AMP 2018 CORPORATE WORKSHOP
DAY PROGRAM
Precision Medicine Starts Here

OCTOBER 31, 2018
Henry B. Gonzalez Convention Center
San Antonio, TX, USA
Welcome to AMP 2018 Workshop Day!

AMP 2018 Corporate Workshop Day
Host Companies

Abbott Molecular*
Adaptive Biotechnologies Corp.

Agena Bioscience, Inc.
Agilent Technologies
Applied BioCode
ArcherDx

AstraZeneca*
Asuragen*
ATCC

Beckman Coulter Life Sciences*
Biocartis
Biolyph

Bio-Rad Laboratories*

Bristol-Myers Squibb*
ChromaCode
Codexis Inc
Color Genomics
Covaris
DiaSorin Molecular
Epigenomics, Inc.

Fabric Genomics, Inc.
GenePOC
GenMark Diagnostics

Hologic*
Horizon Discovery LTD
Illumina, Inc.
IncellDx, Inc.
Invivoscribe Technologies, Inc.

Menarini Silicon Biosystems
Mission Bio
Molecular Health

NanoString Technologies*
NeuMoDx Molecular
N-of-One Inc
OpGen, Inc.

Oracle Health Sciences
Oxford Gene Technology
Paragon Genomics
PerkinElmer

Personal Genome Diagnostics
PierianDx
Pillar Biosciences
Promega Corporation
Q² Solutions

QIAGEN*
Quidel Corporation
Rheonix, Inc.

Roche*
SeraCare Life Sciences, Inc.

Sunquest Information Systems

Takara Bio USA
Tecan

Thermo Fisher Scientific*
TriCore Reference Laboratories

Vela Diagnostics*

*AMP Corporate Partner Company

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<tr>
<td>8:00 AM</td>
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<td>Genomic Medicine in Oncology – What We've Learned about Targeting the DNA-Damage Response</td>
<td>Astrazeneca</td>
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<td>8:00 AM</td>
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<td>Making Sense Out of Microbiome Data – The Importance of Standards</td>
<td>ATCC</td>
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<td>8:00 AM</td>
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<td>Maximizing MDx: Performance, Quality, Stability, and Ease of Use</td>
<td>Biolyph</td>
<td>301A</td>
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<td>8:00 AM</td>
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<td>Bio-Rad’s Unity as a Solution for Molecular Quality Control Data Management</td>
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<td>ePlex® Blood Culture Identification (BCID) Panels: Designed to Improve Patient Care and Clinical Outcomes</td>
<td>GenMark Diagnostics</td>
<td>217BC</td>
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<tr>
<td>8:00 AM</td>
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<td>Immuno-Oncology Biomarkers: Incorporating Tumor Mutation Burden and Micro-Satellite Instability in Routine Tumor Profiling via Next-Generation Sequencing</td>
<td>Illumina</td>
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<td>8:00 AM</td>
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<td>Precision Medicine and Targeted Therapy Applications for Acute Myeloid Leukemia (AML)</td>
<td>Invivoscribe</td>
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<td>8:00 AM</td>
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<td>DEPArrayTM Enables Isolation of Pure Tumor Cells from FFPE Samples for Precise Genomic Analysis</td>
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<td>Tracking MSI Status in Liquid Biopsies from MSI-H Colorectal Cancer Patients on Immunotherapy</td>
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<td>Incorporating ATCC Metagenomics Controls to Standardize Illumina Microbiome Sequencing Methods</td>
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<td>Universal Screening for the CDC Tier 1 Genomic Conditions</td>
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<td>Stakeholder Perspectives on Molecular Medicine: A Panel Discussion</td>
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<td>Rapid Pathogen Identification and Phenotypic Antibiotic Susceptibility Testing (AST) Using Hyb &amp; Seq™ Technology</td>
<td>NanoString Technologies</td>
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<td>9:00 AM</td>
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<td>Standardization of NGS for Oncology – The PGDx elio Model</td>
<td>Personal Genome Diagnostics</td>
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<td>9:00 AM</td>
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<td>Single-vial Amplification Based NGS with Rapid Turn-around-time for Interrogation of Variants in Tumors with Limited Diagnostic Material</td>
<td>Pillar Biosciences</td>
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<td>Clinical Laboratory Evaluation of the EntericBio Gastroenteridis Panel and Evaluation of Solana Strep Complete in a Clinical Setting</td>
<td>Quidel Corporation</td>
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<td>9:00 AM</td>
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<td>From Raw Sample to Sequence-Ready Library: Fully Integrated and Automated Nucleic Acid Extraction and NGS Library Prep System</td>
<td>Rheonix, Inc.</td>
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<td>9:00 AM</td>
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<td>Utilization of Multiple Testing Methodologies to Aid in Lung Cancer Patient Management</td>
<td>Roche</td>
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<td>9:00 AM</td>
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<td>Next-Generation Sequencing Solutions to Streamline Cancer Research and Targeted Therapy Selection in NSCLC</td>
<td>Thermo Fisher Scientific</td>
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<td>10:00 AM</td>
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<td>Advancing Patient Care in Hematology: Innovative Biomarker-based Approaches to Molecular Diagnostics</td>
<td>Abbott Molecular</td>
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<td>New Horizons for AmpliDEX® Technology: Portfolio Expansions to New High Complexity Targets &amp; Beyond</td>
<td>Asuragen</td>
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<td>10:00 AM</td>
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<td>There is Nothing Minimal about Residual Disease</td>
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<td>10:00 AM</td>
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<td>Current and Emerging Biomarkers: Science, Technologies, and Practicalities</td>
<td>Bristol-Myers Squibb</td>
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<td>10:00 AM</td>
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<td>Tackling the Challenge of Translational Gene Signature Development</td>
<td>NanoString Technologies</td>
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<td>Roche Digital PCR</td>
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<td>Scaling Molecular Testing to Deliver Efficient &amp; Effective Precision Medicine Diagnostics</td>
<td>Sunquest Information Systems</td>
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<td>10:00 AM</td>
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<td>Emerging Biomarkers for Immunotherapy: From Tumor Mutational Burden (TMB) to T Cell Receptor Beta (TCRB)</td>
<td>Thermo Fisher Scientific</td>
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<td>Solving the Riddle of Ph-like ALL: Comprehensive and Cost-Effective Detection of BCR-ABL1-like B-Lymphoblastic Leukemia</td>
<td>TriCore Reference Laboratories</td>
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<td>11:00 AM</td>
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<td>Enabling Cancer Genetics: How Agilent’s SureSelect Cancer All-In-One Solution Can Help You Get More From a Single Test</td>
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<td>Multiplexing in the Digital Age: ChromaCode’s Machine Learning-Based High-Definition PCR (HDPCR) Technology</td>
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<td>Redefining Standards – Superior Assay Validation to Establish Reliable NGS Workflows Using Horizon’s Controls</td>
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<td>Evaluating T-Cell Clonality and Minimal Residual Disease (MRD) for Hematopathologic Diagnosis Using Next-Generation Sequencing</td>
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<td>11:00 AM</td>
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<td>High-plex Digital Spatial Profiling Enables Characterization of Complex Immune Biology in the Tumor Microenvironment of Mesothelioma</td>
<td>NanoString Technologies</td>
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<td>Creating Solutions to Support Clinical Decision Support Through High Performance Processing of Genomic and Clinical Data, Data Integration, Advanced Analytics, Machine Learning, and Reporting</td>
<td>Oracle Health Science</td>
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# AMP 2018 Corporate Workshop Day Schedule at a Glance

