APRIL
18-19
2012
HYATT REGENCY
NEWPORT BEACH, CA

Inaugural

INNOVATIVE SAMPLE PREP & TARGET ENRICHMENT IN CLINICAL DIAGNOSTICS

TOPICS INCLUDE:

- **Pre-Analytical Challenges in Point-of-Care Testing**
- **Sample Prep and Target Enrichment in Molecular Diagnostics for Infectious Diseases**
- **Sample Prep and Target Enrichment in Molecular Diagnostics of Cancer**
- **Pre-Analytical Issues in Mass Spectrometry Applications**
- **Sample Prep for Next Generation Sequencing**

Corporate Sponsor:

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This event is not CME-accredited

Cambridge Healthtech Institute
250 First Ave., Ste 300, Needham, MA 02494
Keycode: DX E

TUESDAY
APRIL17
6:30-8:30pm

HYATT REGENCY
NEWPORT BEACH
CALIFORNIA

DINNER SHORT COURSE*

Guidelines for Commercial Launch of Novel Diagnostics

- Medical Necessity
- Assay Validation
- Regulatory Pathway and Considerations
- Reimbursement
- Acceptance and Adoption
- Economic Impact of Pre-analytical Errors
- Cost Effectiveness of Investment in the Pre-analytical Process

Instructors:
Bill Cook, Principal, WECA

Dwight Denham, MBA, Director, Clinical Research, Health Economics & Reimbursement Affairs (CHRA), Beckman Coulter, Inc.

Additional Instructors to be Announced

**Separate Registration Required*

WEDNESDAY, APRIL 18

7:30 am Registration and Morning Coffee

8:15 Welcoming Remarks from Conference Producer

PRE-ANALYTICAL PROCESSING AND SPECIMEN QUALITY AS THE KEY TO PRECISION TESTING

8:25 Chairperson's Opening Remarks

8:30 What's in Your Sample?
Catherine A. Hammett-Stabler, Ph.D., DABCC, FABC, Professor of Department of Pathology and Laboratory Medicine, University of North Carolina
When developing a new test we typically spend a great deal of time and effort optimizing the analytical portion. We need to spend just as much time validating and optimizing the sample. All too often this critical component is neglected. This session will discuss the many issues such as collection, processing, and storage that contribute to sample characteristics and dramatically impact your results.

9:00 Pre-Analytical Challenges in Point-of-Care Testing
James H. Nichols, Ph.D., DABCC, FACB, Professor of Pathology, Tufts University School of Medicine, Medical Director, Clinical Chemistry, Baystate Health, Springfield, MA
As implementation of point-of-care testing (POCT) becomes more widespread, it is important to consider how pre-analytical factors can impact the test result, and ultimately patient care. In this presentation, we will identify important pre-analytical challenges that are present in the POCT process. We will also discuss how laboratories can develop a quality control plan to reduce the risk of errors at the point of care and how manufacturers can assist in development of these QC plans.

9:30 Pre-Analytical Variables of Specimen Processing in Molecular Diagnostics
Helen D. Fernandes, Ph.D., Director, Molecular Diagnostics, Associate Professor, Department of Pathology & Laboratory Medicine New Jersey Medical School
The expanding scope of molecular based assays in clinical diagnostics has mushroomed from detection and quantification of pathogens to next generation sequencing of exomes, genomes and targets. As the field has developed, so have the variety of specimens used and the analytical techniques employed. Specimen type, storage and handling conditions/treatments, extraction methodologies, as well as quality and quantity of nucleic acid recovered, are part of the pre-analytical variables that can affect optimal performance of the assay. Degradation of nucleic acid, particularly target RNA and excess contamination with proteins or inhibitory agents can contribute to inaccurate interpretation of test results. Since molecular diagnostic methods using nucleic acid amplification are inherently variable, minimizing the preanalytical variables surrounding sample acquisition, transport, storage and extraction would help to ascertain a more reliable and reproducible test outcome.

