MASS SPECTROMETRY in Clinical Diagnostics

August 23-25, 2011
The Ritz Carlton • Washington D.C.

Register by July 29 and Save up to $200!

KEYNOTE SPEAKER:

Daniel W. Chan, Ph.D., Professor and Director, Center for Biomarker Discovery and Translation, and Clinical Chemistry Division, Johns Hopkins University

DINNER SHORT COURSE:

Mass Spec Methods for the Clinical Lab

PLENARY DISCUSSION:

Changing Regulation of LDTs

Franklin R. Cockerill, III, M.D., Mayo Medical Laboratories and Mayo Collaborative Services, Inc.

Alberto Gutierrez, Ph.D., Office of in Vitro Diagnostic Device Evaluation and Safety, Food & Drug Administration

MULTI-STAKEHOLDER PLENARY PANEL:

Future of Reimbursement for Molecular Diagnostics

Moderator: Thomas A. Gustafson, Ph.D., Arnold & Porter LLP

Panelists:
Ann-Marie Lynch, Advanced Medical Technology Association (AdvaMed)

David Mongillo, M.P.H., M.S.M., American Clinical Laboratory Association

Marc Hartstein, Centers for Medicare and Medicaid Services (tentative)

NextGenerationDx.com

Part of:
Third Annual
Next Generation Dx Summit
Moving Assays to the Clinic

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FOR MORE INFORMATION, PLEASE CONTACT:

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jvacca@healthtech.com

HOTEL & TRAVEL INFORMATION

Conference Venue and Hotel:

The Ritz-Carlton, Washington, DC
1150 22nd Street, NW
Washington, DC 20037
Tel: 202-835-0500
Fax: 202-835-1588

Room Rate: $235 s/d
Reservation Cutoff: July 18, 2011
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Next Generation Dx Summit

Moving Assays to the Clinic

ABOUT THE SUMMIT

Molecular diagnostics is a powerful player in healthcare today. Technological advances and personalized medicine are driving rapid growth, and the healthcare industry is demanding faster and more accurate diagnosis, along with a tailored approach to the treatment of disease. This transformation promises benefits for patient, healthcare, and industry alike. New tests and diagnostic systems must demonstrate clinical value and validity, and be easy to use, in order to achieve widespread adoption.

The Next Generation Dx Summit (Enabling Point-of-Care Diagnostics, Emerging Molecular Markers of Cancer, Molecular Diagnostics for Infectious Disease, Companion Diagnostics, Commercialization of Molecular Diagnostics, and Translating Proteomics & Metabolomics into the Clinical Laboratory) is designed to bring together all of the major players in the evolving areas of diagnostics. This year, we are introducing proteomic and metabolomic technologies that are making their way into clinical diagnostics. We have assembled an impressive faculty of speakers from industry, government, and leading academic institutions. This meeting will showcase improvements in technology research and development with an emphasis towards application to the clinical laboratory and commercialization. Plan to hear what the key players in the industry are saying about what to expect for the rapid changes ahead.

AUGUST 23-24

Inaugural

MASS SPECTROMETRY IN CLINICAL DIAGNOSTICS

TUESDAY, AUGUST 23

7:30 am Registration and Morning Coffee

OVERCOMING GENERAL CHALLENGES

8:30 Chairperson's Opening Remarks

Daniel W. Chan, Ph.D., Professor and Director, Center for Biomarker Discovery and Translation, and Clinical Chemistry Division, Johns Hopkins University

8:40 KEYNOTE PRESENTATION

Translating Proteomics and Metabolomics into the Clinical Labortatory: The Future is Now

Daniel W. Chan, Ph.D., Professor and Director, Center for Biomarker Discovery and Translation, and Clinical Chemistry Division, Johns Hopkins University

Despite the success of discovering many disease associated biomarkers, very few biomarkers have been translated into clinical diagnostics. To be successful in the translation, we need to develop a roadmap and identify several key steps that are critical in this process. These steps include defining a specific clinical "intended use" for unmet clinical needs, generating sufficient evidence in preliminary validation studies to support the investment for a large-scale validation study, developing assays with analytical performance suitable for the clinical laboratory and conducting clinical trials to demonstrate clinical utilities in order to obtain regulatory approval and gain acceptance by the clinical community. Specific examples will be shown to demonstrate the opportunities and challenges for the development of clinical proteomic diagnostics. The successful translation of these biomarkers into clinical practice will require close collaboration between researcher, industry, regulatory agency and clinician

