Second Annual

SAMPLE PREP & TARGET ENRICHMENT IN MOLECULAR DIAGNOSTICS

April 10-11, 2013 • Hilton Boston Back Bay Hotel • Boston, MA

TOPICS INCLUDE:

- **Tissue as a Sample for Nucleic Acid Testing and Omics Research**
- **Nucleic Acid Extraction and Next Gen Sequencing**
- **Nanotechnology for IVD Sample Prep**
- **Sample Prep Considerations in Pathogen Detection**

DINNER SHORT COURSE:

Guidelines for Commercial Launch of Novel Diagnostics

Instructor:
Jorge Leon, Ph.D., President, Leomics Associates, Inc.

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Second Annual

SAMPLE PREP & TARGET ENRICHMENT IN MOLECULAR DIAGNOSTICS

WEDNESDAY, APRIL 10

7:15 AM Registration and Morning Coffee

7:45-7:55 am Welcome Remarks from Conference Producer

7:55-8:00 Chairperson's Opening Remarks

» 8:00-8:30 KEYNOTE PRESENTATION:
The Sample – Often Forgotten, but Critical to The Result

Catherine A. Hammett-Stabler, Ph.D., DABCC, FACB, Professor of Pathology and Laboratory Medicine; Director, Core Laboratory McLendon Clinical Laboratories

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.

Tissue as a Sample for Nucleic Acid Testing and Omics Research

8:30-9:00 Tissue Samples for Genomic Analysis: RNA Sequence analysis of tissue samples preserved in PAXgene Tissue Fixative and RNAStable Dry Storage

Kristin Ardlie, Ph.D., Director, Biological Samples Platform, The Broad Institute

The Genotype Tissue Expression Project (GTEx) project aims to study human gene expression and regulation in multiple tissues to provide insight into the mechanisms of gene regulation. The collection of tissues (~30 per donor) and the preservation of RNA presents a unique challenge for the project, since all tissues are obtained from recently deceased donors. The PAXgene® Tissue System was implemented to allow for greater flexibility at both the collection sites and for shipping to processing and analysis centers. Data on histology, RNA quality, and RNA sequence data analysis from these samples will be presented.

9:00-9:30 Current National Guidelines for Creating High Quality Tissue Biospecimens

James Robb, M.D., FCAP SAIC-Frederick Consulting Pathologist to the National Cancer Institute, NIH, HHS

Evidence-based national guidelines for creating high quality tissue biospecimens for clinically-applicable genomic testing for patient treatment, such as the CAP-ASCO breast cancer biomarker guidelines, have recently become available. Included topics are: annotating, collecting, transporting, processing, testing, storing, distributing, and post-distribution return of tissue biospecimens. Key points: Cold Ischemia Time <60 min (<20 min optimal) and Total Time In Formalin (6-72 hours). Areas of ongoing discussion and field experience from high quality tissue collection research programs will be discussed.

9:30-10:30 Comparison of Methods for Preserving Morphological, Molecular, and Protein Biomarkers in Tissue

Sponsored by QIAGEN

Lynne Rainen, Ph.D., Scientific Director, PreAnalytiX GmbH

Current fixation methods used in traditional histology to prepare tissue specimens for morphological analysis are of limited use for molecular analysis. Formalin fixatives crosslink biomolecules, destroying or modifying nucleic acids and proteins during the fixation process. In contrast, snap-freezing in liquid nitrogen preserves biomolecules but ultimately leads to disruption of morphological structures. This workshop will compare results of molecular, histological, and protein analyses obtained with formalin fixation and snap-freezing, to a new non-formalin fixative, the PAXgene® Tissue System.

10:00-11:30 Coffee Break with Exhibit and Poster Viewing

10:30-11:00 First Do No Harm: Innovative Tissue Print Technologies for Collecting High Quality Snap-Frozen Samples for Research without Compromising the Diagnostic Specimen

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. 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.