10:00 Sponsored Presentation *(Opportunity Available)*

10:30 Networking Coffee Break with Poster Viewing

SAMPLE PREP AND TARGET ENRICHMENT IN MOLECULAR DIAGNOSTICS FOR INFECTIOUS DISEASES

11:00 Improved Sample/Enrichment from Whole Blood for the Diagnosis of Early Lyme Disease
Mark W. Eshoo, Ph.D., Director, New Technology Development, Ibis Biosciences, Inc., a subsidiary of Abbott Molecular
Early detection and treatment of Lyme disease is crucial to prevent late sequelae and to improve long-term prognosis. However, infection is often difficult to diagnose because of the variability of clinical manifestations and the biologically delayed antibody production upon which current serologic tests are based. Direct molecular tests for early Lyme disease have largely been unsuccessful possibly due to the low levels of circulating pathogen. To address this challenge, we have developed a sensitive assay to detect *B. burgdorferi* directly from whole blood collected during the initial patient visit. This method employs a nested isothermal pre-amplification of the Borrelia DNA followed by PCR and electrospray ionization mass spectrometry. We compared our assay with 2-tiered serology with specimens from 29 patients with clinically defined early Lyme disease. Results of this study demonstrate the ability to detect *B. burgdorferi* in early Lyme disease directly from whole blood specimens prior to seroconversion.

11:30 Electrokinetic Matrix Management for Pathogen Identification and Antimicrobial Susceptibility Testing in Whole Blood
Vincent Gau, Ph.D., President, Molecular Analysis, Genefluidics
An integrated sample preparation and diagnostic system to enable the point-of-care (POC), evidence-based selection of antibiotics for treatment of acute bacterial infections is presented to include sample/reagent delivery, mixing, lysing, 37°C incubation, stringency washing and electrochemical detection in a microfluidic cartridge. The feasibility, accuracy and reproducibility of cartridge-based rapid antimicrobial susceptibility testing are demonstrated on whole blood samples spiked with *E.coli* and *Staphylococcus epidermidis*. The AST culture time inside the cartridge can be as short as 30 minutes followed by the 30-min pathogen identification assay.

12:00 pm Using Next Generation Sequencing in Novel Pathogens Detection
Jamie Platt, Ph.D., Scientific Director, Molecular Microbiology, Quest Diagnostics Nichols Institute

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

SAMPLE PREP AND TARGET ENRICHMENT IN MOLECULAR DIAGNOSTICS OF CANCER

1:55 Chairperson's Remarks

2:00 Capture of Tumor Cells with Albumin Microspheres
Louise de Grandpre, Ph.D., Senior Research Scientist, Research and Development, Iris Molecular Diagnostics
We have developed a method to capture cancer cells from liquids such as whole blood using antibody coated air-filled albumin microspheres. Overall, the process of cell capture with albumin microspheres is simple, quick and can accomplished with supplies found in any lab. Cells are incubated with antibody-coated microspheres and after centrifugation, captured cells rise to the top and unbound cells pellet at the bottom of the tube. Once cell separation is complete, the microspheres are disrupted, leaving an enhanced suspension of the target cells. The methodology of the invention will be discussed and results of cell capture in buffered solutions and whole blood will be presented.

2:30 Fluid Phase of Solid Tumors: Using CTCs as a Real Time Fluid Biopsy
Peter Kuhn, Ph.D., Associate Professor, Scripps Physics Oncology Center, The Scripps Research Institute
The fluid phase of solid tumors is a critical third microenvironment in the development and progression of carcinomas. Cells originating from primary or secondary sites travel through the blood circulatory system to either get cleared out or initiate new tumor growth. Translational research efforts are attempting to identify the various subtypes of circulating tumor cells (CTCs),

their origins, their destinations and their impact on the disease. Understanding and characterizing CTCs is a first step towards utilizing them as both biopsy material and directly as a biomarker. It requires approaches of subtyping CTCs and characterizing them at the single cell level. While new technologies are being developed constantly, even early approaches show uses of certain CTCs as a biomarker. New correlations can be established between CTCs and other fluid phase materials.

