss the cellular and molecular characteristics of classical Hodgkin's lymphoma that render this tumor-type uniquely susceptible to PD-1 blockade and correlations between tissue-based biomarker analysis and clinical outcome with either conventional chemotherapy or immunotherapy, and extensions of these observations to additional lymphoma subtypes.

3:35 PANEL DISCUSSION: Enabling Immune Checkpoint Inhibitors Therapy
Moderator: David L. Rimm, M.D., Ph.D., Professor, Pathology, 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

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Ensuring Success of Innovative Tests

RECOMMENDED PRE-CONFERENCE SHORT COURSES*

SC4: Overcoming Challenges to Commercial Success in Molecular Diagnostics

SC5: Establishing the Value of Diagnostic Tests

**Separate registration required, please see page 5 for details*

WEDNESDAY, AUGUST 24

10:30 am Registration

11:15 PLENARY KEYNOTE SESSION
Please see page 3 for details.

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

1:25 Ice Cream and Cookie Break in the Exhibit Hall with Poster Viewing

PAMA RULE MAKING: HOW WILL IT AFFECT DIAGNOSTIC COMPANIES?

1:50 Chairperson's Opening Remarks
Bruce Quinn, M.D., Ph.D., Senior Director, FaegreBD Consulting

2:00 PAMA Implementation: Coding, Pricing, and Coverage
Sylvia J. Trujillo, Senior Washington Counsel, American Medical Association (AMA)
An overview of the Medicare Clinical Laboratory Fee Schedule provisions of the Preserving Access to Medicare Act of 2014 (PAMA) concerning coding, data collection and pricing, and coverage provisions. The foregoing will include highlights of coding issues raised by stakeholders, data collection challenges for clinical laboratories (particularly for physician office based laboratories), and possible coverage implications.

2:10 Clinical Laboratory Payment Reform: Implementing Provisions of the Protecting Access to Medicare Act
Marc Hartstein, Director, Hospital and Ambulatory Policy Group, Centers for Medicare & Medicaid Services (CMS)
This session will discuss Medicare reform of the Clinical Laboratory Fee Schedule based on private payer prices. Topics will also include Medicare payment for advanced diagnostic laboratory tests, coding and pricing for new clinical diagnostic laboratory tests and more.

2:20 PAMA Reimbursement: Lessons from Pharma ASP Reporting
Rick Zimmerer, Partner, Life Sciences Advisory Services, KPMG LLP
PAMA's price reporting and reimbursement system for laboratories was modeled on the ASP system that has applied to Medicare Part B drug reimbursement for over a decade. The laboratory industry has the opportunity to avoid mistakes and apply lessons learned from that program. This session will summarize key similarities and differences and explore key areas where lessons may be applicable.

2:30 PAMA Final Rule: Key Issues for Advanced Diagnostic Laboratory Tests (ADLTs)
Brian P. Carey, Partner, Foley Hoag LLP
An overview of the key provisions in the Medicare Clinical Diagnostic Laboratory Tests Payment System Rulemaking regarding coding, data collection and reporting, rate-setting and coverage for Advanced Diagnostic Laboratory Tests (ADLTs). In particular, the presentation will address time line for PAMA implementation, including payment for New ADLTs at Actual List Charge and annual data collection and reporting.

2:50 PANEL DISCUSSION

Sponsored by
BOSTON HEALTHCARE

3:30 Value Capture Pathways for Advanced Diagnostic Tests
Charles Mathews, Vice President, Boston Healthcare
\How can diagnostic innovators achieve reimbursement success in today's challenge payer environment? Key factors such as clinical positioning, payer value proposition analysis, and clinical utility evidence development approaches, will be highlighted. This presentation will provide insights into how reimbursement planning can be incorporated into test menu and portfolio development to achieve routine optimal payment regardless of the changing coding and payment landscape.

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

» 4:45 KEYNOTE PRESENTATION: From Volume to Value in Healthcare: A New Business Model for Diagnostics?
Glenn D. Steele, Jr., M.D., Ph.D., Chairman of the Board & Chief, Corporate Strategy, xG Health Solutions, Inc.
A combination of transformative changes in how health care is delivered and paid for will impact the business models of all stakeholders including device manufacturers and molecular diagnostic companies. As value of care to patients is emphasized, and as more targeted diagnosis and therapy become the norm, where care is given, who gives care, who makes product buy decisions, and how the product's cost benefit is evaluated will all change.

CONSTRUCTING CANCER GENE PANELS– Discussion and Debate

5:15 Moderator's Remarks:
Harry Glorikian, Healthcare Consultant
- Is bigger better or should panels be more focused?
- How do you differentiate your institution and its treatment approach from others utilizing genomics?
- How is the data being used by the physician and its effect on the patient?
- How does the number of genes affect reimbursement?

Panelists: Mark D. Myslinski, Chief Commercial Officer, Kew Group
Mark S. Boguski, M.D., Ph.D., Founder & CMO, Precision Medicine Network, Inc.
Gyorgy Abel, M.D., Ph.D., Director, Molecular Diagnostics, Immunology & Clinical Chemistry, Laboratory Medicine, Lahey Hospital & Medical Center
Jerry Conway, Vice President, Reimbursement & Payer Strategy, Foundation Medicine

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6:15 Close of Day

6:00 Dinner Short Course Registration

6:30- 8:30 pm RECOMMENDED DINNER SHORT COURSE*
SC11: Regulatory and Reimbursement Issues with NGS and Multiplex Assays
**Separate registration required, please see page 5 for details*

THURSDAY, AUGUST 25

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

THE CHANGING MANAGED CARE LANDSCAPE:

How LDT Labs and Manufacturers are Being Impacted by Payor Consolidation, ACO Arrangements, and Managed Lab Benefit Programs

8:25 Moderator's Opening Remarks
John Hanna, Vice President, Endocrinology, Veracyte, Inc.
The laboratory market is facing a changing payor landscape including consolidation among private payers and Medicare MAC contractors, a greater push for ACO arrangements and P4P incentive programs, and the introduction of laboratory benefit management programs to control molecular diagnostics spend and utilization. Experts in this session will discuss the challenges these dynamics present to labs and manufacturers in participating in payer networks, launching new products, and demonstrating cost-effectiveness as a diagnostic test provider.

8:30 Showing the Value of Diagnostics in ACOs and Risk-Based Payment Models
Chandra N. Branham, J.D., Vice President, Payment & Health Care Delivery Policy, The Advanced Medical Technology Association (AdvaMed)
This talk will review changing pressures on diagnostic manufacturers and labs to show value and evidence to support their test and highlight industry activities to meet these demands head-on by creating a value framework for diagnostics.

8:45 Lab Benefit Management Programs: Can't Live without Them, but Can We Live with Them?
Lon Castle, M.D., CMO, Molecular Genetics and Personalized Medicine, eviCore healthcare
Securing payment for your diagnostic test used to be simple. You negotiated a contract, you billed for the test and you got paid. Not anymore. Now there are third-party benefit management companies monitoring your billing and coding to determine not only whether or not to pay you, but how much you will be reimbursed. It's a new world out there, and you need to be prepared. This presentation will cover: Observations on what works—and what doesn't, billing using molecular diagnostic codes, and what types of billing practices will get your claim stopped in its tracks.

9:00 Demonstrating Utility Evidence - Increasing Requirements for Reimbursement
Joseph Singer, M.D., Chief Medical Officer, HealthCore, Inc.

9:15 Q&A with Speakers

9:30 Commercialization of Targeted Therapies Outside of Oncology
Sponsored by Diaceutics
Steve Vitale, Managing Director, Diaceutics AIS, Diaceutics Group
With the majority of targeted therapy launches in the marketplace focused on oncology, we hear similar challenges around tumor sample logistics, testing algorithms, and report interpretation, but what's happening outside of oncology? Are we seeing similar trends? And what learnings should we take away to help with targeted launches outside of oncology?

9:45 Collaborations by Design - Manufacturing Frontier for Smart Polymer Parts
Sponsored by Sony DADC
Christoph Mauracher, Ph.D., Managing Director, Sony DADC BioSciences GmbH
Let's discuss collaborations between companies, external vendors, research institutions and/or other external partners as of your success. Especially for products in development which are close to a forseeable market introduction experienced partners are able to accelerate the development and support your Life Sciences & IVD business.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing
Sponsored by Celsee Diagnostics

10:50 Evidence for Diagnostic Tests: Perspectives from Decision Makers
Moderator: Andrew C. Fish, J.D., Executive Director, AdvaMedDx

11:00 Regulatory Perspective
Elizabeth A. Mansfield, Ph.D., Director, Personalized Medicine, Office of In Vitro Diagnostics & Radiological Health, FDA CDRH

11:15 What is the Evidence Doctors Want to See?
Luis A. Diaz, M.D., Associate Professor, Oncology, Johns Hopkins Sidney Kimmel Comprehensive Cancer Center

11:30 Too Much? Too Soon?
Mike Barlow, Vice President, Operations, MolDX Executive Lead, Specialty Contracts, Palmetto GBA
In this talk, I will briefly discuss the challenge of addressing the explosion of molecular testing technology and capability along with the new levels data being developed from these tools. Clinicians and payers alike need a better way to assess, or at least filter, the clinical value of the data and the science behind much of it. The entire community needs a better way to leverage the data in a manner that would more effectively align the forces and clear out the 'noise'.