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<td>11:00 AM</td>
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<td>The Evolution of Speed and Robustness: Overcome Inhibitors and Gain Time with Mutated Polymerases from Roche Custombiotech</td>
<td>Roche</td>
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<td>11:00 AM</td>
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<td>Pushing the Envelope in Cancer Research – From Research to Future Oncology Disease Management</td>
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<td>11:00 AM</td>
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<td>Detecting HIV-1 Genotypic Resistances and Subtypes using the Vela Sentosa “Sample to Answer” Next Generation Sequencing System for Clinical Research</td>
<td>Vela Diagnostics</td>
<td>303C</td>
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<td>MRD Assessment in the Clinical Management of ALL and Myeloma: Why Validation and Standardization Matter</td>
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<td>Updates to the CAP/IASLC/AMP Molecular Testing Guidelines for Selecting Patients with NSCLC Practical Considerations and Real-World Examples</td>
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<td>Automation of NGS Library Generation Protocols to Haplotype-Resolve Structural Variation</td>
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<td>12:00 PM</td>
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<td>Advancing Precision Oncology: Current and Emerging Biomarkers and Pharmacodiagnostic Tools</td>
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<td>12:00 PM</td>
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<td>Engineered DNA Enzymes for Efficient NGS Workflows</td>
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<td>The Panther Fusion® System – Expanding Your Lab’s Potential with a Growing Menu</td>
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<td>Tumor Heterogeneity from Tissue to Blood to Urine: Personalizing Medicine Cell by Cell</td>
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<td>Guidelines for the Interpretation and Reporting of Sequence Variants in Cancer</td>
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<td>Evaluating NGS Liquid Biopsy and Tumor Tissue Assays</td>
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<td>Detecting HCV Genotypic Resistances, Genotypes and Subtypes using the Vela Sentosa “Sample to Answer” Next Generation Sequencing System for Clinical Research</td>
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<td>Implementation of a Comprehensive NGS Panel at a Community Cancer Center</td>
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<td>Evaluation of Quantitative EBV and BKV LDT Implementation on the Open, Automated NeuMoDx 288 Molecular System</td>
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<td>Rapid Prediction of Antibiotic Resistance Using OpGen’s Acuitas® AMR Gene Panel u5.47 (RUO) and Acuitas Lighthouse®</td>
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<td><strong>Rapid Cancer Testing as an Integral Part of Precision Oncology</strong></td>
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<td><strong>Complementary Detection of Somatic Variants from Tissue and Plasma Samples Using the AVENIO Family of NGS Oncology Assays</strong></td>
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<td><strong>Achieving Better ctDNA Assay Sensitivity – Laboratory Perspectives</strong></td>
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<td><strong>Obtaining Clinically Relevant Sequencing Readout from Single Cells and Cell Free DNA</strong></td>
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<td><strong>Next Generation Sequencing meets Next Generation Automation</strong></td>
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<td><strong>Driving down the Cost of Microbial Testing Through Flexible-content Syndromic Panels – Leveraging Nanofluidic and Microfluidic Form-factors on Real-time PCR Platforms</strong></td>
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<td><strong>Vela Diagnostics’ Microbiology Workshop</strong></td>
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<td><strong>Avoid the Compromise: How the Agena MassARRAY System Uniquely Addresses Multiple Challenges in Routine Solid Tumor and Liquid Biopsy Testing</strong></td>
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<td><strong>Implementing NGS to Quantify Human and Pathogen Tumor Markers in Plasma and Tissue</strong></td>
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<td><strong>Multidisciplinary Approach to Optimal and Timely Testing in Lung Cancer</strong></td>
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<td><strong>The Global Explosion of Resistant Pathogens: What Can Be Done?</strong></td>
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<td><strong>Real-life Applications Using NEXTFLEX® Amplicon Panels to Better Understand Infertility and Inherited Diseases</strong></td>
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<td><strong>Tumor Mutational Burden (TMB) Analysis Across Multiple Genomic Platforms with Considerations for Sample Type Utility and Effects on Numerical Representation</strong></td>
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<td><strong>Expanding Applications on the Genereader NGS System to Address Unmet Needs in Cancer Testing</strong></td>
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<td><strong>A Review of the Evidence: How Pharmacogenomics Testing, When Implemented as Part of a Holistic Medication Management Program, Improves Patient Outcomes and Reduces Healthcare Costs</strong></td>
<td>Thermo Fisher Scientific</td>
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<td>Validation and Implementation of a Custom Hematologic Neoplasm NGS Panel</td>
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<td>Update: The Latest in Molecular Testing for P. jiroveci and Group B Strep</td>
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<td>Clinical Application of Methylated DNA for Early Detection of Cancer</td>
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<td>Transforming Targeted NGS Panels through AI-Driven Analysis and Reporting</td>
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<td>MH Guide – A Streamlined Workflow for Variant Interpretation and Reporting</td>
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<td>Molecular Profiling of Malignancies by NGS and FISH</td>
<td>Oxford Gene Technology</td>
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<td>Supporting NGS-Based IVD Assays with the Most Accurate, Comprehensive and Clinically Robust KnowledgeBase</td>
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<td>Why Microsatellite Instability (MSI) Characterization of Tumors by PCR Is Still the Gold Standard in a World of NGS</td>
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<td>Identification of Inherited Genetic Risk Factors of Pancreatic Cancer Using a Targeted Sequencing Approach in a Large Cohort</td>
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<td>Modified Oligonucleotides: Core to Molecular Diagnostics, Therapeutics, Genomics, and Gene Editing</td>
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<td>Chimerism Made Easy: How the ChimericID Panel for the MassARRAY System Simplifies Traditional STR-Based Chimerism Testing</td>
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<td>Powerfully Fast and Suitable for Any Lab – Fully-automated Molecular Testing with Idylla™</td>
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<td>4:00 PM</td>
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<td>Expanding the use of Droplet Digital™ PCR for Clinical Applications</td>
<td>Bio-Rad Laboratories</td>
<td>217D</td>
</tr>
<tr>
<td>4:00 PM</td>
<td>4:50 PM</td>
<td>Moving from Bulk NGS to Precision Sequencing with Single-Cell Genomics: Resolving Heterogeneity in Blood and Solid Tumors</td>
<td>Mission Bio</td>
<td>214A</td>
</tr>
<tr>
<td>4:00 PM</td>
<td>4:50 PM</td>
<td>Making the Right Calls in Precision Oncology</td>
<td>N-of-One Inc</td>
<td>303AB</td>
</tr>
<tr>
<td>4:00 PM</td>
<td>4:50 PM</td>
<td>Ultra-High Multiplexed and Molecular-Barcoded NGS Panels to Enable Genomic-Based Healthcare and Science</td>
<td>Paragon Genomics, Inc.</td>
<td>214C</td>
</tr>
<tr>
<td>4:00 PM</td>
<td>4:50 PM</td>
<td>Delivering on the Promise of Fast Point-of-care Syndromic Testing with QIAstat-DX</td>
<td>QIAGEN</td>
<td>221AB</td>
</tr>
<tr>
<td>4:00 PM</td>
<td>4:50 PM</td>
<td>How Can Labs Implement a Best-in-Class, Robust, and Compliant Next-Generation Sequencing QC Program?</td>
<td>SeraCare Life Sciences, Inc</td>
<td>302B</td>
</tr>
</tbody>
</table>
Genomic Medicine in Oncology – What We’ve Learned about Targeting the DNA-Damage Response