3:00 Tumor Cell DNA Extraction from Urine Samples for Prostate Cancer Diagnostics
Heather R. Sanders, Ph.D., Principal Scientist, Oncology R&D, Quest Diagnostics Nichols Institute
Biomarker detection in urine has been examined as a non-invasive tool in prostate cancer diagnostics. We aimed to define the fraction of urine (cells/sediment, cell-free/microvesicle-associated, or whole) that is most enriched for prostate-derived RNA. Cell-capturing filters and low MW filtration columns were employed to separate cells from urine and concentrate cell-free and whole urine for RNA extraction. Prostate biomarker transcripts were measured by qRT-PCR. It was concluded that the cell-free fraction of urine contained the highest level of prostate-derived RNA.

3:30 Networking Refreshment Break with Poster Viewing

NUCLEIC ACID EXTRACTION AND SEQUENCING

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4:00 Integrated Sample Preparation Solutions for RNA and DNA Sequencing Applications
Steven Kain, Ph.D., Director, Product Marketing, NuGEN Technologies
Next Generation Sequencing (NGS) technology enables the sequencing of genomes and transcriptomes in a matter of hours-to-days. NuGEN's RNA-Seq and library technologies extends the power and flexibility of sequencing to sample preparation directly from total RNA, with input levels as little as 500 pg, or for direct construction of NGS libraries with 1.0 ng of DNA. RNA-Seq solutions that preserve strand information are also available in a complete workflow integrated with low input library construction.

4:30 Target Enrichment Strategies for Next Generation Sequencing Technologies for the Study of Human Diseases: The Example of Hypertrophic Cardiomyopathies
Francesco Salvatore, Professor and Scientific Coordinator of CEINGE
Valeria D'Argenio, M.D., Researcher, Clinical Biochemistry and Molecular Biology, University Federico II of Naples and CEINGE
Advances in genomic technologies have markedly accelerated the search for genetic causes of human diseases and answered previously difficult-to-answer questions regarding disease mechanisms. In particular, NGS technologies have emerged as a powerful tool for diagnostic purposes. Different strategies have been tested to overcome current PCR limitations and efficiently enrich different targets to be simultaneously analyzed in large group of patients. Here, we show some examples with their possible applications, in particular in the field of molecular diagnosis of cardiomyopathies.

5:10 DNA Extraction Technology Review: The Good, the Bad, the Ugly
Crystal R. Icenhour, Ph.D., President & CSO, Phthisis Diagnostics
Why does extracting DNA have to be so complicated – or does it? Explore good, bad, and ugly DNA extraction technologies from clinical samples, including complex sample types such as stool and sputum. Each technology's pros and cons will be presented, providing guidance to clinical laboratories in selecting the technology that best suits their sample, budget, and workflow.

5:40 Welcome Reception

6:40 Close of Day 1

THURSDAY, APRIL 19

8:00 am Breakout Discussions

Sample Prep for Pathogen Detection
Cicely Washington, Ph.D., Technical Leader, Ibis Biosciences, Inc., a subsidiary of Abbott Molecular

Sample Prep in Mass Spectrometry
Randall W. Nelson, Ph.D., Director, The Molecular Biomarkers Laboratory, The Biodesign Institute, Arizona State University

Nucleic Acid Extraction
Martin Siaw, Ph.D., Associate Scientific Director (R&D), Advanced Sequencing, Quest Diagnostics Nichols Institute

PRE-ANALYTICAL ISSUES IN MASS SPECTROMETRY APPLICATIONS

8:55 Chairperson's Remarks

9:00 Why Are Non-Targeted Metabolomics and Proteomics Biased?
Uwe Christians, M.D., Ph.D., Professor, Department of Anesthesiology, University of Colorado Denver; Professor of Experimental and Clinical Pharmacology and Toxicology, Institut für Pharmakologie, Medizinische Hochschule Hannover.
Current technologies capture only a part of the metabolome and/or proteome and therefore produce inherently biased results. This brings up the question of whether or not screening for changes in known metabolic and signaling pathways using a set of targeted validated, quantitative multiplexing assays would be a more robust and reliable approach.