9:10 Regulatory Perspective on Translating Proteomic Biomarkers to Clinical Diagnostics

Jinong Li, Ph.D., DABCC, Regulatory Scientist, FDA/CDRH/OIVD/DCTD

Kellie B. Kelm, Ph.D., Regulatory Scientist, FDA/CDRH/OIVD/DCTD

Issues associated with the translation of complex proteomic biomarkers from discovery to clinical diagnostics have been widely discussed among academic researchers, government agencies, as well as assay and instrumentation manufacturers. Here, we provide an overview of the regulatory framework and type of information that is typically required in order to evaluate ***in vitro*** diagnostic tests regulated by the Office of ***In Vitro*** Diagnostic Device Evaluation and Safety (OIVD) at the US Food and Drug Administration (FDA), with the focus on some of the issues specific to protein-based complex tests.

10:10 Networking Coffee Break

11:00 Criteria for Medical Necessity for Protein and Metabolite-Based Multiplex Assays

Gilbert S. Omenn, M.D., Ph.D., Director, Center for Computational Medicine & Bioinformatics Professor of Internal Medicine, Human Genetics and Public Health, University of Michigan

Major advances in proteomics and metabolomics are enhancing the sensitivity and reproducibility of these measurements with plasma and other clinical specimens. Differential diagnosis may require recognition of post-translational modifications, splice variants, and even sequence polymorphisms of proteins, as well as modeling of effects on interacting signaling pathways. Clinical laboratory criteria, including medical necessity for reimbursement, put a premium on positive-predictive value, narrow coefficient of variation, and results that make a difference in clinical decision-making for patients. The classifiers must be transparent, preferably with open code, to enhance reproducibility and confidence in moving toward personalized medicine.

MULTIPLEX IMMUNOASSAYS

11:30 Enabling Technologies for the Specific Immunoglobulin Analysis in the Diagnosis of Allergic and Autoimmune Diseases

Per Matsson, Ph.D., CTO, Phadia; Associate Professor, Uppsala University

The diagnostic industry is under great change and new emerging technologies allow the possibility to analyze more variables faster and more accurately. Specific Immunoglobulin analysis is today a routine for the diagnosis of allergic and autoimmune diseases. We can presently only analyze different antigens for S-IgE (allergy) or S-IgG (autoimmunity) through traditional sequential immuno-assay systems. The need for more and simultaneous information has encouraged us to search for new possibilities. Therefore, we have developed the possibility to simultaneously analyze >100 different antigens with a minute amount of patient sample. After reviewing a large number of assay technologies we now have the possibility to use multiplexed technologies both in the point-of-care setting, as well as the basis for new laboratory systems. These enabling technologies allow for the development of new information in immunology.

12:00 pm The PreDx® Diabetes Risk Score: A Prognostic Algorithm for Type 2 Diabetes Developed Using a High-Throughput, Quantitative Immunoassay Platform

Steven M. Watkins, Ph.D., CSO, Tethys Bioscience, Inc.

The PreDx Diabetes Risk score is a commercial prognostic test that provides patients with their absolute risk for type 2 diabetes within the next five years. The test was developed by a quantitative scr een of protein concentrations in several large epidemiological cohorts that contained diabetes outcomes. A description of the test as well as a summary of the research technology and validation data will be provided in this talk.

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

1:30 Session Break

MASS SPECTROMETRY APPLICATIONS

1:55 Chairperson's Remarks

Cory Bystrom, Ph.D. , Associate Scientific Director, Quest Diagnostics, Nichols Institute

2:00 Mass Spectrometry as an Enabling Technology in Diagnostics

Cory Bystrom, Ph.D., Associate Scientific Director, Quest Diagnostics, Nichols Institute

Diagnostic use of Liquid Chromatography-Mass Spectrometry has taken off over the last 5 years. The assays provide higher specificity, sensitivity and require smaller sample volumes - ideal for precious samples e.g. pediatrics. The instrumentation allows for multiplexed assays further providing sample savings. These factors have lead to professional bodies endorsing the use of this technology. The ability to automate assays on LC-MS/MS entices labs to adopt the methodology. Since LC-MS/MS is becoming prevalent it is important that users be aware of LC-MS/MS performnce compared to RIAs and ICMAs. This presentation will detail assays through development, validation and use. Examples will differentiate LC-MS/MS results from traditional assays