Room: 217D  Time: 8:00 AM-8:50 AM  Hosted by: Astrazeneca

Recent Multiple studies have provided evidence of the prognostic value of knowing the BRCA1/2 mutation status in women with ovarian cancer. We are learning about the role HRR mutations play as well. This workshop will provide an up-to-date overview of the predisposition, prognostic and predictive value of BRCA and HRR mutation testing as well as timely and optimal testing pathways in clinical settings.

Making Sense Out of Microbiome Data – The Importance of Standards

Room: 302C  Time: 8:00 AM-8:50 AM  Hosted by: ATCC

Next-generation sequencing technologies have influenced microbiome analyses in tremendous ways, opening up applications in the areas of clinical, diagnostic, therapeutic, and environmental research. However, the complexities involved in 16S rRNA community profiling and shotgun metagenomics methods often result in the introduction of biases throughout the workflow, ultimately impacting data interpretation and reproducibility. To address this, ATCC has developed fully sequenced, authenticated microbiome standards that can be used in assay standardization or as daily run controls. This workshop will highlight the utility of these standards and will focus on the assays and sequencing tools from Illumina that facilitate microbiome research.

Maximizing MDx: Performance, Quality, Stability, and Ease of Use

Room: 301A  Time: 8:00 AM-8:50 AM  Hosted by: Biolyph

Biolyph’s Lyophilization Services provide room temperature stability, longer shelf life, reduction in user time, steps, and errors, and more economical transport and storage for your molecular diagnostic reagents, Master Mixes, calibrators, and controls. A single LyoSphere™ can contain multiple reagents in a stable, consistent format, which rehydrates instantly and can be packaged in virtually any device. Learn how BIOLYPH can maximize your MDx value proposition, and how our two new sister companies, NextGen Devices and DaVinci Automation, synergize with BIOLYPH to deliver complete solutions.