9:30 SISCAPA: Combining Immunoaffinity and Mass Spectrometry in a Universal Platform for Sensitive, Specific Measurement of Protein Biomarkers
N. Leigh Anderson, Ph.D., Founder and CEO of the Plasma Proteome Institute
Translation of protein biomarker candidates into clinical diagnostics depends on efficient generation of reliable specific assays. Mass spectrometry of proteotypic peptides provides major advantages over classical immunoassays in terms of specificity, internal standardization and multiplexing, while the enrichment of selected signature peptides by anti-peptide antibodies (SISCAPA) provides the necessary sensitivity and sample throughput. Relevant diagnostic assay examples will be discussed

10:00 Sponsored Presentation *(Opportunity Available)*

10:30 Networking Coffee Break with Poster Viewing

11:00 Quantitative Proteomics Using Peptide Immunoaffinity Enrichment Coupled with Mass Spectrometry
Jeff Whiteaker, Ph.D., Director of Proteomics, Paulovich Laboratory, Fred Hutchinson Cancer Research Center
The use of quantitative targeted mass spectrometry for protein assays has grown tremendously in recent years. The largest limitation to more widespread use is the limited sensitivity in complex matrices. We have implemented a technique using immunoaffinity enrichment of peptides with quantification by mass spectrometry to make assays for a wide range of proteins. The assays have many advantages including improved sensitivity, absolute specificity, relatively less time and money required for development, high levels of multiplexing, and good performance characteristics. This presentation will provide an overview of the development and implementation of these assays for biomarker verification.

11:30 Hemoglobin Depletion Plus Protein Enrichment from Dried Blood Cards
Matthew Kuruc, President, Managment, ProFACT Proteomics
Dried blood cards have been extensively used to preserve, ship and analyze DNA. The same apparent advantages – storage and low-cost shipping, are now being considered for sample preparation of whole blood for proteomic biomarker analyses. However, when samples are prepared from dried blood spots, hemoglobin represents the highest abundance protein. Interferences from hemoglobin are often associated with common protein analytes in serum. Thus, a simple method to efficiently deplete hemoglobin and enrich the underlying protein content has been developed. Using a commercially available silica-based polyelectrolyte matrix, HemoVoid™, blood proteins are concentrated on the surface matrix, and the hemoglobin remains unbound and voids in the flow-through fraction >98%.

12:00 pm Characterization of Protein Complexes Using Novel Integrated Proteomic Strategies
Randall W. Nelson, Ph.D., Director, The Molecular Biomarkers Laboratory, The Biodesign Institute, Arizona State University
Biomarker development requires the implementation of progressively standardized and increasingly rigorous analytical technologies. Regarding proteins, such technologies must be; 1) Highly accurate, sensitive and reproducible, 2) Responsive to large concentration differences and disease-specific qualitative variations, and, 3) Employed at rates sufficient to economically accommodate large clinical sample sets. Here, we present one such technology, mass spectrometric immunoassay (MSIA) and illustrate its use in the development of multi-analyte biosignatures of type 2 diabetes and related cardiovascular diseases.

12:30 Close of Conference

SUPPORTER & EXHIBITOR INFORMATION

CHI can customize a support or exhibit package to meet your company's needs and budget. We offer comprehensive packages that give your company exposure before, during and after the event. Packages may include a talk, exhibit space, conference registrations, branding, use of event mailing lists, and more.

