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Cambridge Healthtech Institute's

PRECISION DIAGNOSTICS SUMMIT

Sample Prep, Digital Detection & Analysis for Dx

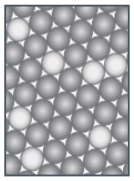
HILTON BACK BAY, BOSTON MA | JUNE 16-18, 2014

JUNE 16-17

Sample Prep and Target Enrichment in Molecular Diagnostics

JUNE 17-18

Quantitative Digital Detection Technologies



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Plenary Keynote:

N. Reginald Beer, Ph.D.

Medical Diagnostics Initiative Leader, Center for Micro and Nanotechnologies, Lawrence Livermore National Laboratory

Featured Speakers:

David R. Walt, Ph.D.

Robinson Professor of Chemistry, Howard Hughes Medical Institute Professor, Tufts University

Carolyn Compton, M.D., Ph.D.

Professor, School of Life Sciences, Arizona State University

PrecisionDiagnosticSummit.com

ABOUT THE CONFERENCE

As personalized medicine integrates into clinical practice, genomic tools and technologies will need to evolve to meet the increasing test volume and required accuracy. Cambridge Healthtech Institute's **Precision Diagnostics Summit** will provide a start-to-finish look at the latest methods for sample preparation, novel tools for nucleic acid detection, and final analysis of results.

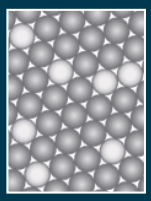
JUNE 16-17

Sample Prep and Target Enrichment in Molecular Diagnostics

Coverage Includes:

- Standardizing preanalytical processing to assure assay accuracy
- FFPE tissue considerations and its alternatives
- Nucleic acid extraction and sequencing
- Novel accelerated sample prep technologies

JUNE 17-18



Quantitative Digital Detection Technologies

Coverage Includes:

- Advances in digital detection including microfluidics, digital PCR, and single cell analysis
- Problem solving case studies in the areas of cancer, genetics, prenatal, and infectious diseases
- Transitioning from analog to digital

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Sample Prep and Target Enrichment in Molecular Diagnostics JUNE 16-17

MONDAY, JUNE 16, 2014

7:15 am Registration & Morning Coffee

STANDARDIZING SAMPLE QUALITY AND PREANALYTICAL PROCESSING

7:45 Welcome Remarks from Marina Filshtinsky, M.D., Conference Director

7:55 Chairperson's Opening Remarks

8:00 Biomarker Development for Precision Medicine: A Systems Approach Beginning with the Right Stuff

Carolyn Compton, M.D., Ph.D., Professor, School of Life Sciences, Arizona State University

The future of precision medicine depends on the development of diagnostic analyses that accurately reflect the biomolecular phenotype of the disease, both for accurate classification and appropriate therapeutic management. In order to develop and use diagnostics, the biospecimens that serve as the test material must be systematically collected, processed and stabilized according to standards that render the samples fit for the analytic approach used in the diagnostic test. Rigorous adherence to standards under a quality management system that includes documentation of of process steps and recording of deviations from protocol is required. Reproducibility and clinical validity cannot be achieved with complex diagnostic analyses without the assurance of the provenance of the specimens being tested. The biomarker qualification program of the Center for Drug Evaluation and Research at the Food and Drug Administration emphasizes the need to document the biospecimen quality of diagnostic biomarkers used for drug development and the Center for Devices and Radiologic Health has similar requirements for approval of diagnostic devices. It is imperative that the diagnostics development community address the need for standardized processes and fit-for-purpose biospecimens to accelerate the delivery of accurate, reproducible, clinically relevant molecular diagnostics for precision medicine.

8:30 The Challenges of Developing and Implementing Biospecimen Evidence-Based Practices

Helen Moore, Ph.D., Program Director, Biorepositories & Biospecimen Research Branch, Cancer Diagnosis Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute

The U.S. National Cancer Institute has led progress in biobanking with the NCI Best Practices for Biospecimen Resources and the Biospecimen Research Network (BRN). Incorporating new scientific data into best practices is another challenge.

9:00 A Call to Standardize Preanalytic Data Elements for Biospecimens

James Robb, M.D., FCAP, Leidos Biomedical Research, Inc.

