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:

Healthtech.com/SMP
**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*
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 DNA. 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

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 extend 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 CEING
Valeria D’Argenio, M.D., Researcher, Clinical Biochemistry and Molecular Biology, University Federico II of Naples and CEING

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 groups 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

THURSDAY, APRIL 19

8:00 am Breakout Discussions

Sample Prep for Pathogen Detection
Cicely Washington, Ph.D., Technical Leader, Iiba 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 Sizel, Ph.D., Associate Scientific Director (R&D), Advanced Sequencing, Quest Diagnostics Nichols Institute

8:55 Chairperson’s Remarks

9:00 Why Are Non-Targeted Metabolomics and Proteomics Biased?
Uve 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 Immunofinity 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 and robust means 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 Immunofinity 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 immunofinity 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 Kuuc, President, Management, 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 solution 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
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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 Peltason 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.
**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, genomics, 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, pharmacogenomics, 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 ACME 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 Credits™. 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 of conflicts and conflicts resolutions will be made prior to the activity, in writing via handout materials, insert, or syllabus.

**AB 195 COMPLIANCE STATEMENT**
This activity is in compliance with California Assembly Bill 1955, which requires continuing medical education activities with patient care components to include curriculum in the areas of cultural and linguistic competency. For specific information regarding Bill 1955 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.

Please use keycode DX E when registering!