Presentations:
CHI has developed several Educational Grant options for your company to participate and contribute to the conference. Companies who provide an educational grant will be promoted for providing the educational support and will have the option of a podium presentation as part of the conference agenda. Whether your goal is to showcase a new product in our exhibit hall, or to present your latest technology or solution during a conference session, your educational support will strategically place you in front of hard to reach, high-level decision makers.

User Group Meeting:
Take advantage of the prestigious audience in attendance to conduct market research or gather feedback on your new product or service on-site at Future Diagnostics. CHI will provide a meeting room set for 50-75 delegates, equipped with AV including an LCD screen. This presents a rare opportunity to meet with a large, targeted group of end-users, and walk away from the conference with qualified leads and information!

Pre-Conference Workshops:
Includes a 15-minute or 30-minute podium presentation during the pre-conference workshop.

CHI's Live Web Symposia Series:
CHI's database includes nearly a million individuals in life sciences. The database can be a very powerful lead generation tool throughout the year. One way of connecting you with key prospects is with our new web symposium series, which offers potential supporters the opportunity to interface with the community and demonstrate your technical expertise.

Exhibit Hall:
Speak face-to-face with prospective clients and showcase your latest product, service, or solution. Don't miss this opportunity to have a presence at this industry-leading event. Reserve your space today to ensure a prime location!

EDUCATIONAL SUPPORT

We wish to thank the following for their educational grant in support of this activity:

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about the various ways your company can participate as an active Supporter or Exhibitor, please contact:

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Manager, Business Development
781-972-5431 | jvacca@healthtech.com

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HOTEL & TRAVEL INFORMATION

CONFERENCE VENUE FOR FUTURE DIAGNOSTICS:

University of California
UCI Student Center, Bldg #113
Pacific Ballroom C • Irvine, CA 92697
Located at the Corner of West Peltason Drive & Pereira Drive

HOST HOTEL & CONFERENCE VENUE FOR SAMPLE PREP AND TARGET ENRICHMENT:

Hyatt Regency Newport Beach
1107 Jamboree Road • Newport Beach, CA 92660
Phone: 949-729-1234
Discounted Room Rate: $144 s/d
Discounted Cut-off Date: March 21, 2012

Please 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.
We understand that you have many choices when making your travel arrangements, and may ultimately decide to stay at another hotel. Please understand that reserving your room in the CHI room block 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.

LOCAL TRANSPORTATION:

The Hyatt hotel offers a complimentary Shuttle to/from Orange County/John Wayne Airport.
Shuttle service will be provided by CHI to University of California, Irvine from the hotel on Monday and Tuesday.

Driving & Parking Directions:
Park in the Student Center Parking Structure (lot). It is located directly across Pereira Drive from the main entrance to the Student Center. Day permits can be purchased for $10.00. Please be aware that the lot fills up early.

Flight Discounts:
Special discounts have been established with American Airlines for this conference. To take advantage of the discount, please use one of the following methods:

- Call 1-800-433-1790 use Conference Code 1942AY.
- Go online at www.aa.com/group and enter Conference Code 1942AY in promotion discount box.
- Contact our designated travel agents at 1-877-559-5549 or chi@protravelinc.com

Car Rental Discounts:
Special discount rentals have been established with Hertz for this conference. To take advantage of the discount, please go to www.hertz.com, or call Hertz directly at 1-800-654-3131, and use our Hertz Convention Number (CV): 04KL0003.

How to Register: healthtech.com/DFX or healthtech.com/SMP

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

Please use keycode **DX E** when registering!