11:45 PANEL DISCUSSION

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Ensuring Success of Innovative Tests

12:20 pm The Relevance and Standardization of Clinical Utility

Sponsored by INTERPACE DIAGNOSTICS

Greg Richard, Senior Vice President, Commercial Services, Interpace Diagnostics

Health plans summarily require Clinical Utility studies before they will consider covering a molecular diagnostic test. The purpose of a Clinical Utility study is to demonstrate that the data from the test being evaluated impacts physicians' treatment of patients. Despite the provision of data from such studies, health plans often do not cover the test. Industry and health plans need to come together to standardize the process and requirements for coverage so it is fair and transparent for all.

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

1:20 Session Break

LIQUID BIOPSY: WHO WILL MAKE IT TO THE MARKET?

2:00 Moderator's Remarks

John Beeler, Ph.D., Vice President, Business Development, Inivata

- How much content is valuable? How many genes are necessary or ideal in a gene panel? What are oncologists and patients looking for?
- How are Doctors using data to make decisions?
- What is the ideal technology to use? Do you need a comprehensive panel upfront?
- How does cost or regulatory approval factor in?

Panelists:

Regulation: *Abraham Tzou, M.D., Medical Officer, FDA*

CLIA New York State: *Stephanie Shulman, M.P.H., M.S., M.T. (ASCP), Director, Clinical Laboratory Evaluation Program, Wadsworth Center, New York State Department of Health*

Policy: *Dr. Sean Tunis, CEO, Center for Medical Technology Policy*

Oncologist: Liquid Biopsy: Use in Clinical Trials

Barbara A. Conley, M.D., Associate Director, Cancer Diagnosis Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute (Tentative)

Liquid biopsies offer the promise of interrogating a patient's cancer without a biopsy, as well as being able to longitudinally sample the molecular profile. Potential uses for "liquid biopsy" in clinical trials include initial diagnosis, target-finding (predictive marker), pharmacodynamics assays and ascertaining development of resistance. Qualities of a fit for purpose liquid biopsy for use in clinical trials for cancer drug development will be presented.

Payor: *Girish Putcha, M.D., Ph.D., Director, Laboratory Science, Palmetto GBA (MolDX)*

Investor: *Eli Casdin, Managing Member, Casdin Capital*

4:05 Close of Conference

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Leveraging Pharmacies for Rapid Diagnostics

Paving the Way for Pharmacy-Based Point-of-Care Diagnostics

WEDNESDAY, AUGUST 24

10:30 am Registration

11:15 PLENARY KEYNOTE SESSION
Please see page 3 for details.

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

1:25 Ice Cream and Cookie Break in the Exhibit Hall with Poster Viewing

POINT-OF-CARE PRACTICE MODELS AND IMPLEMENTATION

1:50 Chairperson's Opening Remarks
Michael E. Klepser, Pharm.D., FCCP, Professor, Pharmacy Practice, Ferris State University College of Pharmacy

2:00 The Impact of POCT on Infectious Disease Screening in the Pharmacy
Speaker to be Announced

2:30 Point-of-Care Diagnostics in a Retail Health Setting
Alexander Sbordone, Manager, Operations, MinuteClinic, CVS Health
As retail health continues to grow, clinics are looking to increase their service offerings. The expansion of services in clinics should include point-of-care (POC) diagnostics that will assist with the proper diagnoses and treatment of patients. This presentation will review current testing utilized at MinuteClinic, how expanded POC testing may allow for additional services in the retail setting, and the challenges that POC testing presents in this environment.

3:00 Successful Disease Management Programs
Michael E. Klepser, Pharm.D., FCCP, Professor, Pharmacy Practice, Ferris State University College of Pharmacy

3:30 Sponsored Presentation *(Opportunity Available)*

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

4:45 Clinical Application of Point-of-Care Testing in Disease State Management Services
Suzanne Higginbotham, Pharm.D., BCACP, Director, Center for Pharmacy Care; Director, Residency Programs, Duquesne University Mylan School of Pharmacy
This presentation will be an overview of point-of-care testing services in disease state and medication therapy management. The speaker will seek to demonstrate the use of point-of-care testing within an MTM model framework, provide clinical pearls on communication and collaboration with this model among other health care providers, and analyze the economic and clinical outcomes of providing this service to the community.

5:15 DISEASE MANAGEMENT COMPETITION: Treating Patients at the POC
This year's Pharmacy-Based Diagnostics event will play host to a Pharmacy Student Point-of-Care Disease Management Competition.
Our competition emulates the APhA Patient Counseling Competition and the ASHP Clinical Skills Competitions. The winning student will be awarded a plaque to designate the accomplishment and a stipend of $250.00. Additional details can be found at www.nextgenerationdx.com/pharmacy-diagnostics/disease-management

6:15 Close of Day

6:00 Dinner Short Course Registration

6:30- 8:30 pm RECOMMENDED DINNER SHORT COURSE*
SC13: Use of CLIA-Waived Point-of-Care and Rapid Diagnostic Tests in Community Pharmacies
**Separate registration required, please see page 5 for details*

THURSDAY, AUGUST 25

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

REIMBURSEMENT FOR PHARMACY-BASED TESTING

8:25 Chairperson's Remarks and Competition Winner Announcement
Donald G. Klepser, Ph.D., MBA, Associate Professor, Pharmacy Practice, University of Nebraska Medical Center

8:30 Engaging Third Party Payers - The Holy Grail of Pharmacy-Based POCT
Donald Klepser, Ph.D., MBA, Associate Professor, Pharmacy Practice, College of Pharmacy, University of Nebraska Medical Center
This talk will provide an overview of the current state of reimbursement of community pharmacy-based point-of-care testing. It will cover opportunities and barriers to enhancing third party reimbursement for POCT services.

9:00 Exploring Retail Consumer Perceptions of Point-of-Care Tests: A Conjoint Analysis Study
Kenneth C. Hohmeier, Pharm.D., Director, Community Affairs, Assistant Professor, Clinical Pharmacy, University of Tennessee Health Science Center
This brief, original research presentation will discuss results from a consumer preference market analysis study. The study's aim was to describe and compare consumer preferences for various characteristics of point-of-care tests using a cross sectional questionnaire that was developed using principles of conjoint (trade-off) analysis. This well researched, popular methodology is used in marketing research internationally and allows the researcher to quantify consumer preferences on product features.

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9:30 Sponsored Presentation *(Opportunity Available)*

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

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THE DIAGNOSTICS LANDSCAPE

10:50 Can We Perform Diagnostic POC Tests for Sexually Transmitted Infections in a Pharmacy?

Charlotte A. Gaydos, MS, MPH, DrPH, Professor, Division of Infectious Diseases, Department of Medicine, Johns Hopkins University

Pharmacies are performing POC tests for influenza. Since POC/rapid tests are becoming available for sexually transmitted infections (STIs) such as chlamydia, gonorrhea, trichomonas, syphilis, and HIV, it may be possible to provide assays for patients who attend pharmacy clinics. Such assays can be performed on self-collected specimens such as urine, vaginal swabs, and finger-stick blood. Privacy and confidentiality are important to patients with STIs. It is time to investigate options.

11:20 Utilizing Point-of-Care Testing in a Pharmacy Setting

Ray Ahmed, Marketing Manager, Sales and Marketing, OraSure Technologies, Inc.

Point-of-care testing is rapidly becoming a benchmark of testing in a variety of clinical settings. This is especially true in the pharmacy setting, where many retail and specialty pharmacies have increased their service offerings outside of the traditional filling of prescriptions for patients. While infectious disease rapid testing is a logical fit in this expanded service offering, there are also challenges with pharmacies implementing rapid testing programs.

11:50 CLIA Waiver: A Primer

Gail Radcliffe, President, Consulting, Radcliffe Consulting, Inc.

12:20 pm Sponsored Presentation *(Opportunity Available)*

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

1:20 Session Break

LEGAL CONSIDERATIONS

2:00 Chairperson's Remarks

Alex J. Adams, Pharm.D., MPH, Executive Director, Idaho State Board of Pharmacy

2:05 Pharmacist Point-of-Care Testing: A State Law Framework

Alex J. Adams, Pharm.D., MPH, Executive Director, Idaho State Board of Pharmacy

Pharmacies must navigate a complex maze of federal and state laws in order to fully engage in point-of-care testing. This session will discuss federal CLIA laws, state-level restrictions on CLIA-waived testing, and Collaborative Practice Laws that enable pharmacists to act on the results of tests.

2:35 Legal Considerations in Point-of-Care Testing in Pharmacies

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

Pharmacists are well-versed in legal matters concerning drugs and dispensing. Adding Point-of-Care Testing services bring in additional regulations and legal considerations. This program will highlight several of the agencies involved in regulating point-of-care testing in community pharmacies.

3:05 PANEL DISCUSSION: PAYOR, PHARMACIST, DEVELOPER

Panelists: Ray Ahmed, Marketing Manager, Sales and Marketing, OraSure Technologies, Inc.

Alexander Sbordone, Manager, Operations, MinuteClinic, CVS Health

Additional Panelist to be Announced

- What can pharmacists expect from tests?
- Which tests fit best in pharmacy?
- How are we getting paid?

4:05 Close of Conference

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NGS Diagnostics: Annotation & Interpretation

Harnessing the Power of Genomic Information

RECOMMENDED PRE-CONFERENCE SHORT COURSES*

SC6: NGS Assay Development and Validation

SC9: Practical Considerations for NGS Data Analysis and Interpretation

**Separate registration required, please see page 5 for details*

WEDNESDAY, AUGUST 24

10:30 am Registration

11:15 PLENARY KEYNOTE SESSION
Please see page 3 for details.