11:00-11:30 A Quantitative Proteomic Analysis of FFPE Patient Melanoma

Nathan L Avaritt Department of Biochemistry, University of Arkansas for Medical Sciences

Molecular pathways regulating melanoma initiation and progression are potential targets of therapeutic development for this aggressive cancer. We present the most comprehensive analysis of formalin-fixed paraffin-embedded human melanoma tissues using quantitative proteomics. Our results reveal that molecular pathways involved with tumor cell proliferation, motility, and apoptosis are mis-regulated in melanoma. These data provide the most comprehensive proteome resource on patient melanoma and reveal insight into the molecular mechanisms driving melanoma progression.

11:30-12:00 pm Sample Prep Comparison for NGS Profiling of FFPE and Fresh Frozen Tumor Samples

Brandon Young, Director of the Genomics and Cell-Based Screening Cores of Scripps Florida

Archival samples preserved in FFPE present a difficult challenge due to sample degradation. Due to the nature of Next Generation Sequencing that relies on data generated from short reads the degradation is no longer the factor it once was. Utilizing Nugen protocols we can now perform NGS experiments on FFPE and Fresh Frozen samples. It is now possible to directly compare retrospective

tumor samples with new samples in a continued effort to advance translational genomics research on prospective patient samples.

12:00 -12:15 Rationalizing Sample Prep with Adaptive Focused Acoustics (AFA): Improved FFPE Nucleic Acid Extraction for NGS

Sponsored by Covaris the pre-analytical advantage

William M. Skea, Ph.D., Scientist, Covaris, Inc.

AFA technology offers a versatile solution to simplify Sample Preparation workflows and improve bioanalytical assay performance. One example is extracting nucleic acids from FFPE tissues; their growing use in genomics and trancriptomics studies requires high quality starting material and a seamless integration with Next Generation Sequencing.

12:15-12:30 Exploring Applications of High Pressure in Biological Sample Preparation

Sponsored by PBI Pressure BioSciences Inc.

Alexander Lazarev, Ph.D., Vice President, Research & Development, Pressure BioSciences, Inc.

Hydrostatic pressure is a significant thermodynamic parameter as importantas temperature. We present several examples of high hydrostatic pressure and pressure cycling technology (PCT) used to facilitate efficient and reproducible extraction of proteins, nucleic acids and lipids from complex biological matrices for -omics studies and targeted analysis.

12:30-1:55 Lunch on Your Own

1:55-2:00 Chairperson's Remarks

Nucleic Acid Extraction and Sequencing

2:00-2:30 Nucleic Acid Extraction and Sequencing Sample Prep for Next-Generation Sequencing: The Story of Two Approaches

Jamie Platt, Ph.D., Scientific Director, Advanced Sequencing, Quest Diagnostics Nichols Institute

2:30-3:00 Sample Prep Consideration for Validation of NGS-Based Clinical Tests

Corey Braastad, Ph.D., Scientific Director, Athena Diagnostics

3:00-3:30 Issues Concerning Extraction Efficiency, Methods, and Direct dPCR

Ross Haynes, Biological Science Technician, Biochemical Science Division, National Institute of Standards and Technology

Extraction of DNA from a sample is necessary in many applications, but leaves only a fraction of the total DNA for analysis. Liquid extraction methods attempt to maintain the entire DNA sample by avoiding washing and precipitation steps. Direct PCR methods bypass extraction entirely, theoretically allowing the analysis of the entire sample, but must overcome PCR inhibitors. Digital PCR has been shown to be less sensitive than qPCR to PCR inhibitors, but only because right shift of the amplification curve does not affect the result in digital PCR. NIST's experience with direct digital PCR will be discussed.