Second Annual
FUTURE DIAGNOSTICS
APRIL 16-17, 2012
UNIVERSITY OF CALIFORNIA, IRVINE

Inaugural
INNOVATIVE SAMPLE PREP & TARGET ENRICHMENT IN CLINICAL DIAGNOSTICS
APRIL 18-19, 2012
HYATT REGENCY NEWPORT BEACH, CA

Pricing and Registration Information

SHORT COURSE PRICING (SUNDAY, APRIL 15 • 1-4PM AND TUESDAY, APRIL 17 6:30-8:30PM)

	Commercial	Academic, Government, Hospital-affiliated
One Short Course	$695	$395
Two Short Courses	$995	$695

Sunday, April 15
Microfluidics Technology and Market Trends

Tuesday, April 17
Guidelines for Commercial Launch of Novel Diagnostics

COMBINED CONFERENCE PACKAGE (APRIL 16 – 19) BEST VALUE

Includes access to both *Future Diagnostics* and *Sample Prep and Target Enrichment* Conferences	Commercial	Academic, Government, Hospital-affiliated
Advance Registration Deadline March 9, 2012	$2125	$995
Registrations after March 9 and on-site	$2325	$1045

SINGLE CONFERENCE PACKAGE

Includes access to ONE conference	Commercial	Academic, Government, Hospital-affiliated
Advance Registration Deadline March 9, 2012	$1545	$775
Registrations after March 9 and on-site	$1745	$875

April 16-17
Future Diagnostics

April 18-19
Sample Prep and Target Enrichment

CONFERENCE DISCOUNTS

Poster Submission-Discount ($50 Off)
Poster abstracts are due by **March 21, 2012**. 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.

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

Additional discounts are available for multiple attendees from the same organization. For more information on group rates contact David Cunningham at +1-781-972-5472

GENERAL INFORMATION

PURPOSE STATEMENT
A number of breakthrough technologies are being incorporated into novel diagnostics to detect a range of molecular and protein biomarkers including PCR, microarrays, sequencing, proteomics, methylation, and mutation detection. There is a need to bridge basic research and translational research. This meeting will highlight the next generation of diagnostic platforms that encompass the latest trends in microfluidics, point-of-care technologies, *in vivo* sensing, and consumer-driven products. A panel of experts will focus on translation to the medical community and the key to success in implementation.

TARGET AUDIENCE
Physicians, Pathologists, Oncologists, M.D.s, Ph.D.s, Scientists, Directors, CEOs and Vice Presidents in the areas of molecular pathology, centralized diagnostics, point-of-care diagnostics, biomedical sciences, molecular diagnostics, oncology and genetics, infectious disease, sequencing, engineering, and business development.

OBJECTIVES
At the conclusion of this activity, participants should be able to:

- Apply novel technologies in daily patient diagnosis
- Implement new diagnostics technologies into the clinic
- Recognize government standards for diagnostic testing

ACCREDITATION STATEMENT
This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of the University of California, Irvine School of Medicine and Cambridge Healthtech Institute. The University of California, Irvine School of Medicine is accredited by the ACCME to provide continuing medical education for physicians.

DESIGNATION STATEMENT
The University of California, Irvine School of Medicine designates this live activity for a maximum of 10.5 *AMA PRA Category 1 Credit(s)™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

GENERAL DISCLOSURE STATEMENT
It is the policy of the University of California, Irvine School of Medicine and the University of California CME Consortium to ensure balance, independence, objectivity and scientific rigor in all CME activities. Full disclosure of conflicts and conflict resolutions will be made prior to the activity in writing via handout materials, insert, or syllabus.

AB 1195 COMPLIANCE STATEMENT
This activity is in compliance with California Assembly Bill 1195, which requires continuing medical education activities with patient care components to include curriculum in the subjects of cultural and linguistic competency. For specific information regarding Bill 1195 and definitions of cultural and linguistic competency, please visit the CME website at www.cme.uci.edu.

ADA STATEMENT
In compliance with the Americans With Disabilities Act, we will make every reasonable effort to accommodate your needs. For any special requests, please call Mari Alvarez at 781 972 5474 on or before April 16, 2012.

If you are unable to attend but would like to purchase the Future Diagnostics or Sample Prep CD for $350 (plus shipping), please visit healthtech.com/DFX or healthtech.com/SMP. Massachusetts delivery will include sales tax. (non-accredited)

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.