Bio-Rad’s Unity as a Solution for Molecular Quality Control Data Management

Room: 221AB  Time: 8:00 AM-8:50 AM  Hosted by: Bio-Rad Laboratories

Management of complex quality control (QC) data is essential to insure high quality patient care and maintain regulatory compliance within clinical laboratories. Robust software solutions for management of QC data exist for clinical chemistry applications but are scarce in molecular diagnostics. This session will provide attendees with the opportunity to explore solutions offered by Bio-Rad Unity for the management of QC data generated in qualitative and quantitative molecular diagnostics assays. Practical examples of the storage, review, and management of QC data generated using Abbott’s HIV-1 viral load assay will be demonstrated.

ePlex® Blood Culture Identification (BCID) Panels: Designed to Improve Patient Care and Clinical Outcomes

Room: 217BC  Time: 8:00 AM-8:50 AM  Hosted by: GenMark Diagnostics

Improving outcomes in bloodstream infections through the partnership of molecular diagnostics and antimicrobial stewardship and a first look at study data from multiple sites in the US.

Presented by
Karen C. Carroll, M.D.
Professor of Pathology, Director, Division of Medical Microbiology, The Johns Hopkins University School of Medicine
Stefan Juretschko, PhD, D(ABMM)
Director, Division of Infectious Disease Diagnostic at Northwell Health System
Incorporating Tumor Mutation Burden and Micro-Satellite Instability in Routine Tumor Profiling via Next-Generation Sequencing

Room: 303AB  Time: 8:00 AM-8:50 AM  Hosted by: Illumina

With the recent increase in oncology therapeutic agent’s options, from targeted therapies to immuno-oncology, a comprehensive tumor profiling can help identify driver-mutations and optimize treatment selection. We will discuss new genomic alterations such as Tumor Mutation Burden and Micro-Satellite Instabilities to define the most appropriate panel design for accurate detection.

Precision Medicine and Targeted Therapy Applications for Acute Myeloid Leukemia (AML)

Room: 214A  Time: 8:00 AM-8:50 AM  Hosted by: Invivoscribe

Understanding the clonal architecture of AML is vital for successful treatments. Many different mutations, genetic aberrations, and downstream abnormalities can generate the same clinical picture in patients, but these differences cause variable responses to therapy – a major hurdle in the treatment of this disease. Through precision medicine and next-generation sequencing, all relevant mutations are identified, both in the prevalent clones, as well as in the “secondary” or “tertiary” clones that could later arise as prominent clones leading to relapse. This information allows for the development of targeted therapy plans specific to the somatic mutations affecting any given patient.

DEPArrayTM Enables Isolation of Pure Tumor Cells from FFPE Samples for Precise Genomic Analysis

Room: 214C  Time: 8:00 AM-8:50 AM  Hosted by: Menarini Silicon Biosystems

The newly launched FFPE Sample Prep Kit makes preparation much easier by simplifying the dissociation and staining process. The kit is intended for dissociation of a sample down to the single-cell level, and contains the reagents for cell-specific staining of both the stromal and epithelial cell compartments of a tumor sample. Small samples, such as FNAs, and low tumor content samples (<20%), can be sorted with ease to reveal genetic variants in tumor populations that would be unidentifiable when analyzing unsorted cell populations. Performing NGS on pure tumor cell recoveries simplifies downstream analysis while saving time and money.

Tracking MSI Status in Liquid Biopsies from MSI-H Colorectal Cancer Patients on Immunotherapy

Room: 301B  Time: 8:00 AM-8:50 AM  Hosted by: Promega

The success of checkpoint inhibitors targeting programmed cell death protein-1, programmed cell death ligand-1, and cytotoxic T lymphocyte antigen-4 in the treatment of patients with colorectal cancers displaying microsatellite instability underscores the need for novel technologies to evaluate the progression of such instability as a means of monitoring therapeutic response. As serial tumor specimens are usually not available while patients are on therapy, we have conducted research in monitoring the MSI status of liquid biopsies from MSI-H colorectal cancer patients to determine if MSI has the potential to be used as a biomarker for immunotherapy response.
Incorporating ATCC Metagenomics Controls to Standardize Illumina Microbiome Sequencing Methods

Room: 302C  Time: 9:00 AM-9:50 AM  Hosted by: ATCC

Next-generation sequencing technologies have influenced microbiome analyses in tremendous ways, opening up applications for human, animal, and environmental health and public safety. However, metagenomics methods require many steps from extraction, library prep, sequencing, and analysis that can introduce biases and affect reproducibility and interpretation. Use of controls, like those developed by ATCC, with high quality assays and sequencing solutions from Illumina, can facilitate standardization of NGS workflow to advance microbiome research.

Universal Screening for the CDC Tier 1 Genomic Conditions

Room: 304C  Time: 9:00 AM-9:50 AM  Hosted by: Color Genomics

Color will discuss an end-to-end implementation approach, including clinical actionability, cost-effectiveness, patient recruitment capability, genetic counseling access, and cascade screening.

Stakeholder Perspectives on Molecular Medicine: A Panel Discussion

Room: 303AB  Time: 9:00 AM-9:50 AM  Hosted by: Illumina

Molecular & Oncology healthcare professionals share how they navigate the challenges of the cancer care continuum.