3:30-4:00 Refreshment Break with Exhibit and Poster Viewing

4:00-4:30 Selective Enrichment of Mitochondrial DNA

Eileen Dimalanta, Ph.D., Group Leader, Applications & Product Development, New England Biolabs

While many mitochondrial DNA (mtDNA) mutations are benign, some are associated with deficiencies in mitochondrial function and result in a substantial proportion of mitochondrial disorders in children and adults. Current methods of mtDNA mutation detection rely on long range PCR or hybridization based capture followed by Next-Gen sequencing. However, homologous well-characterized mtDNA sequences in the nuclear genome (NUMTs) may also be amplified, complicating the analysis of low-level heteroplastic abnormalities. To address this problem, we have developed a unique method for the separation of human genomic DNA from mtDNA. This simple methodology can be used to analyze low-level mtDNA mutations from a variety of clinical samples in a cost-effective manner utilizing established Next-Gen sequencing platforms, as well as newer single molecule sequencing technologies.

4:30-5:00 Panel Discussion: Nucleic Acid Sample Prep Considerations for Validation of Clinical Tests

- Sample prep points to consider for validation of digital PCR
- Issues specific to validation of amplicon based NGS tests
- Considerations for validation of capture-based of NGS tests
- Validation approaches in light of current NGS guidelines

Moderator: Jamie Platt, Ph.D., Scientific Director, Advanced Sequencing, Quest Diagnostics Nichols Institute

5:10-6:00 Welcome Reception in the Exhibit Hall with Poster Viewing

6:00 Close of the day

6:00-6:15 Short Course Registration

6:15-9:00 Dinner Short Course: Guidelines for Commercial Launch of Novel Diagnostics*

Jorge Leon, Ph.D., President, Leomics Associates, Inc.

David Parker, Ph.D., Vice President, Boston Healthcare

This short course is focused on development of molecular diagnostics as they make their way from identification of a medical need through to commercial launch. The course will emphasize identification of critical hurdles that when addressed early, can materially accelerate progress. Vital areas to be addressed include disease management, validation, reimbursement strategies including provider engagement, regulatory pathway decisions and education of the medical community. Examples and case studies of diagnostic companies will be shared to illustrate a real world roadmap including:

- Disease Management
- Assay Validation
- Regulatory Pathways and Considerations
- Reimbursement
- Acceptance and Adoption

**Separate registration required*

THURSDAY, APRIL 11

8:00-8:55am Breakout Discussions and Morning Coffee

Nanotechnology for IVD Sample Prep

8:55-9:00 Chairperson's Remarks

9:00-9:30 Quantitative Nanomechanical Diagnostics –Direct Label Free Noncoding RNA Detection from Serum

Martin Hegner, Ph.D., Professor, Centre for Research on Adaptive Nanostructures and Nanodevices, Trinity College Dublin, Ireland

Ultra sensitive nanomechanical sensing platforms for label-free qualitative and quantitative bio-analytical measurements will change the way we perform diagnostics. We demonstrate that cantilever array sensors are capable to directly track the pharmacokinetics of therapeutic siRNA molecules in tissues and the early detection of miRNA biomarker molecules, which indicate organ pathology induced by adverse drug effects measured from blood serum.

9:30-10:00 Nanofiber-Based Sample Preparation for Diagnostic Devices

Antje Baeumner, Ph.D., Professor, Biological and Environmental Engineering, Cornell University

We investigate the use of electrospun nanofibers as highly effective material for the selective enrichment of analytes from samples. We have demonstrated the reliable fabrication of nanofiber mats embedded in microfluidic channels. We have also demonstrated selective capture and release of nanoparticles and bacterial cells. We have further shown that nanofiber mats can function as effective passive microfluidic mixer. Applications for complex microTAS and simple Point-of-Care devices are targeted.