Biospecimens must have appropriate clinical annotation to ensure optimal quality for both patient care and research. A quantitative list of 170 clinical preanalytic variables (data fields), along with their relative importance, which can vary depending on downstream use, institutional needs, and information technology capabilities, have been developed and published by the College of American Pathologists. Notes, definitions, and negative impacts have been provided for each variable. This list can be used as a guide for site-specific implementation into patient care and/or research biorepository processes.

9:30 Ultracold vs. LN2 Cryopreservation for Biospecimens Destined for Genomically-Informed Precision Medicine

Mark Cosentino, D.P.M., Ph.D., Head, BioProcessing and DNA Extraction, Staging Laboratories, Biogen

The storage temperature of biospecimens of various material types tends to be selected based on historical antidotal information. What is needed is scientific-based research to define "Best Practices" that links the appropriate storage temperature of analytes to specific downstream testing applications. This is not a trivial matter. The presentation will discuss the possibility of storing biospecimens below the Glass Transition Temperature of Water (GTTW). An experimental approach and call for scientific collaboration will also be discussed.

10:00 Development of an NGS Mediated Assay Targeting High Frequency Somatic Alterations in AML Patients Utilizing the WaferGen SmartTETM System

Sponsored by WAFERGEN BIOSYSTEMS

Mark Landers, Director, Research Services, Research & Development, AltheaDx

We have developed an NGS mediated assay targeting 30 of the most frequently mutated genes reported in AML disease progression for the purposes of supporting translational research. The WaferGen SmartChipTM TE panel reliably detects point mutations across all exons of the targeted genes as well as specific genomic rearrangements including FLT3 ITD and MLL PTD.

10:30 Coffee Break with Exhibit and Poster Viewing

11:00 Quantitative Measurement of Protein Degradation in FFPE Samples

Veronique Neumeister, M.D., Specialized Translational Services Laboratory, Department of Pathology, Yale University

Companion diagnostic tests are critically dependent on tissue quality. However, tissue handling and processing are not always tightly controlled and pre-analytical variables can significantly alter tissue quality. Cold ischemic time is amongst the most important variables. This presentation will discuss the effect of this variable in the diagnostic and research setting and show data on analytes that are particularly sensitive to this issue. Tools to control tissue quality will be discussed and the construction of an internally calibrated tissue quality index (TQI) as a way to monitor tissue quality for immunological assessments will be illustrated.

11:30 Practical Approaches to Expanding Biorepository Representation: Innovative Tissue Print Technologies for Collecting High Quality Snap-Frozen Specimens for Biomarker Research

Sandra M. Gaston, Ph.D., Director, Molecular Biomarkers Research Laboratory, Department of Pathology and Laboratory Medicine, Tufts Medical Center Assistant Professor of Pathology, Tufts University School of Medicine

Most human tissue samples obtained from clinical biopsy and surgical resections are only secondarily considered as research specimens, and any plan to collect tissue for research must put first priority on patient care. . Remnant tissues obtained from fresh surgical specimens are the mainstay for biorepositories that provide high quality snap-frozen samples for research, but many critical areas of a surgical resection and most diagnostic biopsies cannot be easily "divvied up" before the tissue is submitted for processing as a formalin-fixed paraffin embedded (FFPE) specimen. Our group has developed a set of tissue print micropeel technologies that offer an innovative and practical approach to obtaining high quality RNA and DNA from biopsies and other "high value" specimens without compromising pathology diagnosis. Application of these technologies for cancer biomarker discovery will be discussed.

SAMPLE PREP FOR NEXT GENERATION SEQUENCING ASSAYS

12:00 Development, Validation and Implementation of Sample Prep Procedures for Clinical Whole Exome Sequencing at the Broad Institute

Niall J. Lennon, Ph.D., Director, Technology Development, Genomics Platform & Clinical Applications Development, Clinical Research Sequencing Platform, Broad Institute of MIT & Harvard

The development of the Whole Exome Sequencing assay offered by the Broad clinical lab will be discussed as an example of the need for, and application of, process design and quality management systems in molecular diagnostics. Though the documentation and validation requirements may differ between clinical and research processes there are a common set of challenges that must be tackled through the identification and elimination of process variability, rigorous supply chain control, enhanced tracking and troubleshooting, and automation of both lab and analytical pipeline functions.