2:40 Quantifying Proteins by LC-MS/MS

Andrew N. Hoofnagle, M.D., Ph.D., Assistant Professor, Laboratory Medicine, Departments of Laboratory Medicine and Medicine, University of Washington

There have been significant advances in the quantification of proteins by liquid chromatography-tandem mass spectrometry. Targeted proteomics workflows have major advantages over traditional automated immunoassays in the clinical laboratory. In addition, they are more precise than shotgun proteomics approaches. Using standard isotope dilution methods, we have developed several assays that demonstrate the utility of targeted mass spectrometry for the quantification of proteins in human samples. We will discuss the development of these assays and their application to tumor marker detection in serum and to studying the mechanisms of lipoprotein metabolism.

3:10 Absolute Protein Quantification by MS

Sponsored by promise ADVANCED PROTEOMICS *Promise*

Virginie Brun, Ph.D., CSO & Cofounder, Advanced Proteomics

Promise proposes an innovative technology (PSAQ™) based on the use of full-length stable isotope-labeled protein standards and mass spectrometry analysis. Compared to ELISA, this method allows better results in terms of precision, specificity and accuracy, for the dosage of proteins such as biomarkers in complex biological matrices.

3:25 Networking Refreshment Break with Exhibits and Poster Viewing

4:00 Evaluation of Cancer Biomarkers using Multiple Reaction Monitoring Cubed (MRM³)

Genevieve Choquet-Kastylevsky, M.D., Ph.D., Scientific Advisor, BioMarker Department, R&D, BioMerieux

Stable isotope dilution-selected reaction-monitoring mass spectrometry (SID-SRM-MS), or stable isotope dilution-multiple reaction-monitoring mass spectrometry (SID-MRM-MS), carried out in triple quadrupole instruments has emerged as a promising alternative to ELISA for validation of putative protein biomarkers discovered during proteomics projects.

4:30 Enhanced Detection of Low-Abundance Protein Modifications and Potential Biomarkers by Hexapeptide Libraries

Sricharan Bandhakavi, Ph.D., Sr. Scientist, New Technologies R&D, Life Science Group, Bio-Rad

Dynamic range compression (DRC) by hexapeptide libraries increases MS/MS-identification of lower-abundance proteins in biological samples. However, two questions impede fully realizing DRC's potential. First, does DRC enhance identification of protein post-translational modifications (PTMs)? Second, can DRC be incorporated into differential analyses? Using DRC, we doubled identified salivary glyco- and phospho-proteins by MS/MS. Secondly, DRC enabled identification of novel changes to lower-abundance salivary proteins from breast cancer patients. Thus, DRC offers value for enhancing protein/PTM-based biomarker detection studies.*ol*

5:00 Opening Reception in the Exhibit Hall with Exhibits and Poster Viewing

6:00 Close of Day

WEDNESDAY, AUGUST 24

Enjoy Your Morning!

PLENARY KEYNOTE SESSION

KEYNOTE DISCUSSION

11:50 Changing Regulation of LDTs

Moderator: *Franklin R. Cockerill, III, M.D., Ann and Leo Markin Professor of Microbiology & Medicine; Chair, Department of Laboratory Medicine and Pathology, Mayo Clinic College of Medicine; President and CEO, Mayo Medical Laboratories and Mayo Collaborative Services, Inc.*

Featured Guest: *Alberto Gutierrez, Ph.D., Deputy Director, Office of In Vitro Diagnostic Device Evaluation and Safety, Food & Drug Administration*

Audience will be asked to submit questions in advance for the discussion.

MULTI-STAKEHOLDER PANEL

12:30 Future of Reimbursement for Molecular Diagnostics

Moderator: *Thomas A. Gustafson, Ph.D., Senior Policy Advisor, Arnold & Porter LLP*

- Status of CPT coding and fee schedules (clinical lab vs. physician fee)
- Impact of new CPT coding for reimbursement of tests
- What do changes in regulation portend for suppliers and reimbursement?