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

1:25 Ice Cream and Cookie Break in the Exhibit Hall with Poster Viewing

CHALLENGES IN WHOLE EXOME AND WHOLE GENOME INTERPRETATION

1:50 Chairperson's Opening Remarks
Wayne W. Grody, M.D., Ph.D., UCLA School of Medicine

» 2:00 KEYNOTE PRESENTATION: WHY PRECISION MEDICINE REQUIRES IMPRECISE MEASURES

Isaac Kohane, M.D., Ph.D., Lawrence J. Henderson Professor of Pediatrics; Chair, Boston Children's Hospital Informatics Program; Co-Director, Center for Biomedical Informatics, Lawrence J. Henderson Professor, Pediatrics and Health Sciences and Technology, Harvard Medical School

Much has been written about the importance of new molecular markers for precision diagnostics and therapeutics. I will illustrate with several examples how the focus on the molecular is causing diagnostic and prognostic imprecision. I will highlight integrative approaches that address this problem.

3:00 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, University of Calfornia Los Angeles 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%. While similar diagnostic yields are reported by other centers offering WES, there appear to be wide differences in the number of less certain, uncertain, and off-target variants being reported. The genomic testing community needs to consider whether a greater or lesser scope of reported variants helps the ordering physician or merely makes their job more difficult and causes greater anxiety for the patient.

3:30 Sponsored Presentation *(Opportunity Available)*

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

4:45 Interpretation of Wes Variants: Uncertain Until Proven Guilty

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

The use of whole exome sequencing (WES) for diagnosis of genetic diseases is quickly becoming standard diagnostic procedure in many cases. However, a major hurdle is the interpretation of the large number of sequence variants identified. In the NCGENES study, we have employed various strategies to streamline variant analysis and interpretation, including establishment of diagnostic gene lists tailored to the patient's clinical phenotype. Nonetheless, a significant proportion of results are of uncertain clinical significance for the individual diagnosis. I will discuss different categories of uncertain results generated by WES and the imperative of distinguishing uncertain results from definitive diagnostic results in reporting of WES analysis.

5:15 Precision Medicine – Challenges Associated with Annotation and Interpretation of Somatic Mutation Data

Roger D. Klein, M.D., J.D., Medical Director, Molecular Oncology, Cleveland Clinic Foundation

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.

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AUGUST
24 - 25

Cambridge Healthtech Institute's Second Annual

NGS Diagnostics: Annotation & Interpretation

Harnessing the Power of Genomic Information

5:45 PANEL DISCUSSION: Incidentalome in Genomic Medicine: An Obstacle or a Driver?

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

Next-generation sequencing has transformed genetic research and is poised to revolutionize clinical diagnosis. However, the vast amount of data and inevitable discovery of incidental findings require novel analytic approaches. We therefore implemented for the first time a strategy that utilizes a priori structured framework and a conservative threshold for selecting clinically relevant incidental findings.

6:15 Close of Day

6:00 Dinner Short Course Registration

THURSDAY, AUGUST 25

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

ADVANCES IN SOMATIC MUTATION ANALYSIS

8:25 Chairperson's Remarks

Susan Mockus, Ph.D., The Jackson Laboratory for Genomic Medicine

8:30 Precision Pathology for Cancer Clinical Trials: Data Considerations

Michael H. A. Roehrl, M.D., Ph.D., Memorial Sloan Kettering Cancer Center

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 Memorial Sloan Kettering Cancer Center.

9:00 Pushing the Limits- Challenges of Somatic Variant Detection

Robert Daber, Ph.D., Vice President, Genomics Operations and Development, Laboratory Medicine, Bio Reference Laboratories

NGS continues to emerge as a powerful diagnostic methodology for the characterization of mutation status in a variety of tumors. Here we describe our experience detecting various complicated somatic mutation types in across a variety of tumor types, including both low allele frequency mutations as well as complicated insertion and deletion events. We will also discuss our strategies for decreasing the lower limit of detection by customizing the limits of detection for each genomic loci independently.

9:30 Sapientia - Faster, More Accurate Diagnosis Using a Data Sharing Platform

Sponsored by CONGENICA GENOME BASED MEDICINE

Mike Furness, Head, Sales & Marketing, Congenica

Using NGS technology, genetic testing is moving from small gene panels to whole genome testing, such as the UK 100,000 Genomes Project. Our platform SapientiaTM is already in the majority of NHS clinical genetics labs, and we are providing clinical reports on rare disease patients for the 100,000 Genomes Project. Other commercial and academic sites around the world are also adopting Sapientia. Examples of the benefits of genomic versus panel approaches will be shown.

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

Sponsored by Celsee Diagnostics™

10:50 Challenges and Solutions with Interpretation of Large Genomic Panels

Susan Mockus, Ph.D., Manager, Clinical Analytics & Curation, The Jackson Laboratory for Genomic Medicine

Somatic tumor profiling in the clinic has been widely dependent on single-gene assays and small hotspot panels, however with the decreased cost and more mature NGS technology, larger gene panels are more routinely utilized. Interpretation challenges associated with large gene panels include co-mutations and connectivity to targeted therapies and available clinical trials. Systematic data capture solutions for interpretation will be discussed in context.

11:20 Advantages and Challenges of Detecting Molecular Biomarkers in Oncology: Data Analysis Perspective

Francine B. Blumental de Abreu, Ph.D., Genomic Analyst, Laboratory for Clinical Genomics and Advanced Technology (CGAT), Pathology and Laboratory Medicine, Dartmouth Hitchcock Medical Center

In recent years, NGS has become an integral tool in routine clinical molecular diagnostics. For this reason, the number and diversity of sequencing and data analysis solutions have increased at an exponential rate. However, despite the breath of solutions available, there still remain a number of challenges associated with the bioinformatics of NGS data, though sample quality and preparation remain critical components in generating high quality NGS data.

11:50 AI & Cognitive Computing: Implications for Digital Pathology

Navid Farahani, M.D., Pathology, Informatics, University of Pittsburgh Medical Center

Artificial Intelligence (AI) and so-called cognitive computing technologies, which are derived from the various branches and sub-branches of AI, are becoming increasingly pervasive across multiple sectors, including the healthcare industry. This presentation aims to familiarize one with various types of AI approaches, cognitive technologies, and review the relevance of both of the aforementioned in the realm of digital pathology

12:20 pm Sponsored Presentation *(Opportunity Available)*

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

1:20 Session Break

KNOWLEDGE BASES AND THEIR APPLICATION

2:00 Chairperson's Remarks

Matthew Lebo, Ph.D., Partners Personalized Medicine

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NGS Diagnostics: Annotation & Interpretation

Harnessing the Power of Genomic Information

2:05 Viscap: Inference and Visualization of Germ-Line Copy-Number Variants from Targeted Clinical Sequencing Data
Matthew Lebo, Ph.D., FACMG, Director, Bioinformatics, Partners Personalized Medicine; Instructor, Pathology, Brigham and Women's
Effective implementation of precision medicine will be enhanced by a thorough understanding of each patient's genetic composition to better treat his or her presenting symptoms or mitigate the onset of disease. This ideally includes the sequence information of a complete genome for each individual.

2:35 Navigating the Landscape of Commercially Available Knowledge Bases: How to Find the Right Fit for Your Clinical Application and Laboratory Environment
Jamie Platt, Ph.D., Managing Director, BRIDGenomics, LLC.
The upsurge of clinical NGS applications has created an increasing demand for bioinformatics solutions and knowledge bases. Clinical research labs are no longer constrained solely to in-house manual curation of the literature in order to support their clinical NGS offerings. A number of knowledge bases and annotation solutions are now commercially available. However, it is still difficult to understand the nuances of each of these solutions and find the best fit for the application and the specific laboratory environment. An overview of the commercial landscape of knowledge bases and annotation solutions will be provided with respect to each lab's unique needs.

3:05 Complex Cases: The Rarest of the Rare
Daniel Helbling, Senior Clinical Genomics Analyst, Human Molecular Genetics Center, Medical College of Wisconsin
The world of NGS diagnostics for rare disease tends to favor results that deviate from the norm. However, beyond the expected unusual lies another layer of complex cases. I will present these cases and their molecular diagnosis.

3:35 FDA Perspective on NGS Data Analysis
Xueying Sharon Liang, M.D., Ph.D., Regulatory Scientist, Division of Molecular Genetics and Pathology, OIR/CDRH/FDA
This presentation on next-generation sequencing (NGS) technology, data formats standardization and promotion of interoperability protocols aims to facilitate establishing discussion for ensuring the safety and quality of next-generation sequencing (NGS)-related-information without sacrificing scientific merit or interfering with innovative processes.

4:05 Close of Conference

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Advances in Microbiome Diagnostics

New Research and Developments for Utilizing the Microbiome in Diagnostics

RECOMMENDED PRE-CONFERENCE SHORT COURSES*

SC5: Establishing the Value of Diagnostic Tests

**Separate registration required, please see page 5 for details*

FRIDAY, AUGUST 26

8:00 am Registration & Morning Coffee

MICROBIOME SAMPLE PREP AND ANALYSIS

8:25 Chairperson's Opening Remarks
Willy Valdivia, CEO, Orion Integrated Biosciences, Inc.

8:30 Collecting Fecal Samples for Microbiome Analyses in Epidemiology Studies
Rashmi Sinha, Senior Investigator, Metabolic Epidemiology Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute
Some of the most important attributes of any sampling method are reproducibility, stability, and accuracy. We compared seven fecal sampling methods (no additive, RNAlater, 70% ethanol, EDTA, dry swab, Fecal Immunochemical Test (FIT), and pre/post development fecal occult blood test (FOBT)) using 16S rRNA microbiome profiling in two laboratories. We evaluated nine commonly used microbiome metrics: abundance of 3 phyla, two alpha-diversities, and four beta-diversities. We determined the technical reproducibility, stability at ambient temperature, and accuracy.