12:30 Use of a Next-Generation Sequencing Assay to Compare Results Obtained from Matched Formalin-Fixed and Frozen Tissue Specimens

Patrick Hurban, Ph.D., Senior Director, Translational Research and Development, Global Head, Genomic Research and Development, Expression Analysis, The Quintiles Company

Formalin-fixed tissues present many sample preparation, extraction and method development challenges. It can also be challenging to understand whether certain findings stem from intrinsic genetic properties of the sample, or alternatively, are a product of how the sample was handled. Despite advancements in preservation methods, vast collections of FFPE material await analysis. Results will be presented comparing matched formalin-fixed and frozen tumor samples analyzed using a sensitive next generation sequencing assay.

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

1:35 How To Choose The Right Assay On The Right Platform: A Clinical Diagnostic Laboratory Perspective

Elizabeth Duffy Hynes, Laboratory Manager for Clinical Development, Laboratory for Molecular Medicine, Partners HealthCare Center for Personalized Genetic Medicine

Clinical diagnostic and research laboratories may have similar fundamental criteria for evaluating instruments, technologies, and platforms, but there are additional facets and layers of stringency that need to be considered when in a clinical setting. At a technical level, assays have to have the best possible sensitivity and specificity scores and cutting-edge technologies should be proven to meet or exceed gold standard metrics, or current standard of care. Routine laboratory operations considerations, such as cost, hands on time, ease of use, and turn-around-time, among others must also be evaluated. Of course, these factors must be carefully balanced with proven clinical utility in order to provide the highest quality healthcare service to patients and their physicians. Experiences and decision making processes of the Laboratory for Molecular Medicine will be discussed.

2:00 Development, Validation, and Implementation of Clinical Targeted Next Generation Sequencing using Anchored Multiplex PCR (AMP)

Long Phi Le, M.D., Ph.D., Medical Director, Clinical Research Sequencing Platform, Broad Institute; Assistant Professor of Pathology, Massachusetts General Hospital

Targeted next-generation sequencing (NGS) is an important approach for both research and clinical applications. This presentation will describe a novel method termed anchored multiplex polymerase chain reaction (AMP) which offers a rapid, economical, and scalable target enrichment solution. We share our experience with developing, validating, and implementing AMP in several clinical assays for fusion transcript detection and cancer genotyping (single nucleotide variants, insertions/deletions, and copy number) using formalin-fixed paraffin-embedded specimens. The use of pre-analytical steps to assess nucleic acid quality from FFPE specimens and post-analytical steps to qualify sequencing data will be discussed in the context of clinical testing.

2:30 A Novel Method of Active Paraffin Removal, and Efficient Extraction of NGS-Quality DNA from FFPE Tissues

Sponsored by Covaris

Hamid Khoja, Ph.D., Principal Scientist, Covaris Inc.

FFPE tissue preservation, conceived primarily to facilitate histological analysis, is now routinely used in clinical oncology as a source of DNA for targeted and whole genome sequencing. The paraffin matrix and chemical crosslinks of FFPE-preserved samples present significant challenges for the robust extraction of nucleic acids. To provide reliable access to DNA of clinical FFPE samples, we present a novel method for consistent and reproducible extraction and purification of DNA from FFPE samples using Covaris Adaptive Focused Acoustics™(AFA).

3:00 Comparison of Various Preanalytical Strategies in Molecular Testing for Infectious Diseases

David R. Hillyard, M.D., Medical Director, Molecular Infectious Diseases, Arup Laboratories

Molecular infectious disease testing places unique demands on pre-analytic methods for organismal disruption, nucleic acid release, purification, and concentration. For both high throughput core platforms and the increasing number of near point-of-care devices, nucleic extraction is a key pre-analytic step for good test performance. This presentation will review both currently available and emerging approaches to pathogen nucleic acid extraction, and issues relevant to its integration with downstream amplification and analysis technologies.