Panelists: *Ann-Marie Lynch, Executive Vice President, Payment and Health Care Delivery Policy, AdvaMed*

David Mongillo, M.P.H., M.S.M., Vice President, Policy and Medical Affairs, American Clinical Laboratory Association

1:20 - 2:20 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

2:20 - 2:30 Session Break

NOVEL TECHNOLOGIES FOR CLINICAL DIAGNOSTICS – AN OVERVIEW OF THE FIELD

2:30 pm Chairperson's Remarks

Franklin R. Cockerill, III, M.D., Ann and Leo Markin Professor of Microbiology & Medicine; Chair, Department of Laboratory Medicine and Pathology, Mayo Clinic College of Medicine; President and CEO, Mayo Medical Laboratories and Mayo Collaborative Services, Inc.

2:35 The Rapidly Changing Era of Molecular Diagnostics: New Technologies and New Promises

Christine C. Ginocchio, Ph.D., MT(ASCP), Senior Director, Division

of Infectious Disease Diagnostics, North Shore-LIJ Health System; Associate Professor, Department of Pathology and Laboratory Medicine and Department of Molecular Medicine, Hofstra University School of Medicine in collaboration with the North Shore-LIJ Health System

Global travel, the threat of new pandemics, and the spread of re-emerging infectious diseases highlight the need for comprehensive pathogen detection. Identification of the infectious agent(s) is essential to provide an accurate diagnosis, appropriately manage patient care and in certain cases reduce the risk of transmission within the community and health care settings. To meet these challenges, innovative technologies have been developed that detect single pathogens, multiple syndromic related pathogens and genotypic drug resistance. This lecture will provide an overview of new technologies including cartridge based test systems for point of care diagnostics, chip and bead based arrays, next-gen sequencing platforms, and mass spectrometry analysis. Their current and future roles in clinical diagnostics will be discussed.

CLINICAL APPLICATIONS OF MASS SPEC IN INFECTIOUS DISEASE

3:05 Bacterial and Yeast Identification in the Clinical Microbiology Laboratory Using Matrix-Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry

Robin Patel, M.D.(CM), FRCP(C), (D)ABMM, FACP, Consultant, Divisions of Clinical, Microbiology and Infectious Diseases, Professor of Microbiology and Medicine, College of Medicine, Mayo Clinic

Traditional microbial identification in the clinical microbiology laboratory is accomplished by phenotypic analysis using manual, automated, and molecular approaches. Most require hours to days to final results. Matrix-assisted laser desorption ionization–time of flight (MALDI-TOF) mass spectrometry (MS) can rapidly identify and analyze signature bacterial and fungal proteins in colonies of these organisms, enabling identification of grown organisms within minutes. Mass spectrometers, software and microbial mass spectrum libraries have been compiled into automated systems resulting in user-friendly platforms for microbial identification using MALDI-TOF MS.

3:35 MALDI-MS and NGS for Diagnosis of Infectious Disease

Dag Harmsen, Ph.D., Professor, University Münster, Germany

Matrix-assisted laser desorption ionization-time of flight mass spectrometry (MALDI-TOF) has emerged as a rapid, cost-effective, and highly intra- and inter-laboratory reproducible method for bacterial species identification. Next generation sequencing (NGS) has fundamentally altered genomic research. New developments will bring NGS costs and performance down to an everyman's technology with extreme potential for ultra fast and accurate molecular bacterial typing as it provides the ultimate whole genome information. Currently, however, bioinformatics constraints restrict the application of NGS to a few highly experienced laboratories.

4:05 Networking Refreshment Break with Exhibit and Poster Viewing

4:45 A Staged Strategy to Pathogen Detection and Discovery

Thomas Briese, Ph.D., Associate Professor of Clinical Epidemiology, Mailman School of Public Health, Columbia University

Clinical syndromes are only infrequently specific for single pathogens; thus, diagnostic tools must consider multiple agents simultaneously. As new therapeutics offer growing opportunities to reduce morbidity and mortality through targeted drug therapies, rapid identification of an agent becomes essential. New and emerging pathogens pose continuing challenges to diagnostics in a world with ample opportunity for rapid spread through increasing international travel and trade. To address the need for sensitive, highly multiplexed assays, we are applying multiple new platforms in a staged strategy: the multiplex MassTag PCR platform; the GreeneChip microarray platform; and a high-throughput pyrosequencing approach that identifies truly new agents. In reviewing the strengths and limitations of the various platforms, I will provide examples that illustrate how they can be applied to clinical problems, zoonotic surveillance, and surveillance efforts.