9:00 Benchmarking Controls Reveal That Differences in Library Preparation Can Influence Genomic and Functional Predictions in Microbiome Research
Sarah Highlander, Professor, Genomic Medicine, J. Craig Venter Institute
Conflicting interpretations of microbiome work has made it clear that standardized methods are needed for sample collection, storage, nucleic acid isolation, library preparation and sequencing. We used a synthetic community of bacterial DNAs, and a bacterial spike-in calibrator for stool samples, to benchmark PCR and PCR-free library preparation methods for the Illumina sequencing. Significant differences in error profiles, bias and taxonomy were observed between the methods, with PCR-free performing best.

9:30 Pacbio-Based Species-Level Microbiome Analyses
Garth D. Ehrlich, Ph.D., FAAAS, Professor, Microbiology and Immunology, Otolaryngology Head and Neck Surgery, Drexel University College of Medicine
Microbiomics have revolutionized our understanding of microbial ecologies, but have suffered from two problems: lack of species-specificity and over-calling the number of taxa. Using the long read-lengths of the Pacbio and its ability to perform circular iterative sequencing of single DNAs, together with algorithmic improvements has overcome these limitations. As part of our validation process we analyzed a mock microbiome from which we correctly called all 19 eubacterial species present and did not call anything that was not present.

10:00 Sponsored Presentation *(Opportunity Available)*

10:30 Coffee Break

MICROBIOME MECHANISMS AND BIOMARKERS

11:00 Quantitative Prediction of Microbiota Dynamics
Georg K. Gerber, M.D., Ph.D., MPH, Assistant Professor of Pathology, Harvard Medical School; Co-Director, Center for Clinical and Translation Metagenomics, Director, Computational Unit, Associate Pathologist, Department of Pathology, Brigham and Women's Hospital
I will present our progress on discovery of networks of commensal bacteria protecting against Clostridium difficile and prediction of stability of configurations of bacteria in an immune-modulating probiotic cocktail. I will also describe the computational algorithms that we have developed that have enabled this work, the Microbial Dynamical Systems INference Engine (MDSINE), which infers dynamical systems models from noisy microbiome sequencing time-series datasets and predicts future behaviors of the microbiota.

11:30 Salivary Microbiome and Diagnostics: Emerging Biomarkers
Jennifer Kerr, Ph.D., Assistant Professor, Biology, Oral Microbiology, Notre Dame Maryland University
Our oral cavity hosts an extraordinary microbiome in both healthy and disease states. Paired with other host saliva biomarkers, the oral microbiome presents a novel noninvasive diagnostic tool for monitoring changes in human physiology and a potential shift toward disease. This talk will address novel work toward understanding the role of bacteria in diseases/conditions and carcinogenesis and how it can serve as an oral biomarker for early detection of disease.

12:00 pm Metagenomics as a Novel Strategy to Detect Colonization with Multidrug Resistant Bacteria
David Haslam, M.D., Associate Professor, Pediatrics, Cincinnati Children's Hospital Medical Center
Prevention of multi-drug resistant (MDR) bacterial infections relies on accurate detection of these organisms. We are utilizing fecal metagenomics to identify colonization with MDR organisms. In many cases, the genome of an MDR organism could be assembled from raw metagenomic data. Phylogenetic analysis and comparison with MDR organisms from other patients has the capacity to reveal patient-to-patient transmission networks.

12:30 Sponsored Presentation *(Opportunity Available)*

1:00 Luncheon Presentation *(Sponsorship Opportunity Available)*
or Enjoy Lunch on Your Own

1:30 Session Break

NOVEL RESEARCH TOWARD CLINICAL APPLICATIONS

2:00 Chairperson's Remarks
Keith Batchelder, M.D., CEO & Founder, Genomic Healthcare Strategies

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Advances in Microbiome Diagnostics

New Research and Developments for Utilizing the Microbiome in Diagnostics

2:05 FEATURED PRESENTATION: Metagenomics for Diagnosing Polymicrobial Infections in the Gut Microbiome

Rita Colwell, Ph.D., Distinguished Professor, Department of Cell Biology & Molecular Genetics, College of Computer, Mathematical, & Natural Sciences, University of Maryland

In an era of climate change and emerging and re-emerging diseases, genomics tools are proving valuable in understanding, tracking, and diagnosing infectious disease and identifying disease agents. One finding to date is that polymicrobial infections are now frequently being detected, requiring reassessment of Koch's postulates in this new century, with the application of metagenomics. Prime examples of waterborne infections, including cholera and related diarrhoeal diseases, will be discussed.

2:35 Predicting Chemotherapy-Induced Sepsis with the Pre-Treatment Microbiota

Dan Knights, Assistant Professor, Computer Science and Engineering, Biotechnology Institute, University of Minnesota

Trillions of bacteria live in our gut, protecting us from infection and aiding our digestion. A bad mixture of bacteria, or dysbiosis, may contribute to obesity, diabetes, Crohn's disease, infections, and other diseases, yet these microbiomes are so complex that we need advanced computational tools to study them. This talk will present new methods for building highly precise diagnostics using the microbiota, and an application to predicting life-threatening chemotherapy-induced infections.

3:05 Refreshment Break

3:35 Skin Microbiome-Based Radiation Diagnostics

Eric Huang, Ph.D., Professor, Dermatology, University of California, San Diego

We study the reaction of Propionibacterium acnes (P. acnes), a commensal bacterium in the human skin microbiome, to radiation to identify the early surrogate markers for radiation risk. We highlight that uncovering response of skin microbiome to radiation will facilitate the development of pre-symptomatic diagnosis of radiation risk in a battlefield exposure, nuclear accidents, terrorist attacks, or cancer imaging/therapy.

4:05 The Microbiome in Human Reproduction

Jason Franasiak, M.D., FACOG, Attending Physician, Reproductive Medicine Associates of New Jersey, Assistant Professor of Obstetrics, Gynecology, and Reproductive Sciences, Rutgers University, Reproductive Endocrinology and Infertility, Robert Wood Johnson Medical School

The human microbiome has been termed the "second human genome" and it appears every bit as complex. The microbiome in human reproduction impacts both the reproductive tract and gametogenesis. Recent data have furthered our understanding of the microbiome, the biofilms it creates, and its impact of health and disease in human reproduction.

4:35 Close of Symposium

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Predictive Cancer Biomarkers

Pushing Discovery to Advance Clinical Translation

RECOMMENDED PRE-SYMPOSIUM SHORT COURSES*

SC3: Translating CTCs for Clinical Use

SC14: Liquid Biopsy: Clinical Applications and Business Considerations

**Separate registration required, please see page 5 for details*

FRIDAY, AUGUST 26

8:00 am Registration & Morning Coffee

IDENTIFYING BIOMARKERS AND PATHWAYS

8:25 Chairperson's Opening Remarks

Anuradha Murali, Ph.D., MSCR, Clinical Trial Manager, Gastroenterology Associates of Orangeburg

8:30 Integrated Genomic Analysis of Pancreatic Ductal Adenocarcinomas Reveals Genomic Rearrangement Events as Significant Drivers of Disease

George Vasmatzis, Ph.D., Director, Biomarker Discovery Program, Center for Individualized Medicine, Mayo Clinic

In this study, we performed mate pair sequencing (MPseq) on genomic DNA from 24 PDAC tumors, including 15 laser-captured microdissected PDAC and 9 patient-derived xenografts, to identify genome-wide rearrangements. Large genomic rearrangements with intragenic breakpoints altering key regulatory genes involved in PDAC progression were detected in all tumors. SMAD4, ZNF521, and FHIT were among the most frequently hit genes. Conversely, commonly reported genes with copy number gains, including MYC and GATA6, were frequently observed in the absence of direct intragenic breakpoints, suggesting a requirement for sustaining oncogenic function during PDAC progression. Additionally, a number of potentially targetable amplifications and fusions have been observed opening the possibility to genomically driven targetable treatment in PDAC.

9:00 Towards Cancer Diagnostics Based on Interphase Spatial Genome Positioning

Karen Meaburn, Ph.D., Research Scientist, NCI, NIH

The genome is non-randomly organized in the cell nucleus. We have identified several genes that robustly alter position in breast or prostate cancer. These genes, used singularly or in combination, are able to distinguish cancer from normal tissue with high accuracy. We are working towards exploiting these changes in positioning patterns to develop a novel diagnostic strategy for the detection of cancer.

9:30 FEATURED PRESENTATION: Ultraconserved Elements: The Enigma and the Potential

C.-Ting Wu, Ph.D., Professor, Genetics, Harvard Medical School

Ultraconserved elements (UCEs) are DNA sequences that have been perfectly (100%) conserved for 300-500 million years. Because neither protein coding, nor enhancer, nor transcription factor binding, nor promoter regions require such conservation, the mere existence of UCEs has been a long debated conundrum. We propose that UCEs contribute to genome integrity and, hence, may provide a strategy by which otherwise healthy tissues can be culled of cells harboring deleterious rearrangements.

10:00 A Novel rRNA Depletion Method to Enable Whole Transcriptome Analysis of Single Cells with RNA-Seq

Sponsored by NuGEN

Maureen Peterson, Ph.D., Product Development Scientist, Research & Development, NuGEN Technologies

RNA-Seq analyses of transcripts from large numbers of cells often masks biologically relevant differences that occur in individual cells. Understanding RNA expression in a single cell has great potential for biomarker development, and monitoring disease progression and therapy. We describe a method for generating RNA-Seq libraries from single cells that enables removal of specific transcripts without perturbing the original total RNA population, providing a solution for biomarker discovery and diagnostic applications using extremely limited samples.