3:30 Refreshment Break with Exhibit & Poster Viewing

4:00 Inferring Dynamic Signatures of Microbes in Complex Host Ecosystems

Lynn Bry, Ph.D., M.D., Associate Professor of Pathology, Institution Brigham and Women's Hospital

4:30 Panel Discussion: Matching Nucleic Acid Extraction Method with the Goals of an Assay

Moderator: Patrick Hurban, Ph.D., Senior Director, Translational Research and Development, Global Head, Genomic Research and Development, Expression Analysis, The Quintiles Company

Panelists: Monday Speakers

5:10 Welcome Reception with Exhibit & Poster Viewing

6:00 Short Course Registration

6:15-9:00pm Dinner Short Course: How to Launch a Laboratory Test: Everything You Wanted to Know but Were Afraid to Ask *

Instructors: Steven Gutman, M.D., Strategic Advisor, NA, Myraqa, Inc.

Tonya Dowd, Director, Reimbursement Policy, Quorum Consulting, Inc.

** Separate Registration Required*

TUESDAY, JUNE 17

CUTTING-EDGE INNOVATIONS IN MOLECULAR TESTING: THE FUTURE IS NOW

8:15 am Breakout Discussions with Continental Breakfast

9:10 Chairperson's Remarks

9:15 Challenges and Prospects of Circulating RNA

Kai Wang, Ph.D., Principle Scientists, Institute of Systems Biology

Since extracellular microRNAs (miRNAs) were discovered, their impact on biomarker related applications has been a surprising and exciting field. The discovery of exogenous RNAs in circulation further expands the possibility of using circulating RNA to assess the interactions between host and microbiome. The fundamental requirement for biomarker development is a reliable and accurate measurement method, which is still lacking for miRNA and other short RNAs in circulation. Factors that are known to affect circulating RNA measurements include sample type, sample preparation, storage condition, measurement platform, and many others. While new measurement methods are needed, caution needs to be taken in interpreting circulating RNA based results.

9:45 Electronic Label-Free Biosensing Assays

Mark A. Reed, Harold Hodgkinson Professor of Electrical Engineering, Departments of Electrical Engineering and Applied Physics, Yale University

Nanoscale electronic devices have the potential to achieve exquisite sensitivity, selectivity, and portability as sensors for detection of protein biomarkers. Nanowire-FETs compatible with standard microelectronics technology enable a high yield and low-cost technology with simple system integration. This talk discusses the application of this technology to a wide range of label-free biochemical and macromolecule sensing at clinically important concentrations for biomarker assays.

10:15 Sponsored Presentation *(Opportunity Available)*

10:30 Coffee Break with Exhibit and Poster Viewing

11:00 MAD NAAT: Multiplexable Autonomous Disposable Nucleic Acid Amplification Test for Low-Resource Settings

Barry Lutz, Ph.D., Research Assistant Professor, Department of Bioengineering, University of Washington

We are developing tests for DNA and RNA that can be performed anywhere, including your home. All steps from sample preparation to visual readout are carried out automatically without an instrument. Data collection by a cell phone will allow transmission of results to a healthcare provider and medical record. Project goals include commercializable tests as well as broad platform capabilities for future tests.

11:30 A Microfluidic DNA Library Preparation Platform for Next-Generation Sequencing

Kamlesh Patel, Ph.D., Manager, Advance Systems Engineering and Deployment, Sandia National Labs

DNA sequencing is advancing at an unprecedented rate, but sample preparation methods rely on manual bench-top processes, which are labor-intensive. The introduction of fast, low-throughput sequencers warrant a need to automate these protocols. We report on our work to integrate novel digital microfluidic technology to automate DNA library preparation workflows for characterization of novel and emerging pathogens from clinical samples.

12:00 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

SAMPLE PREP INTEGRATION INTO DIGITAL DETECTION WORKFLOW

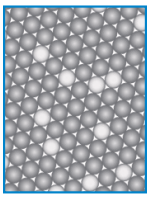
1:00 Chairperson's Remarks

1:05 PLENARY KEYNOTE: Sample Preparation Considerations for Digital Technologies

N. Reginald Beer, Ph.D., Medical Diagnostics Initiative Leader, Center for Micro and Nanotechnologies, Lawrence Livermore National Laboratory

Digital PCR provides extremely accurate quantification as compared to traditional standard curve methods but pre-detection processing remains pivotal. Critical factors such as sample preparation, sample homogeneity, reaction volume measurements, thermal cycler uniformity, template GC content and methylation can all effect data quality. In this talk we will discuss the benefits of digital technologies as well as steps to ensure accurate measurement. Attention will be given to future trends driving the field and moving out of the lab and onto the bench.