5:15 The Role of Molecular Diagnostics in the Changing Paradigm of Hepatitis C Treatments

David Bernstein, M.D., AGAF, FACP, FACG, Chief, Division of Gastroenterology, Hepatology and Nutrition, North Shore University Hospital/Long Island Jewish Medical Center; Professor of Clinical Medicine , Albert Einstein School of Medicine

Combination interferon and ribavirin-based therapies to treat hepatitis C infection are rapidly evolving with the addition of protease inhibitors, nucleoside and non-nucleside polymerase inhibitors and future interferon free based regimens. These therapies, while more effective in achieving a sustained virological response, have the potential to lead to the development of HCV resistance. Molecular therapies such as quantitative HCV-RNA assays, HCV genotyping and IL28B genotyping are becoming increasingly important in the early management of hepatitis C therapies. This presentation will discuss some of the important issues regarding the use of molecular diagnostics in the new paradigm of hepatitis C treatment.

5:45 Breakout Sessions

Concurrent Problem Solving Breakout Sessions are interactive, topic-specific discussions hosted by a moderator. These sessions are open to all attendees, sponsors, exhibitors, and speakers and provide a forum for discussing key issues and meeting potential partners. Please pick a topic of your choice and join in.

Molecular Diagnostics for Infectious Viral Agents
Moderator: *Christine C. Ginocchio, Hofstra University School of Medicine in collaboration with the North Shore-LIJ Health System*

Next Gen Sequencing and Infectious Diagnostics
Moderator: *Charles Chiu, UCSF Clinical Microbiology Laboratory*

Clinical Adoption of Mass Spec
Moderator: Robin Patel, College of Medicine, Mayo Clinic

Measurable Outcomes of Rapid Screening Programs
Moderator: Denise Uettwiller-Geiger, John T. Mather Memorial Hospital

EVENING SHORT COURSE*

6:30 - 8:30 pm Mass Spec Methods for the Clinical Lab

MALDI-TOF mass spectrometry is a rapid, inexpensive identification method that detects biomarker spectra characteristics for individual species of organisms with an accuracy equivalent to gene sequencing. The introduction of mass spectrometry methods into clinical microbiology laboratories brings many possibilities for new clinical laboratory interventions in support of patient care. This course will describe and review mass spectrometry methods with current and potential application to diagnostic clinical microbiology laboratories.

Instructor: *Thomas Briese, Ph.D., Associate Professor of Clinical Epidemiology, Mailman School of Public Health, Columbia University*

**Separate Registration Required*

MASS SPECTROMETRY in Clinical Diagnostics

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CONFERENCE PRICING

SINGLE CONFERENCE

(Includes access to 1 conference, excludes short courses)	Commercial	Academic, Government, Hospital-affiliated
Advance Registration Discount until July 29, 2011	$1495	$625
Registrations after July 29, 2011, and on-site	$1695	$695

August 23-24	August 24-25
Mass Spectrometry in Clinical Diagnostics	Molecular Diagnostics for Infectious Disease
Enabling Point-of-Care Diagnostics	Companion Diagnostics
Emerging Molecular Markers of Cancer	Commercialization of Molecular Diagnostics
Translating Proteomics into the Clinical Laboratory	

SUMMIT PRICING — BEST VALUE!

(Includes access to 2 conferences, excludes short courses)	Commercial	Academic, Government, Hospital-affiliated
Advance Registration Discount until July 29, 2011	$2095	$945
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SHORT COURSES

(Includes access to short course(s) only)	Commercial	Academic, Government, Hospital-affiliated
One short course	$695	$395
Two short courses	$995	$695
Three short courses	$1195	$795

Monday, August 22nd – Morning	Monday, August 22nd – Afternoon	Wednesday, August 24th – Dinner
SC1 Micro- and Nanofluidics in Diagnostics and Life Sciences	SC4 Applications of Detection Theory in Diagnostics	SC8 The Future of Point-of-Care Diagnostics
SC2 Smarter Studies: Boosting Omics and Biomarker Projects through Study Design	SC5 Automation Solutions for Molecular Diagnostics	SC9 Mass Spec Methods for the Clinical Lab
SC3 Advances in Molecular Pathology, Pt. I (Basic)	SC6 Business Strategies for Companion Diagnostics	
	SC7 Advances in Molecular Pathology, Pt. II (Advanced)	

CONFERENCE DISCOUNTS

Poster Submission-Discount ($50 Off)
Poster abstracts are due by **July 26, 2011**. 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.

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

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