10:30 Coffee Break

MOVING TOWARDS CLINICAL APPLICATIONS

11:00 Circulating Cell-Free DNA, RNA and Exosomes – Key Biomarkers for Early Cancer Detection and Liquid Biopsy Diagnostics

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

Exosomes and their associated RNA and proteins, as well as circulating cell-free DNA are now considered to be important key biomarkers for cancer diagnostics ranging from early detection to liquid biopsy for patient management and therapy monitoring. Nevertheless, the isolation and detection of these biomarkers, exosomes in particular, require considerable time and effort which greatly limits their practical, reliable and more widespread use in cancer diagnostics. Using a DEP device, we are now able to isolate all of these key biomarkers, including exosomes, in 15-20 minutes from 25-50ul of blood, plasma or serum. In the case of glioblastoma exosomes isolated from plasma, specific surface and interior proteins CD63 and TSG101 could then be detected by immunofluorescence, and EGFRvIII mutations in mRNA were detected by RT-PCR.

11:30 Using Molecular Profiling in Early Clinical Trials

Barbara Conley, M.D., Associate Director, Cancer Diagnosis Program, Division of Cancer Treatment & Diagnosis, National Cancer Institute (NCI)

The talk will inform the audience of the thinking behind the design of the NCI-MATCH trial, which profiles a fresh biopsy of patients with malignancies who have progressed on standard treatment. This trial uses a validated locked platform of NGS, supplemented by IHC assays, to assign patients to treatment arms based on molecular eligibility criteria, regardless of histology. The trial accrued very robustly from first opening. The MATCH trial is a signal-finding trial based on levels of evidence for both

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the treatments and the molecular eligibility criteria. Lessons learned will be presented. As such it represents a type of clinical validation of potentially predictive molecular features, and presents the opportunity to learn about the effect of co-mutations on response rate.

12:00 pm Tumor Heterogeneity and the Course of Mutation Detection Following Treatment

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

The routine implementation of NGS in the diagnosis and decision making process of malignancies has increasingly become part of routine clinical care. For most malignancies tested, only one specimen is received; however there are increasingly more patients assessed at additional time points throughout their disease allowing for tracking of the response to targeted and traditional chemotherapy. In hematological malignancies there has been the greatest uptake for the use of NGS to track disease response, as these patients can be serially assessed. This talk will focus on the mutation patterns before and after treatment and patient response to targeted therapies, on clinical trials and off-label.

12:30 Non-Bisulfite Epigenetic Profiling of DNA Methylation Enables Epigenetic Diagnostic Biomarker Discovery

Sponsored by GenPro Genome Profiling, LLC

Adam Marsh, Ph.D., CSO, Genome Profiling LLC

We have developed a novel computational platform for NGS quantitative DNA methylation profiling. This diagnostic platform has great utility for CDx applications. A use case in patients with Acute Myeloid Leukemia shows high confidence in pre-treatment identification of responders and non-responders to a hypomethylating drug therapy.

12:45 Sponosred Presentation

(Opportunity Available)

1:00 Luncheon Presentation: Elucidation of Circulating miRNA Biomarkers in Oral Cavity Cancer Utilizing Multiplex qPCR Array

Sponsored by QUARKBIO

Eric Yang, Ph.D., Vice President, Quark Biosciences

Numerous publications have illustrated that microRNAs can be of diagnostic, prognostic and predictive values in the field of oncology. Utilizing PanelChip™, a qPCR array technology developed by Quark Biosciences, we've looked at the level of 160 microRNAs in the plasma of oral cavity cancer patients before and after surgery. Preliminary result suggests that PanelChip™ can be of a powerful tool to screen and validate cell-free miRNA biomarkers for translational medical researchers.

1:30 Session Break

EXAMINING CLINICAL UTILITY

2:00 Chairperson's Remarks

Magali Droniou, Director, Applications, Stilla Technologies

2:05 Crucial Considerations for Pipelines to Validate Circulating Biomarkers for Breast Cancer

Karen Anderson, M.D., Ph.D., Associate Professor, School of Life Sciences, Biodesign Institute, Arizona State University

There has been significant progress in the discovery of potential circulating biomarkers, including proteins, autoantibodies, nucleic acids, exosomes, and circulating tumor cells, but the vast majority of these biomarkers have not progressed beyond initial research discovery, and none have yet been approved for clinical use in early stage disease. We will review the crucial considerations of developing pipelines for the rapid evaluation of circulating biomarkers for breast cancer.

2:35 Germline Findings in Tumor-Only Sequencing

Victoria M. Raymond, Adjunct Clinical Assistant Professor, Licensed Certified Genetic Counselor, Cancer Genetics Clinic, University of Michigan Health System

Precision oncology holds great potential to improve patient outcomes. Tumor sequencing is rapidly moving into clinical care as our understanding of the cancer genome and the availability of targeted therapies increase. Analysis of the cancer genome is most informative when paired with germline DNA to delineate inherited and somatic variants. Although tumor-only analysis remains the most common methodology, it holds the potential to identify clinically significant germline variants.

3:05 Refreshment Break

3:35 PANEL DISCUSSION: Clinical Utility and Cost Effectiveness of Predictive Cancer Biomarkers

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

Panelists: David Hoon, Ph.D., Director of the John Wayne Cancer Institute

Christos Hatzis, PhD, Assistant Professor, Medicine; Director, Bioinformatics, Breast Medical Oncology, Yale Comprehensive Cancer Center, Yale School of Medicine

Raj Krishnan, Ph.D., CEO, Biological Dynamics

Among other things, the use of a cancer biomarker is determined by its predictive value and any cost saving that enables a physician to better determine treatment, to modify or change treatment and which increases the likelihood of patient survival. Information that allows switching the patient from an expensive, ineffective, or toxic therapy earlier or faster will be most beneficial. On the other side of the equation is the intrinsic cost of the assay or technology required to detect and analyze the biomarker(s). Improvements in this area will allow better cost to benefit ratios, and lead to more widespread use of the biomarker in cancer diagnostics.

4:35 Close of Symposium

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Non-Invasive Prenatal Testing

Advances in Cell-Free and Cell-Based Prenatal Screening and Diagnostics

RECOMMENDED PRE-SYMPOSIUM SHORT COURSE*

SC15: Preimplantation Genetic Screening and Diagnostics: A Technology Overview

**Separate registration required, please see page 5 for details*

FRIDAY, AUGUST 26

8:00 am Registration & Morning Coffee

CELL-FREE DNA VS. INTACT FETAL CELLS

8:25 Chairperson's Opening Remarks

W. Andrew Faucett, Professor, Genomic Medicine, Geisinger Health System

» 8:30 KEYNOTE PRESENTATION: The Future of NIPT: Cell-Free DNA vs. Intact Fetal Cells vs. Invasive Diagnostic Testing

Ronald J. Wapner, M.D., Professor, Obstetrics and Gynecology, Vice Chair, Research, Director, Reproductive Genetics, Columbia University Medical Center

Noninvasive prenatal testing is constantly evolving. The use and application of currently available technology will be explained and compared with what is on the horizon. Next-generation sequencing and new technologies along with their indications will be explored.

9:00 Noninvasive Prenatal Diagnosis: Using Fetal Cells is a Reality

Arthur L. Beaudet, M.D., Professor, Molecular & Human Genetics, Baylor College of Medicine; Consultant, Baylor Miraca Genetic Labs

We are focused on developing a fetal cell-based method of NIPT during the first trimester as a routine clinical test. We are now able to molecularly confirm recovery of fetal cells on a regular basis. Using whole genome amplification of 1-5 cells, it is possible to perform array CGH and NGS-based copy number analysis with these fetal cells. This method has the potential to detect CNVs at a resolution of 1 megabase.

9:30 TRIC: A New Window into the Developing Placenta and Fetal Genome

D. Randall Armant, Professor, Obstetrics & Gynecology, Wayne State University School of Medicine

Safe access to fetal tissue is the "Holy Grail" of noninvasive prenatal testing. Trophoblast Retrieval and Isolation from the Cervix (TRIC) captures placental cells as early as 3 weeks after conception, and holds promise for fetal genetic and obstetrical complication testing. TRIC provides an intact human genome for molecular analysis. Additionally, biomarker analysis after TRIC can assess perinatal risk in the first trimester for preeclampsia, fetal growth restriction and miscarriage.

10:00 Genome-Wide Prenatal Cell Free DNA Testing: Validation and Clinical Experience

Sponsored by sequenom

Daniel S. Grosu, MD, MBA, CMO, Clinical and Medical Affairs, Sequenom, Inc.

A significant proportion of chromosomal and subchromosomal abnormalities in the prenatal setting are not detectable by conventional cfDNA testing. Most of this informational gap can be bridged through a genome-wide approach that reports on copy number variation at a karyotype level of resolution (≥7 Mb in size) across the entire genome, in addition to select microdeletions less than 7 Mb in size.

10:30 Coffee Break

PRACTICAL APPLICATIONS OF NON-INVASIVE PRENATAL TESTING

11:00 False Negative cell free DNA Screening Result in a Newborn with Trisomy 13

Yang Cao, PhD, Fellow, Clinical Cytogenetics/Molecular Genetics, Laboratory Medicine and Pathology, Mayo Clinic

We report a case of false negative cell free DNA (cfDNA) screening due to fetoplacental mosaicism. An infant male with negative cfDNA screening result was born with multiple congenital abnormalities. Postnatal cytogenetic studies suggested that extra-embryonic tissue mosaicism is likely responsible for the false negative cfDNA screening result. This case illustrates that a negative result does not rule out the possibility of a fetus affected with a trisomy, as cell free fetal DNA is derived from the placenta and therefore may not accurately represent the fetal genetic information.