2:05 Close of Sample Preparation Conference



Quantitative Digital Detection Technologies

JUNE 17-18

TUESDAY, JUNE 17

12:00 pm Conference Registration

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2:05 Session Break

ADVANCES IN DIGITAL DETECTION

» 2:35 KEYNOTE PRESENTATION: SINGLE MOLECULE DETECTION FOR ULTRASENSITIVE ANALYSIS

David R. Walt, Ph.D., Robinson Professor of Chemistry, Howard Hughes Medical Institute Professor, Tufts University

Counting single molecules is the ultimate method for making measurements. Biological molecules are of particular interest because these molecules exist at levels of 1-1000 molecules per cell, beyond the sensitivity of most analytical methods. Methods for counting individual molecules are being developed that enable the enumeration of individual molecules. Some of these methods are simple to implement and will facilitate new discoveries as well as revolutionize clinical diagnostics.

3:05 Sensitive Detection of Hematopoietic Chimerism using Chip-Based Digital PCR

Sponsored by life technologies

Stephen Jackson, Ph.D., Associate Director, Product Applications, Life Science Solutions, Life Technologies

Hematopoietic chimerism occurs in leukemia samples when cells from bone marrow donor and recipient are present in the recipient's bone marrow at the same time. Increasing chimerism is associated with increased risk of relapse after transplant. Digital PCR (dPCR) provides an ideal mechanism for quantifying genetic chimerism. In this study, we show how chip-based dPCR facilitates quantification of hematopoietic chimerism. Furthermore, we show that its extreme sensitivity can detect chimerism in samples earlier than qPCR, facilitating earlier.

3:35 Refreshment Break with Exhibit and Poster Viewing

4:15 Absolute Quantification by Droplet Digital PCR versus Analog Real-Time PCR

Muneesh Tewari, M.D., Ph.D., Associate Professor, University of Michigan (tentative)

Nanoliter-sized droplet technology paired with digital PCR (ddPCR) holds promise for highly precise, absolute nucleic acid quantification. Our comparison of microRNA quantification by ddPCR and real-time PCR revealed greater precision (coefficients of variation decreased 37–86%) and improved day-to-day reproducibility (by a factor of seven) of ddPCR but with comparable sensitivity. When we applied ddPCR to serum microRNA biomarker analysis, this translated to superior diagnostic performance for identifying individuals with cancer.

4:45 Digital PCR in Cancer Molecular Pathology

Alexander Dobrovic, Ph.D., Laboratory Head, Translational Genomics and Epigenomics, Ludwig Institute for Cancer Research

Digital PCR is a breakthrough technology whose power has been released by commercially available new instrumentation. It is particularly applicable in the clinical milieu where samples are often limited in quantity and quality and where low copy number targets require quantification. As well as giving an overview of this field, several innovative applications enabling low-cost fast turnaround time diagnostics will be presented.

5:15 Reception in the Exhibit Hall with Poster Viewing

6:15 Dinner Short Course Registration

WEDNESDAY, JUNE 18

7:30 am Registration and Morning Coffee

MICROFLUIDIC PLATFORMS

8:00 Chairperson's Remarks

8:05 A Flexible Platform for On-Chip Droplet Digital PCR

Rémi Dangla, Ph.D., Co-Founder & CEO, STILLA Technologies

Stilla Technologies introduces a novel digital PCR solution, which combines droplet- and array-based approaches. Thanks to a breakthrough microfluidic technology, samples are partitioned into droplets and subsequently assembled into an array or droplet crystal, all within a single chip and without the need for complex microfluidic actuators. The chip can then be thermocyled, and the results read with a fluorescence microscope or scanner. The instruments are compatible with a range of chips, bringing flexibility to the field of digital PCR.