Rapid Pathogen Identification and Phenotypic Antibiotic Susceptibility Testing (AST) Using Hyb & Seq™ Technology

Room: 304AB  Time: 9:00 AM-9:50 AM  Hosted by: NanoString Technologies

With rising rates of drug-resistant infections, there is a need for diagnostic methods that rapidly can detect the presence of pathogens and reveal their susceptibility to antibiotics. The traditional culture-based assays, though accurate, are too slow to guide early antibiotic selection, while newer genotypic methods require more knowledge of antibiotic resistance mechanisms to predict phenotype. This presentation highlights the ability of a novel hybridization based sequencing system, Hyb & Seq™ technology, and RNA signature based approach to allow a rapid universal pathogen identification and phenotypic AST assay, agnostic to the genetic basis for resistance.

Standardization of NGS for Oncology – The PGDx elio Model

Room: 303C  Time: 9:00 AM-9:50 AM  Hosted by: Personal Genome Diagnostics

The role of NGS testing in informing clinical decisions has greatly expanded, now including biomarkers like MSI and Tumor Mutational Burden (TMB) for immune therapies. As oncology begins adopting widespread clinical use of NGS, standardization becomes essential. We are developing IVD NGS assays optimized for these complex and comprehensive tumor profiling applications. Our ctDNA and tissue assays are designed to empower local laboratories, bringing NGS technologies into standard of care for patients worldwide.

This workshop will discuss: 1) the clinical utility of NGS; 2) the need for NGS standardization; 3) a kitted IVD solution for NGS in tissue and plasma.
Single-vial Amplification Based NGS with Rapid Turn-around-time for Interrogation of Variants in Tumors with Limited Diagnostic Material

Room: 302A  Time: 9:00 AM-9:50 AM  Hosted by: Pillar Biosciences

Due to limited tumor tissue available for testing, NGS libraries that use amplification methodologies, have been increasingly used for interrogation of clinically relevant variants. DNA input, compromised DNA quality, technical difficulty, turn-around-time and vetted bioinformatics are factors that are important for adoption of NGS assays in routine diagnostics. This presentation will focus on the single tube Stem-Loop Inhibition Mediated Amplification (SLIMampTM) technology for accuracy and sensitivity of detection of variants in solid tumors.

Clinical Laboratory Evaluation of the EntericBio Gastroenteridis Panel and Evaluation of Solana Strep Complete in a Clinical Setting

Room: 301C  Time: 9:00 AM-9:50 AM  Hosted by: Quidel Corporation

Evaluating the EntericBio panel from Serosep. Evaluation of the Solana Strep Complete Assay (GAS + C/G) on the Solana Instrument performed at Tampa General Hospital lab and how it fits into a laboratory routine.

From Raw Sample to Sequence-Ready Library: Fully Integrated and Automated Nucleic Acid Extraction and NGS Library Prep System

Room: 214B  Time: 9:00 AM-9:50 AM  Hosted by: Rheonix, Inc.

Next-Generation Sequencing (NGS) library preparation remains a manual or semi-automated process, requiring intensive manual labor and/or multiple instruments to perform nucleic acid extraction, library prep and quantitation. In this workshop, learn from industry experts how they used the fully integrated and automated Encompass Optimum™ workstation to obtain high quality sequencing results directly from raw samples including FFPE, blood, buccal swabs, and bacteria, while reducing technician time, turnaround time, and cost.

Utilization of Multiple Testing Methodologies to Aid in Lung Cancer Patient Management

Room: 221CD  Time: 9:00 AM-9:50 AM  Hosted by: Roche

In the last few years multiple testing methodologies such as immunohistochemistry, PCR and sequencing have been FDA approved to aid in the management of patients with lung cancer. In this workshop you will learn how these very different technologies serve specific needs and how creating a testing strategy that employs many of these different methodologies can provide the information clinicians need to make the best treatment decisions of their critically ill patients.

Next-Generation Sequencing Solutions to Streamline Cancer Research and Targeted Therapy selection in NSCLC

Room: 217A  Time: 9:00 AM-9:50 AM  Hosted by: Thermo Fisher Scientific

In the journey to realizing the promise of precision medicine, NGS has quickly emerged as a helpful tool to study multiple genes and mutation types in a single assay, thus preserving precious samples and significantly reducing the time to results. This workshop will highlight some of the latest NGS innovations in NSCLC research and diagnostics testing. Additionally, case studies will be presented on how NGS has been successfully implemented in different types of laboratories to streamline the testing.
Advancing Patient Care in Hematology: Innovative Biomarker-based Approaches to Molecular Diagnostics

Room: 217D          Time: 10:00 AM-10:50 AM          Hosted by: Abbott Molecular

Abbott Molecular Scientific Affairs invites you to an introduction to biomarker-based molecular technologies in clinical hematology research applications.

Moderator: Tony Marble, Global Scientific Affairs Manager Oncology, Abbott Molecular

New Horizons for AmplideX® Technology: Portfolio Expansions to New High Complexity Targets & Beyond

Room: 217BC          Time: 10:00 AM-10:50 AM          Hosted by: Asuragen

AmplideX® PCR technology provides easy-to-use, reliable and accurate genotyping solutions for complex gene targets such as FMR1 and DMPK. This versatile technology is the basis for the recently launched AmplideX PCR/CE SMN1 Kit (RUO) that uses a common workflow with our existing products to determine copy number. The workshop will address a range of challenging genetic questions by highlighting attributes of this new kit as well as additional products under development for SMN1/2 and HTT (huntingtin gene).