11:25 Maternal Cell-Free DNA-Based Screening for Fetal Microdeletions: Clinical Experience and Diagnostic Follow-Up

Svetlana Yatsenki, Associate Director, Clinical Genomics Labs, Obstetrics, Gynecology, & Reproductive Sciences, University of Pittsburgh, School of Medicine

Commercial companies are now offering expanded NIPS panels including screening for common microdeletion syndromes, as well as for genome-wide abnormalities. We present our clinical experience with a phenotypically normal mother and fetus who tested positive for 22q deletion via maternal plasma cfDNA testing, and discuss pitfalls of NIPS, clinical and diagnostic approach to a patient with a positive NIPS result.

11:50 pm Non-Invasive Prenatal Testing for Fetal Aneuploidy: Clinical Service Issues

Peter Benn, Professor, Genetics and Genome Sciences, University of Connecticut Health Center

Noninvasive testing for fetal aneuploidies through the analysis of cell-free DNA in maternal plasma has become a well-established component of prenatal care. Performance of the testing and reasons why there are false-positive and false-negative results are becoming understood. Testing is increasingly being used by low-risk women and the scope of testing now includes additional abnormalities, notably microdeletion syndromes. Recent studies that document performance of the testing will be reviewed.

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AUGUST 26 SYMPOSIA

Cambridge Healthtech Institute's Inaugural

Non-Invasive Prenatal Testing

Advances in Cell-Free and Cell-Based Prenatal Screening and Diagnostics

12:10 pm Circulating Fetal DNA Plus Subsequent Cytogenetics Distinguish Placental and Fetal Mosaicism.

Roger V. Lebo, Ph.D., FACMG, Professor Emeritus, Pathology, Northeast Ohio Medical University

Abnormal NIPT results identify chromosomal mosaicism that may be confined to the placenta. One case revealed a phenotypically normal newborn with a complex mosaic karyotype decreasing the newborn's eventual reproductive fitness. This case establishes the importance of karyotyping the placenta and cord or peripheral blood when inconsistent or mosaic karyotypes are identified following an abnormal cfDNA result and a normal newborn phenotype without a prenatal karyotype.

12:30 Sponsored Presentation *(Opportunity Available)*

1:00 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:30 Session Break

FDA PERSPECTIVE ON NIPT

2:00 Chairperson's Remarks

Ronald J. Wapner, M.D., Professor, Obstetrics and Gynecology, Vice Chair, Research, Director, Reproductive Genetics, Columbia University Medical Center

2:05 Points to Consider When Validating an NIPT for FDA

Donna Roscoe, Ph. D., Branch Chief, Molecular Genetics Branch, Division of Molecular Genetics and Pathology, Office of In Vitro Diagnostics, CDRH, FDA

Non-invasive prenatal testing (NIPT) is an innovative diagnostic method for prenatal screening to identify chromosomal abnormalities. To help promote the availability of safe and effective NIPTs, companies interested in seeking FDA approval for their test can work interactively with FDA using the pre-submission process to develop analytical and clinical validation strategies. This talk will discuss the points to consider when planning validation protocols for the unique aspects of NIPTs.

CLINICAL IMPACT OF NIPT

2:25 Implementation of a Non-Invasive Prenatal Diagnostic Test for Multiple Single Gene Disorders into a Clinical Setting: Experience from the UK

Michael Parks, Ph.D., Developmental Scientist, Regional Genetics, Birmingham Women's NHS Foundation Trust

Through the NIPSIGEN project, we have recently proven that non-invasive prenatal diagnosis of single gene disorders can also be implemented into clinical service at a feasible cost for the UK National Health Service. The molecular diagnostic method that we have developed at Birmingham Women's Hospital for NIPD of a panel of single gene disorders has proven to be both accurate and affordable. After having successfully tested patients at risk of bearing a child affected by Duchenne/Becker muscular dystrophies, spinal muscular atrophy, congenital adrenal hyperplasia and cystic fibrosis, we have now implemented such testing into clinical practice. This talk will include clinical data from the newly developed genetic test and will elaborate on the implementation process of NIPD for SGDs into clinical practice.

2:45 Helping Patients Decide if NIPT is the Best Test

W. Andrew Faucett, Professor, Genomic Medicine, Geisinger Health System

NIPT is a screening test with unique communication and informed consent issues, not a diagnostic test. Patients want to know their future child will be healthy and often do not understand the types of chromosomal changes that can be detected prenatally today. With our growing knowledge about the risk for pathogenic copy number variations, how do we insure patients are receiving test results that will help them make informed decisions?

3:05 Refreshment Break

EXPANDED CARRIER SCREENING IN THE PRENATAL CLINIC

3:35 Introducing Expanded Carrier Screening in the Reproductive and Prenatal Genetic Clinic

Ignatia B. Van den Veyver, Professor, OB-GYN and Molecular Human Genetics, Baylor College of Medicine

Pan-ethnic expanded carrier screening (ECS) is now offered by various providers and includes more conditions than recommended by professional societies. Different ECS test employ different methods for mutation detection and include variable numbers of diseases. I will review current professional guidelines for carrier screening, differences between standard carrier screening and ECS, different ECS platforms, benefits and pitfalls of ECS, as well as practical and ethical aspects will be discussed.

4:05 PANEL DISCUSSION: Expanded Carrier Screening – A Changing Paradigm

Moderator: Ignatia B. Van den Veyver, Professor, OB-GYN and Molecular Human Genetics, Baylor College of Medicine

Anthony R. Gregg, MD, FACOG, FACMG, B.L. Stalnaker Professor, Director, Division of Maternal Fetal Medicine, Director, Obstetrics - UF Health Shands, University of Florida College of Medicine

James Goldberg, MD, Chief Medical Officer, Counsyl

Kim Martin, MD, Senior Global Medical Director, Women's Health, Natera

Expanded carrier screening has become an oft-debated topic in the prenatal clinic as the number of disorders it can detect increases and the applications become more widespread. Questions for discussion include:

- Should all couples undergo expanded carrier screening either preconception or prenatally?
- Is it time to modify professional guidelines on carrier screening?
- Can expanded carrier screening account for a diverse modern population?

4:35 Close of Symposium

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AUGUST 26 SYMPOSIA

Cambridge Healthtech Institute's Inaugural

Health and Wellness Genomic Screening

Personal Genome Sequencing for Health Maintenance and Genome-Based Care

FRIDAY, AUGUST 26

8:00 am Registration & Morning Coffee

GENOMIC HEALTH SCREENING

8:25 Chairperson's Opening Remarks
Jamie Platt, Ph.D., Managing Director, BRIDGenomics, LLC.

8:30 Genomic Sequencing in the Clinic: Today & Tomorrow
David Bick, M.D., CMO & Faculty Investigator, HudsonAlpha Institute for Biotechnology; Founder & CMO, Envision Genomics
Genomics is changing the practice of medicine. At present, genomic sequencing (whole exome sequencing and whole genome sequencing) is used in the diagnosis of rare Mendelian disorders. This technology is also used in oncology to help guide the choice of chemotherapeutics. This presentation will discuss how genomics is currently integrated into the practice of medicine and will explore how we will soon use it to promote health and wellness.

9:00 Personalized Genomics: Beyond Precision Medicine and Ancestry
Jamie Platt, Ph.D., MB(ASCP), Managing Director, BRIDGenomics, LLC.
Personalized genomics is an expanding area of interest that is rapidly reaching beyond medicine and ancestry. While Next-Generation Sequencing (NGS) technologies have catapulted precision medicine applications through both research and clinical diagnostic efforts, many other applications remain. Ancestry applications have been consistently gaining traction and social attention, but other applications are not as mature. The opportunities for personalized genomics outside of medicine and ancestry will be discussed with attention to the key issues that must be addressed as we bridge genomics to segments that interface more directly with the public.

9:30 Genomic Health Screening: The Hype, Hope, and Reality
Wendy Chung, M.D., Ph.D., Kennedy Family Associate Professor of Pediatrics and Medicine, Director of Clinical Genetics, Columbia University
Since the human genome sequence became available, it has been the goal of genomic medicine to use an individual's genome information to facilitate early detection and prevention of disease. With the dramatic drop in the cost of sequencing, it is now possible to realistically consider genomic health screening on a population-wide basis. This talk will focus on what is currently possible and what the barriers are to implementation of genomic health screening.

10:00 Sponsored Presentation *(Opportunity Available)*

10:30 Coffee Break

GENOMIC HEALTH SCREENING (CONT.)

11:00 Emerging Aspects of Genetic Studies in Humans and Implications for Informing Dietary Recommendations
Hooman Allayee, Ph.D., Associate Professor, Preventive Medicine, University of Southern California, Keck School of Medicine
An understanding of the genetic basis for common diseases, such as heart disease and diabetes, has been revolutionized by large-scale studies in human populations and rapid advances in genomics technologies. Despite this success, the susceptibility genes identified to date still only explain a small fraction of the overall heritability for any particular disease, which implies either 1) the existence of additional genes with smaller effect sizes, 2) higher order interactions between genes and environmental factors, such as diet, and/or 3) rare susceptibility alleles. An overview of the current state of common disease genetics and how this information can be leveraged towards improving dietary recommendations will be presented.

11:30 Implementing Genomic Testing into a Wellness Program$1000 Genome, Implications for Future of Preventive and Precision Medicine
Mirza Cifric, CEO, Veritas Genetics
The presentation will look at the implications of high quality $1000 genome and interpretation in the future of Preventive and Precision medicine. Additionally, it will explore the changes in preventative care as a result of a "healthy" subject receiving whole genome sequencing and changes in patient mindset of healthy to sick continuum over lifetime. Technical, clinical, ethical, regulatory and reimbursement considerations will be discussed.