8:35 SD Chip for Digital Biological Measurements

Daniel T. Chiu, Ph.D., A. Bruce Montgomery Professor, Chemistry; Endowed Professor, Analytical Chemistry; Professor, Bioengineering, University of Washington, Seattle

This presentation describes a very simple and robust microfluidic device for digitizing samples into a large array of discrete volumes; we called this the SD (Self Digitization) Chip. As a demonstration of the utility of SD Chip, we describe digital nucleic acid amplification, including digital PCR and digital isothermal amplification.

9:05 Precise Quantitation of Nucleic Acids with the RainDrop™ Digital PCR System

Darren Link, Co-Founder and CTO, Raindance Technologies, Inc.

9:35 Breaking the fg/ml Barrier with Ultrasensitive Immunoassays

Sponsored by MSD

Pankaj Oberoi, Ph.D., Vice President, Commercial Assay, Meso Scale Discovery

MSD's MULTI-ARRAY® electrochemiluminescence technology is used extensively to measure low levels of proteins in biological and clinical samples. We developed a next-generation assay format that is 100 to 1000 times more sensitive than the current limits of ELISA technology. We will present

the ability to measure sub-fg/ml levels of cytokines and other biomarkers on established MSD® instrumentation. These new assays allow quantitation of previously unmeasurable baseline samples and have the capability of being multiplexed, allowing for the preservation of precious samples. These assays allow for the measurement of previously undetected biomarkers and could lead to the development of the next set of high sensitivity companion diagnostics and clinical assays.

10:05 Coffee Break with Exhibit and Poster Viewing

SINGLE CELL ANALYSIS METHODS

10:35 All-Optical Electrophysiology for High-Throughput Single-Cell Analysis

Adam Cohen, Ph.D., Professor, Departments of Chemistry and Chemical Biology; Physics Investigator, HHMI

The electrical firing patterns of neurons are the primary functional readout of their physiological state, in health and disease. But these firing patterns have been notoriously difficult to study: manual patch-clamp measurements are too slow to be used in screening, and multielectrode arrays only provide low-resolution aggregate information. We developed a system for all-optical electrophysiology, in which light pulses stimulate and record electrical activity in neurons. This system provides functional data in wild-type and disease model neurons with a throughput and information content unmatched by any other technology.

11:05 Live Single-Cell Functional Phenotyping in Droplet Nanoliter Reactors

Tali (Tania) Konry, Ph.D., Assistant Professor, Pharmaceutical Science, Northeastern University

Here we describe a nano-liter droplet microfluidic-based approach for stimulation and monitoring of surface and secreted markers of live single immune dendritic cells (DCs) as well as monitoring the live T cell/DC interaction. This nano-liter *in vivo* simulating microenvironment allows delivering various stimuli reagents to each cell and appropriate gas exchanges which are necessary to ensure functionality and viability of encapsulated cells. Thus live cell stimulation, secretion and surface monitoring can be obtained simultaneously in distinct microenvironment, which previously was possible using complicated and multi-step *in vitro* and *in vivo* live-cell microscopy, together with immunological studies of the outcome secretion of cellular function.

11:35 Quantitative Single Cell and Single Molecule Proteomics for Clinical Studies

Keith Willison, Ph.D., Chair, Chemical Biology; Professor, Chemistry, Imperial College London

We have developed a label free, microfluidic antibody capture chip platform called the MAC chip to quantify precisely the copy numbers of several proteins from a single cell in a multiplexed single assay format. We are extending the capability of the MAC chip devices in order to count proteins in circulating tumour cells (CTCs) isolated from biopsies of cancer patients undergoing chemotherapy. We hope to discover biomolecular signatures which correlate with intrinsic biological properties of tumour cells and clinical outcomes during treatment.

12:05 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

PROBLEM-SOLVING CASE STUDIES

1:00 Chairperson's Remarks

CANCER

1:05 HER-2 Testing by Digital PCR: Challenges and Opportunities

Bruno Ping, Laboratory Manager, Royal Surrey County Hospital

With increased financial pressures on molecular diagnostic laboratories to perform more testing in a cost effective manner, the advent of digital PCR is potentially the perfect opportunity to introduce cost savings in the lab without compromising patient quality. In our research, we looked at HER-2 testing as a proof of principle model, in a cohort of Her-2 amplified and non-amplified cases and then extrapolated potential lab savings based on an alternative testing algorithm.