There is Nothing Minimal about Residual Disease

Room: 221AB          Time: 10:00 AM-10:50 AM          Hosted by: Bio-Rad Laboratories

Measurable residual disease (MRD) is an indicator of disease burden and the strongest predictor of relapse in hematological malignancies. MRD provides an early assessment of disease response and is an important part of routine disease management. CML exemplifies how MRD is utilized in treatment algorithms and research trial design. Current monitoring strategies (qPCR) are limited in sensitivity by signal to noise barriers, whereas droplet digital PCR (ddPCR) offers greater sensitivity by partitioning signal to single molecule, “yes/no” outputs. ddPCR may help select CML patients with deep molecular response for therapy discontinuation.

Speaker: Jerald Radich, MD
Fred Hutchinson Cancer Research Center

Current and Emerging Biomarkers: Science, Technologies, and Practicalities

Room: 301B          Time: 10:00 AM-10:50 AM          Hosted by: Bristol-Myers Squibb

At Bristol-Myers Squibb, we recognize pathologists play a crucial role in furthering advancements that may help predict which patients are likely to benefit from immuno-oncology therapies. Join us as we explore one of the hottest topics in molecular pathology: immuno-oncology biomarkers. Light refreshments will be provided.

Tackling the Challenge of Translational Gene Signature Development

Room: 304AB          Time: 10:00 AM-10:50 AM          Hosted by: NanoString Technologies

The importance of Gene Signatures in diagnostic, prognostic, and predictive assays is established and the rate of new signature development is increasing. Developing and operationalizing these signatures poses unique challenges to molecular pathologists. During this workshop, we will learn how two leading clinicians are tackling the challenge of developing Gene Signatures.
**Roche Digital PCR**

*Room: 221CD  Time: 10:00 AM-10:50 AM  Hosted by: Roche*

Digital PCR uses direct absolute quantification to give precise measurements of nucleic acid. This can be used to quantify subtle changes in copy number variation, insertions, deletions and rearrangements.

Come learn about what Roche is doing with Digital PCR*. With automation, efficient workflow and connectivity, we believe digital PCR will no longer simply be a research tool but can be an integral part of your routine clinical laboratory.

*Roche’s Digital PCR tool is currently in development.

**Scaling Molecular Testing to Deliver Efficient & Effective Precision Medicine Diagnostics**

*Room: 214A  Time: 10:00 AM-10:50 AM  Hosted by: Sunquest Information Systems*

With the advent of precision medicine, molecular labs are facing greater testing demand than ever before, particularly for highly-specialized, complex tests such as next-generation sequencing and quantitative PCR. To ensure high-quality clinical care reaches patients and actionable decision-support reaches physicians, the most successful labs will address workflow complexities and operational challenges with proactive, purpose-built infrastructure to support more efficient testing. In this session, learn about real world examples of how labs have scaled molecular and genetic testing capabilities for greater accuracy, lower costs, and shorter throughput times – all critical components of advancing higher-quality care tailored to the individual patient.

**Emerging Biomarkers for Immunotherapy: From Tumor Mutational Burden (TMB) to T Cell Receptor Beta (TCRB)**

*Room: 217A  Time: 10:00 AM-10:50 AM  Hosted by: Thermo Fisher Scientific*

Use of immune checkpoint inhibitors (ICIs) in immunotherapies is increasingly common, especially in monotherapy and combination therapy. Tumor Mutational Burden (TMB) has been recently validated as a clinical biomarker in response to ICIs. Widespread adoption of TMB in a routine setting will require a streamlined turnkey solution in addition to standardized TMB calculation and reporting. Additionally, new potential biomarkers like TCR clonality can further augment immune therapy success. This workshop will highlight Friends of Cancer Research’s TMB Harmonization Project, how Oncomine Tumor Mutation Load Assay can streamline TMB assessment, and introduce an emerging liquid biopsy biomarker for immunotherapies using TCR sequencing.

**Solving the Riddle of Ph-like ALL: Comprehensive and Cost-Effective Detection of BCR-ABL1-like B-Lymphoblastic Leukemia**

*Room: 302B  Time: 10:00 AM-10:50 AM  Hosted by: TriCore Reference Laboratories*

BCR-ABL1-like or Philadelphia (Ph)-like ALL is a high-risk subtype with a gene expression signature similar to BCR-ABL1-positive ALL. More than 8,000 patients in COG and adult clinical trials have been screened using a patented low density array (LDA) gene expression assay, which is now available to all patients. Here, we discuss cost-effective screening with the LDA card and subsequent confirmatory testing to comprehensively identify Ph-like ALL and associated targetable genetic alterations. BCR-ABL-like ALL occurs in up to 25% of pediatric and 30% of adult ALL patients.
Enabling Cancer Genetics: How Agilent’s SureSelect Cancer All-In-One Solution Can Help You Get More from a Single Test

Room: 214B  Time: 11:00 AM-11:50 AM  Hosted by: Agilent Technologies

Join Dr. Jason Rosenbaum, from the University of Pennsylvania, as he discusses his recent publication in Nature, Modern Pathology, on the investigation of ALK fusion events in non-small-cell lung cancer. Dr. Rosenbaum and his team utilized NGS capture of fusions and ALK IHC on 33 lung adenocarcinoma samples previously tested positive for ALK rearrangement with FISH. Building on Dr. Rosenbaum’s findings of fusion detection, Dr. Ronda Allen, Senior Director of R&D at Agilent Technologies, will continue the story on how to get even more information from your cancer samples in a single workflow.