10:00-10:30 Sponsored Presentations
(Opportunities Available)

10:30-11:00 Coffee Break with Exhibit and Poster Viewing

Sample Prep Considerations in Pathogen Detection

11:00-11:30 Sample Preparation for Molecular Diagnostics in a CLIA Certified Clinical Laboratory: Nucleic Acid Extraction and Target Enrichment for Pathogen Testing by Next-Generation Sequencing

Martin Siaw, Ph.D., Staff Scientist and Associate Director, Advanced Sequencing Core, Advanced Sequencing, Quest Diagnostics Nichols Institute

Sample preparation is an important component of any molecular testing that is being done in clinical laboratories. Improvements in nucleic acid extraction and target enrichment are considered to be critical to the workflow of diagnostic tests involving the use of NGS My presentation will focus on the requirements for CLIA certified clinical laboratories, the various patient specimens to be tested, the methods currently in use for nucleic acid extraction and target enrichment and the commercial kits available in the market. The focus will be on pathogen testing by NGS.

11:30-12:00 pm Direct Selection of Microbiome DNA from Human DNA

Erbay Yigit, Scientist, Applications and Product Development, New England Biolabs

Microbiome is an integral part of human life, and perturbations in microbiome-host balance can lead to human disease. Recently, next generation sequencing technologies have enabled the analysis of the human microbiome. However, the analysis of a microbiome can be both monetarily and computationally expensive, due to the contamination of host DNA in a sample, requiring deep sequencing to be able to detect some microbial species. To overcome this problem, we developed a microbiome enrichment kit that reduces host DNA contamination nearly 50-fold, corresponding to ~90-95% microbiome DNA in the enriched fraction. This simple methodology can be used to analyze entire microbiomes in a cost-effective manner utilizing established next generation sequencing platforms, as well as newer single molecule sequencing technologies.