1:35 Quantification of Plasma miRNAs Using Digital PCR for Lung Cancer Diagnosis

Feng Jiang, M.D., Ph.D., Associate Professor, Department of Pathology, University of Maryland School of Medicine

To evaluate the utility of digital PCR for analysis of miRNAs in lung cancer diagnosis, we first determined dynamic ranges and sensitivities of digital PCR for measuring plasma miRNAs. We then used digital PCR to quantify plasma miR-21-5p and miR-335-3p in lung cancer patients and controls. Our data suggest that digital PCR is a robust tool for quantitative assessment of plasma miRNAs in lung cancer diagnosis.

GENETICS

2:05 Analysis of Germline and Somatic Genome Variation Using Integrated NGS and PCR-Based Technology

Alexej Abyzov, Ph.D., Division of Biomedical Statistics and Informatics (BSI), Department of Health Sciences Research (HSR), Mayo Clinic

This presentation will report on our work investigating genome variants that affect brain development and function. We study germline variants as well as somatic variants using both tissue culture models and primary tissue samples. For these purposes we use combinations of next-generation sequencing based approaches, targeted-capture and whole-genome, respectively, as well as PCR based methods such as standard PCR, qPCR and digital droplet PCR.

INFECTIOUS DISEASE

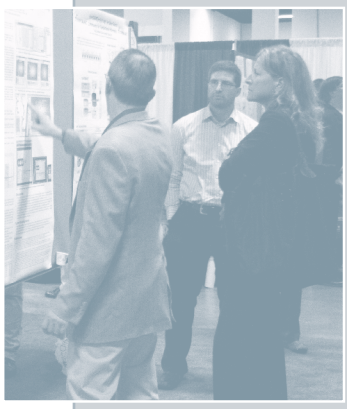
2:35 Universal Digital High Resolution Melt for Rapid Bacterial Identification in Polymicrobial Infections

Stephanie Fraley, Ph.D., Burroughs Wellcome Fund Fellow, Emergency Medicine and Infectious Disease, The Johns Hopkins School of Medicine

A key challenge in clinical diagnostics and biomarker research involves the ability to quantitatively and accurately profile heterogeneous biological samples for detection of numerous and even unexpected genotypes. We have developed Universal Digital High Resolution Melt (U-dHRM), a molecular diagnostic approach that overcomes critical limitations to accomplish rapid, high-content, broad-based detection of individual genotypes within heterogeneous samples. We apply this identify bacterial pathogens in polymicrobial infections.

3:05 Close of Quantitative Digital Detection Conference Registration for Post-Conference Short Course

Present a Poster and Save!



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To secure a poster board and inclusion in the conference materials, your abstract must be submitted, approved and your registration paid in full by May 9, 2013

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- Reception style
- Plated dinner with specific conversation focus

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HOTEL & TRAVEL INFORMATION

Hilton Boston Back Bay
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T: 617-236-1100

Room Rate: $245 s/d
Reservation Cutoff: May 19, 2014

Please visit our conference website to book your reservations online or call the hotel directly to reserve your sleeping accommodations. You will need to identify yourself as a Cambridge Healthtech Institute conference attendee to receive the discounted room rate with the host hotel. Reservations made after the cut-off date or after the group room block has been filled (whichever comes first) will be accepted on a space- and rate-availability basis. Rooms are limited, so please book early.

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Special discounts have been established with American Airlines. Please use one of the following methods:

- Call 1-800-433-1790 and use Conference code 7654AA
- Go online to www.aa.com/group and enter Conference code 7654AA in promotion discount box
- Contact our designated travel agent Rona Meizler at 1-617-559-3735 or rona.meizler@protravelinc.com.

Car Rental Discounts:
Special discount rentals have been established with Hertz for this conference. Please use one of the following methods:

- Call HERTZ, 800-654-3131 and use our Hertz Convention Number (CV): 04KL0005
- Visit www.hertz.com and use our Hertz Convention Number (CV): 04KL0005

WHY STAY AT THE HILTON BOSTON BACK BAY?