BioCode® Gastrointestinal Pathogen Panel with an Efficient, Automated MDx-3000 System

Room: 304C  Time: 11:00 AM-11:50 AM  Hosted by: Applied BioCode

Applied BioCode develops, manufactures, and commercializes multiplex solutions for the IVD market. Please join us and learn about newly FDA-cleared BioCode® Gastrointestinal Pathogen Panel (GPP) and MDx 3000 platform for multiplex molecular detection, using Digital Barcoded Magnetic Bead (MBM) technology. This flexible and highly cost-effective platform can produce syndromic pathogen panel results from 188 clinical samples within 8 hours with minimal hands-on time. The BioCode® GPP is FDA-cleared for identification of 17 pathogenic intestinal bacteria/toxin, viruses, and parasites. Stop by our booth #1907 in the exhibit hall.

Multiplexing in the Digital Age: ChromaCode’s Machine Learning-Based High-Definition PCR (HDPCR) Technology

Room: 302A  Time: 11:00 AM-11:50 AM  Hosted by: ChromaCode

Machine learning, Artificial Intelligence, and other data pattern recognition processes have impacted everything from self-driving cars to facial recognition to online advertising. Join us as Dr. Yaser Abu-Mostafa, Caltech, whose online machine learning course has attracted more than 5 million views on YouTube and iTunesU, discusses the emergence of these tools in life sciences and diagnostics. He’ll also introduce how ChromaCode is using these tools to enable high-density molecular multiplexing. Following Dr. Abu-Mostafa, Dr. Greg Tsongalis, Dartmouth-Hitchcock, will review his experiences with ChromaCode’s novel HDPCR™ technology and present data highlighting multiplexing using common real-time PCR and digital PCR platforms.

Redefining Standards – Superior Assay Validation to Establish Reliable NGS Workflows Using Horizon’s Controls

Room: 301C  Time: 11:00 AM-11:50 AM  Hosted by: Horizon Discovery

Speaker: Kevin Balbi, PhD – Head of Bioinformatics, and Sarah Cannon Molecular Diagnostics

Kevin Balbi will discuss the validation of targeted sequencing panels on the Ion Torrent platform using Horizon Discovery’s Tru-Q reference standard and how those controls are being used for ongoing internal quality control (IQC). Validation of targeted sequencing panels for clinical diagnostic use requires reference material with a range of known variants and confirmed variant frequencies. Additionally, the continual assessment of assay performance is key to ensuring robust and reliable results.

Dr. Balbi will demonstrate how they have validated three targeted DNA sequencing panels for clinical diagnostic use, and assessed their limit of detection, using the Horizon Discovery Tru-Q controls.
### Evaluating T-Cell Clonality and Minimal Residual Disease (MRD) for Hematopathologic Diagnosis Using Next-Generation Sequencing

**Room:** 301A  
**Time:** 11:00 AM-11:50 AM  
**Hosted by:** Invivoscribe

Evaluating primary clonality is an essential component in the pathologic diagnosis of hematolymphoid proliferations. As diagnostic hematopathology navigates through the era of precision medicine, determination of lymphoid clonality by next generation sequencing (NGS) can provide insights into pathologic disease states that are helpful for diagnostic classification, in addition to providing greater clinical utility when compared with PCR clonality assays. Furthermore, NGS provides better detection of minimal residual disease (MRD) in mature B and T cell neoplasms and B-Acute Lymphoblastic Leukemia. MRD causes relapse in blood cancers, so it is vital to monitor patient remission status to efficiently detect recurrences.

### High-plex Digital Spatial Profiling Enables Characterization of Complex Immune Biology in the Tumor Microenvironment of Mesothelioma

**Room:** 304AB  
**Time:** 11:00 AM-11:50 AM  
**Hosted by:** NanoString Technologies

Malignant mesothelioma is an aggressive cancer with poor prognosis and few effective therapies. Since mesothelioma is derived from the mesothelium of the lung, we hypothesize that immune cells in the tumor microenvironment (TME) may behave differently than other solid tumors. Here we describe a novel combination of two technologies, Nanostring's Digital Spatial Profiling and Definiens' Immune-Oncology Profiling (IOP) to spatially characterize the interface between mesothelioma cells, stroma and immune cells in the TME in a high-plex, digital capacity.

### Creating Solutions to Support Clinical Decision Support Through High Performance Processing of Genomic and Clinical Data, Data Integration, Advanced Analytics, Machine Learning, and Reporting

**Room:** 214D  
**Time:** 11:00 AM-11:50 AM  
**Hosted by:** Oracle Health Science

Clinical decision support is a rapidly evolving area in research and clinical practice. We will present examples of innovative data management workflows that support the use of clinical and genomic data from source to reporting for research and clinical decision support at scale. These flexible workflows allow for the integration of tools for genomic data processing (such as GATK) in high-performance computing environments, data integration (clinical and genomic), data management and access control capabilities, analytics, machine learning and reporting. We will discuss the ability of these solutions to integrate with multiple environments and tools from both open-source and commercial sources.

### The Evolution of Speed and Robustness: Overcome Inhibitors and Gain Time with Mutated Polymerases from Roche Custombiotech

**Room:** 221CD  
**Time:** 11:00 AM-11:50 AM  
**Hosted by:** Roche

Inhibition is an inherent challenge in the development of PCR-based IVD assays. To cope with inhibitor presence in complex biological samples, laborious DNA extraction and purification methods are necessary. During this presentation you will learn how mutated DNA polymerases from Roche CustomBiotech can help overcome challenges posed by inhibitors, without sacrificing speed or assay performance. Join CustomBiotech for this industry workshop to explore the features of the mutated DNA polymerases and discover new options for your IVD development.
Precision Medicine Starts Here

Pushing the Envelope in Cancer Research – From Research to Future Oncology Disease Management

Room: 217A    Time: 11:00 AM-11:50 AM    Hosted by: Thermo Fisher Scientific

As the implementation of targeted therapies continue to rise, the relevance of molecular testing in prognosis and treatment management is becoming increasingly apparent. However, clinical gaps such as which patients should receive therapy and which patients should simply be observed, highlight the need for studies which lend to the identification and standardization of biomarkers that will change the current standards of care in patient management. This workshop will examine the studies at various institutions, and how they may ultimately lead to diagnostic improvements and better therapeutic management for patients fighting cancer.