12:00 Close of Conference

PAST PARTICIPANTS

454 Sequencing - Staff Scientist
AB Sciex Molecular Devices - Sr Marketing Mgr
Abbott Labs
Affymetrix Inc - VP Market Dev Asia
Agilent Technologies - LC MS Tech Specialist
Agilent Technologies - Market & Bus Dev Mgr
Aichi Cancer Ctr Research Institute - Chief
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Applied Biosystems - Exec Dir
Applied Biosystems - Managing Partner
Applied Biosystems - VP
Arizona State Univ - Research Prof
Asterand plc - Dir Molecular Biology & Sr Scientist
Australian Natl Univ - Tech Specialist
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BBI Diagnostics - East Coast Sales Mgr
BBI Diagnostics - Project Scientist
BD - VP Product Lifecycle Mgmt
BD BioSciences - Project Engineer
BD BioSciences - Scientist
BD Diagnostics - Sr Scientist
BD Technologies - Leader
BD UK Ltd - VP GM CLS Europe
Beecher Instruments - CSO
Bio Rad Labs - Grp Mgr
Bio Rad Labs - Sr Product Mgr
Biocartis NV
BioCision LLC - VP Scientific Affairs
BioGenex Labs Inc - Project Mgr
bioMerieux - Mgr
Biotechnology Application Ctr - VP Global Marketing & Sales
BioTrove Inc / Life Technologies - Dir Strategic Relationships
Boston Univ School of Medicine - Research Affiliate
Brigham & Womens Hospital - Asst Prof
California Institute of Technology - Graduate Student
Caliper Life Sciences - Account Mgr
Caliper Life Sciences - Applications Mgr
Carnegie Institution Of Washington - Research Fellow
Catholic Univ of Korea - Prof
CEINGE Advanced Biotechnology - Researcher
Cepheid - Sr Systems Integraiton Engineer
Clarient Inc - Product Dev Mgr
Clinical Data Inc - Dir
Cogenics - Tech Support Mgr
Comsol Inc - Marketing Asst
Comsol Inc - VP
Corning Life Sciences - New Products Mgr
Corning Life Sciences - Sr Marketing & Sales Analyst
Cortex Biochem Inc - CSO & VP R&D
Covaris Inc - President & CEO
CDC - Research Microbiologist
Cybio US - Sr Product Mgr
Dana Farber Cancer Institute - Bioinformatics Analyst
DNA Genotek Inc - Product Mgr
Duke Univ - Assoc Prof
Dynal Biotech AS - Product Mgr
Dynal Biotech AS - Sr Scientist
Eastman Chemical Co - Sr Chemist
Edge Bio - Sr Scientist
Eksigent Technologies LLC - Dir Global Publications
EMD Biosciences Inc - Product Mgr
Millipore Corp - Grp Product Mgr
Millipore Corp - R&D Mgr
Millipore Corp - Research Scientist
Eppendorf AG - Mgr
Eureka Genomics Corp - Scientist
EVOTEC Technologies - Sr Scientist
EXACT Sciences Corp - Sr VP R&D
Expression Analysis Inc - President & CEO
Expression Pathology Inc - CoFounder & CSO
Festo Corp - MedLab Industry Specialist
Fluid Mgmt Systems Inc - President
Fred Hutchinson Cancer Research Ctr - Dir of Proteomics Lab
GE Healthcare - Application Mgr
GE Healthcare - Product Mgr
GeneFluidics - President Molecular Analysis
GenExprex Corp - Managing Dir
Genome Institute of Singapore - Grp Leader
GenVault Corp - VP Biosciences
GlaxoSmithKline - Sr VP R&D
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Iris Molecular Diagnostics - Sr Research Scientist
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Matritech Inc - VP Product Dev
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NuGenesis Technologies Corp - Global Acct Executive
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ParAllele BioScience - Dir Genotyping & Sequencing
Partek Inc - Marketing
Pathogenica - VP Regulatory Affairs
PerkinElmer Life Sciences
Pfizer Global R&D - Research Scientist
Pfizer Global R&D - Sr Assoc Scientist
Phthisis Diagnostics - President & Dir Research
Pierce Biotechnology - Founder & Managing Dir
Plasma Proteome Institute - Founder & CEO
Proteome Systems Inc - Sr Research Scientist
QBIOgene - VP Sales & Marketing
Qiagen - CEO & President
Qiagen - VP R&D
Quest Diagnostics Nichols Institute - Principal Scientist
Quest Diagnostics Nichols Institute - Scientific Dir
Quest Diagnostics Nichols Institute - Staff Scientist
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Roger Williams Medical Ctr - Research Asst
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Thermo Fisher Scientific Inc - Product Mgr
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TTP LabTech Ltd - Sales Mgr
UMDNJ - Assoc Prof & Program Dir
Unilever R&D - SEAC Toxicology Unit
Univ of Auckland - Marsden Fund Research Fellow
Univ of Bern Inselspital - Nephrology & Hypertension
Univ of Chicago - Asst Prof
Univ of Cincinnati - Regional Sales Mgr
Univ of Colorado Denver - Prof
Univ of Connecticut Farmington - Prof
Univ of Edinburgh - Microarray Technologist
Univ of Houston - Research Assoc Prof
Univ of Louisville - Prof
Univ of Newcastle Upon Tyne - Sr Research Assoc
Univ of North Carolina Chapel Hill - Prof
Univ of Oklahoma Norman - George Lynn Cross Research Prof
Univ of Pennsylvania - Research Project Mgr
Univ of Tennessee Knoxville - Asst Prof
Univ Of Vermont - Lab Tech III
Univ of Wisconsin Madison - Asst Scientist Biochemistry
V&P Scientific Inc - Dir R&D
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Whatman Inc / GE - Dir Genomics & Proteomics Bus Dev
Whatman Inc / GE - Field Applications Scientist
Wistar Institute - Caspar Wistar Prof & Dir

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HOTEL & TRAVEL INFORMATION

Conference Venue & Hotel:
Hilton Boston Back Bay
40 Dalton St.
Boston, MA 02115
T: 617-236-1100
Discounted Room Rate: $239 s/d
Discounted Reservation Cutoff: March 13, 2013

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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.

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Guidelines for Commercial Launch of Novel Diagnostics	Digital PCR: A Technology Primer

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If you are unable to attend but would like to purchase the Sample Prep and Target Enrichment in Molecular Diagnostics CD for $350 (plus shipping), please visit Healthtech.com/SMP.com. Massachusetts delivery will include sales tax.

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