The Hilton Boston Back Bay is a **2013 TripAdvisor Certificate of Excellence Award winner**. Located only **4 miles from Logan International Airport**, in Boston's trendy Back Bay neighborhood, attendees will enjoy **complimentary wireless internet** in guest rooms and access to a **state-of-the-art fitness center** and indoor swimming pool. **Walk to restaurants, shopping, and nightlife** or visit Boston's **historic sites or Fenway Park, just minutes away** by subway.

We understand that you have many choices when making your travel arrangements. Please understand that reserving your room in the CHI room block at the conference hotel allows you to take full advantage of the conference sessions, events and networking opportunities, and ensures that our staff will be available to help should you have any issues with your accommodations.

For sponsorship and exhibit information, please contact:

Jay Mulhern
Business Development Manager
781-972-1359 | jmulhern@healthtech.com

Cambridge Healthtech Institute's

PRECISION DIAGNOSTICS SUMMIT

Hilton Back Bay, Boston MA | June 16-18, 2014

Pricing and Registration Information

SHORT COURSES

	Commercial	Academic, Government, Hospital-affiliated
One short course	$699	$399

SC1: Dinner Short Course: How to Launch a Laboratory Test: Everything You Wanted to Know but Were Afraid to Ask
~~**SC2:** Dinner Short Course: Experiment Design for Digital Technologies~~
~~**SC3:** Post Conference Short Course: IT in Laboratory Medicine~~

SUMMIT PRICING

BEST VALUE (Includes Access to **Both** Sample Prep **AND** Digital Detection Conferences, Excludes Short Courses)

Early Registration Discount until March 21, 2014	$2049	$1029
Advance Registration Discount until June 13, 2014	$2199	$1099
Registrations after June 13, 2014 and on-site	$2399	$1149

INDIVIDUAL CONFERENCE PRICING

(Includes Access to One Conference, **Either** Sample Prep **OR** Quantitative Digital Detection, Excludes Short Courses)

Early Registration Discount until March 21, 2014	$1399	$649
Advance Registration Discount until June 13, 2014	$1599	$729
Registrations after June 13, 2014 and on-site	$1799	$799

Required For Individual Conference Pricing Please select the **one** conference you will attend:

June 16-17	June 17-18
Sample Prep and Target Enrichment	Quantitative Digital Detection Technologies

CONFERENCE DISCOUNTS

Poster Discount ($50 Off): Poster abstracts are due by **May 9, 2014.** Once your registration has been fully processed, we will send an email containing a unique link allowing you to submit your poster abstract. If you do not receive your link within 5 business days, please contact jring@healthtech.com. *CHI reserves the right to publish your poster title and abstract in various marketing materials and products. **NOTE:** Special poster restrictions apply.

Alumni Discount SAVE 20%: Cambridge Healthtech Institute (CHI) appreciates your past participation at **Sample Prep and Target Enrichment** and **Quantitative Digital Detection Methods**. As a result of the great loyalty you have shown us, we are pleased to extend to you the exclusive opportunity to save an additional 20% off the registration rate.

REGISTER 3 - 4th IS FREE: Individuals must register for the same conference or conference combination and submit completed registration form together for discount to apply.

Alumni Discount and **Register 3 and 4th is Free Discount** cannot be combined

Group Discounts are Available! Special rates are available for multiple attendees from the same organization. For more information on group rates contact David Cunningham at +1-781-972-5472

If you are unable to attend but would like to purchase the Precision Diagnostics Summit CD for $750 (plus shipping), please visit PrecisionDiagnosticSummit.com. Massachusetts delivery will include sales tax.

ADDITIONAL REGISTRATION DETAILS

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

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

To view our Substitutions/ Cancellations Policy, go to http://www.healthtech.com/regdetails

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

How to Register: PrecisionDiagnosticSummit.com

reg@healthtech.com • P: 781.972.5400 or Toll-free in the U.S. 888.999.6288

Please use keycode **MDX F** when registering!

Please refer to the Registration Code below:

Cambridge Healthtech Institute
250 First Avenue, Suite 300, Needham, MA 02494
www.healthtech.com • Fax: 781-972-5425