12:00 pm PANEL DISCUSSION: Harnessing the Power of Genomics
Moderator: Keith Batchelder, M.D., CEO & Founder, Genomic Healthcare Strategies
Panelists: Speakers of the Day
Breaking Down the Barriers: Genomic information offers potential individualized insights into health, wellness and disease. Yet many feel that Genomics is slow to be incorporated into everyday patient management (beyond oncology). The current US healthcare system might be described as more of "sick-care," as opposed to healthcare, putting prevention and screening at low priority. Are the incentives for Genomics, like screening, and even understanding personal drug metabolism and/or adverse effects, aligned with current market forces in the US? What are necessary steps, infrastructure and reimbursement changes that need to make Genomics part of everyday healthcare. Who will be leaders in Genomic "health" adoption, traditional healthcare, public health initiatives, integrated healthcare delivery networks, direct-to-consumer organizations?

- Explore where Genomic information is valued – what areas are ripe for genomics
- What infrastructure is needed to utilize and potentially improve genomic information – is big data just a buzzword
- Will innovation come from inside or outside the healthcare establishment?

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1:00 Luncheon Presentation *(Sponsorship Opportunity Available)*
or Enjoy Lunch on Your Own

1:30 Session Break

WELLNESS AND PREDISPOSITION TESTING

2:00 Chairperson's Remarks
Dana Farengo Clark, MS, MS, LCGC, Genetic Counselor, Oncology Program, University of Pennsylvania

2:05 Implementing Genomic Testing into a Wellness Program
Karen L. Huyck, M.D., Ph.D., Assistant Professor, Occupational and Environmental Medicine, Geisel School of Medicine, Dartmouth College
The Dartmouth-Hitchcock Weight and Wellness Center (WWC) Biorepository is being developed to archive comprehensive datasets including but not limited to: genomic, microbiomic, clinical, demographic, anthropomorphic, and psychosocial data, wellness and lifestyle data, and functional brain imaging information from patients with obesity. Much like the beginning of our nascent understanding of cancer, when rudimentary treatments were not targeted to specific types of tumor cells, obesity is often treated with a "one size fits all" approach. Effective treatment for obesity will benefit from organized, large-scale study, and precision research approaches.

2:35 It's Not You, It's Your Tumor: Navigating the journey from somatic tumor testing to the genetics clinic
Dana Farengo Clark, MS, MS, LCGC, Genetic Counselor, Oncology Program, University of Pennsylvania
Cancer genetics is being challenged by the uptick of NGS of tumor DNA. Somatic testing, while providing therapeutic information, may contain incidental germline findings, influencing cancer risk. The results of somatic testing may be directed to the genetic counselor to elucidate if the somatic finding necessitates clinical germline testing and by what criteria patients should be referred. The University of Pennsylvania's novel algorithm for referring patients for germline testing, its implementation, and early outcomes will be discussed.

3:05 Refreshment Break

NUTRITIONAL GENOMICS

3:35 Using Genetic Information for Adapting Nutrition Plans to Individual Needs
Martin Kohlmeier, M.D., Ph.D., Research Professor, Department of Nutrition, UNC Schools of Medicine and Public Health, Chapel Hill, and Nutrigenetics Laboratory, UNC Nutrition Research Institute
Numerous common genetic variants influence what we should eat and what we actually end up eating. Reliable genetic testing is affordable and the evidence base for gene-food interactions is steadily expanding. The challenge now is to combine both elements into effective precision nutrition practice. This presentation will highlight how computing can help professionals and consumers to make sense of the many different gene-food interactions and inform about good nutrition choices.

4:05 Nutritional Genomics: Opportunities for Captivating and Engaging Wider Audiences
Ron L. Martin, Founder and President, Nutrigenetics Unlimited, Inc.
Nutrition applies to everyone, and can be used to help introduce genetics/genomics to wider audiences, including members of the public. Engagement of the public will be helpful or even essential for moving genetics/genomics into the mainstream of healthcare consciousness. Examples of the emerging evidence-base will be described, along with online tools for increasing both awareness and utility of the increasingly actionable information which can captivate the imaginations of most anyone.

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5:05 Close of Symposium

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AUGUST 26 SYMPOSIA

Cambridge Healthtech Institute's Inaugural

The Business of Telemedicine

How Telemedicine and the Internet of Things are Driving Change in Healthcare

FRIDAY, AUGUST 26

8:00 am Registration & Morning Coffee

PART I: TELEHEALTH TECHNOLOGY AND INTEGRATION

8:25 Chairperson's Opening Remarks

» 8:30 KEYNOTE PRESENTATION: The Business of Telemedicine

Mark Blatt, (former) Worldwide Medical Director, Intel Corporation; Mark Blatt Associates, Inc.

In the last five years telemedicine has gone from nice to have to "gotta have". Remote care technologies have come of age. The EMR infrastructure to support digital care delivery is in place. The cost of the technology has plummeted, and its complexity continues to vanish. Wearables and IoT are the new buzzwords. So, what will it take to make a living with Telemedicine? Come hear how the Business of the Telemedicine can be realized today.

9:00 Remote Patient Monitoring – A New $37 Billion Industry by 2020

Steven Gerst, M.D., MBA, MPH, CHE, CMO, ARC Devices Limited

Home patient monitoring systems/services, including automated prescription pharmaceutical compliance tracking, will help health systems, IPAs/ACOs and health insurers save an estimated $300 billion over the next 4 years while improving access and quality of care. RPM/Telemedicine is growing from 19.7 to a projected 158 million visits. Health systems can now capture the new $41.90 capitated monthly fee for CPT Code 99490 for non-face-to-face chronic care management as well as the $163.88 and $230.86 Transitional Care management fees under Codes 99495 and 99496, potentially adding millions of dollars in revenue to the bottom line.

9:30 Value-Based Virtual Care: The Opportunity to Get the Most Out of Telehealth

Nicholas G. Assad, Senior Vice President, Business Development, CirrusMD, Inc.

Health care is shifting rapidly from fee for service to fee for access, or value-based payment arrangements. I will be discussing what that looks like for health systems, insurance companies and patients and how value-based virtual health will play a critical role in the success of this healthcare transition. I will briefly discuss the evolution of telemedicine and immediately go into how value-based virtual health will impact on health systems, insurance companies and government.

10:00 Network Effects in Telemedicine

Payam Pakravan, Vice President, Strategy & Planning, OTN (Ontario Telemedicine Network)

Over the past 10 years, the Ontario Telemedicine Network (OTN) has developed one of the largest telemedicine networks in the world. As the network evolves from a utility to a virtual healthcare platform, the value proposition of telemedicine is being significantly broadened. This presentation highlights some of the key lessons learned so far in the "mainstreaming" of telemedicine in Ontario.

10:30 Coffee Break

11:00 Integrating EHRs

Bret Shillingstad, M.D., CMIO, Epic

11:30 Late Breaking Presentation

12:00 pm Talk Title to be Announced

William Morris, CMIO, Cleveland Clinic

12:30 Sponsored Presentation *(Opportunity Available)*

1:00 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:30 Session Break

PART II: POLICY, PROTOCOL, AND REIMBURSEMENT

2:00 Chairperson's Remarks

2:05 Telehealth Business Arrangements and Contracting

Nathaniel Lacktman, Partner, Telemedicine and Virtual Care Practice, Foley & Larnder

The rapid growth of telehealth technologies offers enormous benefits to the healthcare community, along with new provider business models and arrangements. When designing a telehealth offering, companies should explore the various financial opportunities and compensation models. These arrangements must be not only financially viable, but structured to comply with federal and state compliance laws and regulations. This session will focus on legal business models and compensation methodologies in telehealth.

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The Business of Telemedicine

How Telemedicine and the Internet of Things are Driving Change in Healthcare

2:35 Impact & Opportunity—Evolution of Laws and Policy in the Business of Telehealth

Alexis S. Gilroy, Partner, Digital Health & HIT, Jones Day

Laws and policy impacting digital health are quickly evolving in a variety of ways both across the US and globally, and the globalization of remote care delivery is advancing this change like never before. This session will discuss strategies for evaluating and managing multi-jurisdictional laws and regulations while scaling your digital health business. From whether telehealth has changed the standard of care to whether a second opinion is the practice of medicine, the speaker will propose possible theories for the next frontier of legal and policy modifications expected to drive further change and business opportunity in digital health.

3:05 Refreshment Break

3:35 PANEL DISCUSSION: Policy and Establishing a Telemedicine Business

Moderator: Mark Blatt, (former) Worldwide Medical Director, Intel Corporation; Mark Blatt Associates, Inc.

Panelists: Alexis Slagle Gilroy, Partner, Jones Day

Alice Borrelli, Director, Global Health and Workforce Policy, Intel

Payam Pakravan, Vice President, Strategy & Planning, OTN (Ontario Telemedicine Network)

4:35 Close of Symposium

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Cambridge Healthtech Institute's Fifth Annual

Digital PCR

Technologies & Tools for Precision Diagnostics

RECOMMENDED PRE-SYMPOSIUM SHORT COURSE*

SC7: Digital PCR: Technologies, Quantification, and Analysis

**Separate registration required, please see page 5 for details*

FRIDAY, AUGUST 26

8:00 am Registration & Morning Coffee

TECHNICAL CONSIDERATIONS FOR DIGITAL PCR

8:25 Chairperson's Opening Remarks

Hatim Husain, M.D., Assistant Professor, Medicine, Hematology and Oncology, University of California, San Diego

8:30 DNA Methylation Analysis Using Droplet Digital PCR

Ming Yu, Ph. D., Staff Scientist, Clinical Research, Fred Hutchinson Cancer Center

Droplet digital (ddPCR) is a recent advance in PCR technology that enables the precise detection and absolute quantification of nucleic acid target sequences that has a range of applications for both research and clinical diagnostic studies. In this talk, I will discuss the parameters important in the design and performance of ddPCR for the detection and quantification of methylated DNA. I will present an example that demonstrates the sensitivity and precision of the method for detecting methylated DNA in the promoter region of mir342/EVL, a potential DNA methylation biomarker for colon cancer risk.

9:00 Novel Method to Detect MicroRNAs Using Chip-Based QuantStudio 3D Digital PCR

Orazio Fortunato, Ph.D., Experimental Oncology, Fondazione IRCCS Istituto Nazionale Tumori

Research efforts for the management of lung cancer are directed to identify new strategies for early detection. miRNAs are a new class of circulating biomarkers but lack of consensus on data normalization has affected their diagnostic potential. There is a growing interest in techniques that allow miRNAs absolute quantification. We described an interesting approach for profiling miRNAs in plasma samples using a chip-based QuantStudio 3D digital PCR. Given its reproducibility it would be a robust tool for quantitative assessment of miRNA for diagnosis of lung cancer and other diseases.

DESIGNING DIGITAL PCR EXPERIMENTS

9:30 Generalized Linear (and Mixed) Models for the Analysis and Design of Digital PCR Experiments

Robert M. Dorazio, Research Statistician, Biological Resources Division, United States Geological Survey

Generalized linear models of binomial responses and extensions of these models for extra-binomial sources of variation are appropriate for the analysis and design of experiments that use digital PCR (dPCR) to quantify nucleic acid concentration. These models are versatile and easy to fit using conventional statistical software. As illustrations, I analyze dPCR data from different kinds of experiments, including serial dilution, evaluation of copy number variation, and quantification of gene expression.

10:00 Sponsored Presentation *(Opportunity Available)*

10:30 Coffee Break

INTERFACING DIGITAL PCR WITH NGS

11:00 Strategies and Challenges for Accurate Quantification of NGS Libraries with Digital PCR

Peter A. Schweitzer, Ph.D., Director, Genomics Facility, Institute of Biotechnology, Cornell University

The Cornell University Genomics Facility uses dPCR as an integral part of our Illumina sequencing operation for pooling samples and accurate quantification of final sequencing libraries. This has improved our ability to provide high quality DNA sequence data in a timely and cost efficient manner and avoiding costly reruns. One significant challenge is accurately performing the large dilutions required and I'll describe an internal reference to correct for variability during dilution.

11:30 pm Using Picodroplet Digital PCR Technology on NGS Libraries to Create Rapid, Highly Sensitive Assays for Mutation Detection

Maria Arcila, Ph.D., Director, Diagnostic Molecular Pathology Laboratory, Associate Attending Pathologist, Memorial Sloan Kettering Cancer Center

Although next generation sequencing (NGS) is a highly attractive technology for comprehensive assessment tumor samples, this approach alone may not provide sufficiently rapid and sensitive detection for some mutations in clinical practice. Dedicated single gene testing may lead to tissue exhaustion in some settings, precluding further assessment of the sample by NGS. We describe our clinical application of picodroplet digital PCR for rapid mutation detection using small aliquots of NGS libraries prepared for comprehensive profiling, fully maximizing broad genomic analysis on limited samples.

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Cambridge Healthtech Institute's Fifth Annual

Digital PCR

Technologies & Tools for Precision Diagnostics

CLINICAL APPLICATIONS OF DIGITAL PCR

12:00 pm Utility and Advantages of Digital PCR Technique in Management of Hematological Malignancies

Rashmi Kanagal-Shamanna, M.D., Assistant Professor, Hematopathology, Molecular Pathologist, MD Anderson Cancer Center

The talk discusses the 1) principles of digital PCR 2) and potential applications in management of hematological neoplasms. The talk is specifically geared towards its applications in assessment of minimal residual disease in patients diagnosed with acute myeloid leukemia, myelodysplastic syndromes and myeloproliferative neoplasms.

12:30 Sponsored Presentation *(Opportunity Available)*

1:00 Luncheon Presentation to be Announced

Sponsored by BIO-RAD

1:30 Session Break

CLINICAL APPLICATIONS OF DIGITAL PCR (CONTD.)

2:00 Chairperson's Remarks

Maria Arcila, Ph.D., Director, Diagnostic Molecular Pathology Laboratory, Associate Attending Pathologist, Memorial Sloan Kettering Cancer Center

2:05 Early Response Monitoring with Circulating Tumor DNA in Lung Cancer

Hatim Husain, M.D., Assistant Professor, Medicine, Hematology and Oncology, University of California, San Diego

Non-invasive drug response biomarkers for early assessment of tumor response can enable adaptive therapeutic decision-making for individualized patient treatment and proof-of-concept for target inhibition of tumor cells by investigational drugs. Circulating tumor DNA (ctDNA) is released into the blood by tumor cell turnover and excreted into urine. Sampling flexibility of urine was leveraged to determine whether detection and quantitation of ctDNA biomarkers in urine could assess early tumor response within days of a patient receiving targeted therapy. Findings suggest that tyrorsine kinase inhibitors induced tumor apoptosis within days of initial patient dosing. We demonstrate that daily monitoring of ctDNA by non-invasive urine sampling provides temporal and quantitative dissection of early tumor response.

2:35 Liquid Biopsies in Biomarker Driven Cancer Care

Filip Janku, M.D., Ph.D., Assistant Professor, Investigational Cancer Therapeutics (Phase I Program), MD Anderson Cancer Center

The optimal choice of cancer therapy depends upon analysis of the tumor genome for molecular alterations. The tumor heterogeneity of cancers creates substantial challenges, as molecular profile depends on time and site of tumor tissue acquisition. To capture the entire molecular profile, multiple biopsies from primary and metastatic sites at different time points would be required, which is ethically and economically problematic. Molecular analysis of circulating cell-free DNA offers a novel, minimally invasive method that can be performed at multiple time-points and plausibly better represents the prevailing molecular profile of the cancer. Molecular analysis of this cell-free DNA offers multiple clinically useful applications, such as identification of molecular targets for cancer therapy, monitoring of tumor molecular profile in real time, detection of emerging molecular aberrations associated with resistance to particular therapy, determination of cancer prognosis and diagnosis of cancer recurrence or progression.

3:05 Refreshment Break

3:35 Digital PCR for Infectious Disease

Alexandra Whale, Ph.D., Senior Researcher, Molecular and Cell Biology Team, Science and Innovation Division, LGC

It has been suggested that digital PCR may offer a number of advanced applications that potentially enable improved detection and management of infectious diseases. To test this, we evaluated its performance in the detection of a range of microbial targets, including oseltamivir resistance in Influenza.

» 4:05 FEATURED PRESENTATION: Droplet Digital PCR for Microbial Risk Assessment in Beach Water

John Griffith, Ph.D., Principal Scientist, Southern California Coastal Water Research Project

Molecular methods have become routine in clinical applications, but are recent additions to the environmental monitoring and risk assessment toolbox. This talk will describe how digital PCR is being utilized to monitor water microbial water quality, identify sources of fecal contamination and quantify pathogens for risk assessment, and how a flow-through digital PCR instrument now under development has the potential to revolutionize the field of water quality testing.

4:35 Close of Symposium

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Plenary Keynote Sponsorship

Sponsor will participate as a panelist in the Disruptive Innovation in Lab Medicine Plenary Keynote Panel. The Plenary keynote brings together the attendees across all tracks at the event, 4-6 companies will participate in the panel along with a moderator (from AMP). Each company will be introduced by the moderator and then participate in a lively debate around pertinent issues in the industry. No slides. The Panel will discuss disruptive innovations and their effect on the traditional molecular diagnostics/ molecular pathology laboratory.

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Showcase your solutions to a guaranteed, targeted audience. Package includes a 15- or 30-minute podium presentation within the scientific agenda, exhibit space, on-site branding, access to cooperative marketing efforts by CHI, and more.

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- Focus group
- Reception style
- Plated dinner with specific conversation focus

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Associate Director, Business Development
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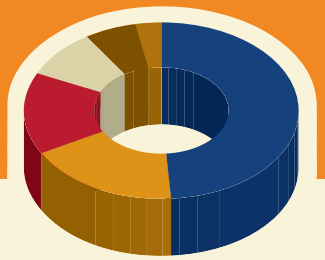

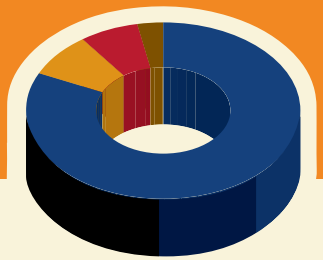

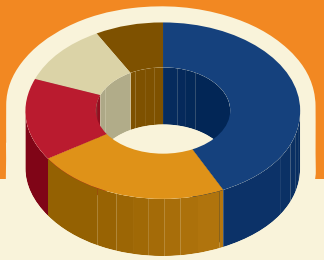

2015 ATTENDEE DEMOGRAPHICS

COMPANY TYPE

Commercial (Biotech + Pharma)	49%
Academic	18%
Healthcare Provider	15%
Government	9%
Services/Societies	6%
Other	3%

GEOGRAPHIC LOCATION

USA	82%
Asia	8%
Europe	7%
Other	3%

USA Breakdown

East Coast	48%
West Coast	36%
Midwest	16%

DELEGATE TITLE

Executive/Director	43%
Scientist/Technologist	23%
Other	15%
Professor	11%
Manager	8%

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HOTEL & TRAVEL INFORMATION

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Phone: 202-582-1234

Reservations: Go to the travel page of nextgenerationdx.com

Discounted Room Rate: $205 s/d
Discounted Cut-off Date: July 25, 2016

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