Detecting HIV-1 Genotypic Resistances and Subtypes using the Vela Sentosa “Sample to Answer” Next Generation Sequencing System for Clinical Research

Room: 303C    Time: 11:00 AM-11:50 AM    Hosted by: Vela Diagnostics

Detecting HIV-1 Genotypic Resistances and Subtypes using the Vela Sentosa “Sample to Answer” Next Generation Sequencing System for Clinical Research.

MRD Assessment in the Clinical Management of ALL and Myeloma: Why Validation and Standardization Matter

Room: 302C    Time: 12:00 PM-12:50 PM    Hosted by: Adaptive Biotechnologies Corp.

The utilization of next-generation sequencing (NGS) technology to detect and quantify residual disease (MRD) is enabling advances in the assessment and management of patients with lymphoid cancers. Clinicians increasingly view MRD as a critical tool to inform clinical decision-making, so the selection of a reliable and robustly-validated clinical MRD assay is becoming an important decision in which pathologists should play a central role.

The clonoSEQ Assay is a CLIA-regulated LDT that is under review for FDA de novo 510(k) clearance for use in the detection and monitoring of MRD in bone marrow from patients with multiple myeloma and ALL.

Updates to the CAP/IASLC/AMP Molecular Testing Guidelines for Selecting Patients with NSCLC Practical Considerations and Real-World Examples

Room: 217D    Time: 12:00 PM-12:50 PM    Hosted by: Astrazeneca

This presentation will provide education on key updates to the CAP/AMP/IASLC EGFR guideline recommendations for molecular testing in patients with NSCLC. The program will focus on changes that directly affect clinical practice and will be illustrated using testing scenarios based on real-world cases.
Automation of NGS Library Generation Protocols to Haplotype-Resolve Structural Variation

Room: 302B  Time: 12:00 PM-12:50 PM  Hosted by: Beckman Coulter Life Sciences

Ashley D. Sanders*, Jürgen Zimmermann#, Vladimir Benes#, Jan Korbel*
*Genome Biology Unit, #GeneCore, European Molecular Biology Laboratory (EMBL)

Querying the human genome and transcriptome at the single cell level reveals not only a deep insight into cellular dynamics, but requires also a high degree of automation to generate NGS libraries reliably in a high-throughput fashion. We have automated several single cell NGS protocols, including Strand-seq, a single cell and single strand sequencing method that preserves the identity of individual homologues to immediately phase variants to their parental haplotypes, without the need for generational information.

Next Generation Sequencing of the Immune System: From Bulk RNA to Single Cell

Miranda Byrne-Steele, Ph.D.
Director Operations and R&D
iRepertoire

Advancing Precision Oncology: Current and Emerging Biomarkers and Pharmacodiagnostic Tools

Room: 301B  Time: 12:00 PM-12:50 PM  Hosted by: Bristol-Myers Squibb

The use of biomarkers in cancer treatment has allowed for increased patient segmentation. This has been enabled by advances in development of new biomarkers that allow for further characterization of the tumor microenvironment. This talk will focus on ongoing use of current and emerging biomarkers and use of composite biomarkers as pharmacodiagnostic tools that are paving the path towards precision medicine.

Engineered DNA Enzymes for Efficient NGS Workflows

Room: 303AB  Time: 12:00 PM-12:50 PM  Hosted by: Codexis Inc

Molecular diagnostic NGS assays are critically dependent on the ligation of sequencing specific adapters to patient derived DNA (e.g. FFPE, cfDNA). Inefficient ligation limits the potential clinical utility of any NGS molecular diagnostic, as it limits parameters such as test sensitivity. Given this, Codexis has engineered a novel DNA ligase, which has been specifically evolved to increase the efficiency of the critical adapter/DNA insert ligation process. This workshop will provide industry knowledge and insights from field testing sites on this ligase. We will illustrate its performance under a variety of library preparation workflows, and demonstrate its improvement to clinical utility.

The Panther Fusion® System – Expanding Your Lab’s Potential with a Growing Menu

Room: 217BC  Time: 12:00 PM-12:50 PM  Hosted by: Hologic

The Panther Fusion® GBS assay is the latest to join the growing Panther Fusion® portfolio. Join us to hear from presenters who have evaluated the performance of the Panther Fusion GBS assay compared to both culture and other molecular methods. Learn more about how to expand your laboratory’s molecular testing with the full Panther Fusion® system or add the Panther Fusion® module to your existing Panther® system. The Panther Fusion system joins the flexibility of PCR with the power of transcription-mediated amplification (TMA) to give your lab multiple valuable chemistries on a single platform.
**Tumor Heterogeneity from Tissue to Blood to Urine: Personalizing Medicine Cell by Cell**

*Room: 214A  Time: 12:00 PM-12:50 PM  Hosted by: IncellDx, Inc*

One of the diagnostic conundrums in the market today is the paradox between discussions of tumor heterogeneity and the common practice of digesting a tumor, purifying nucleic acids and performing NGS on a completely heterogenous sample with no context from which cells carry specific mutations. Profiling individual cells for protein, mRNA, and cell cycle has yielded extensive information on the behavior and the therapeutic possibilities on cell by cell to the point where one can predict who will respond/regress and who will have metastatic/progressive disease. Possible approaches to answer these questions will be presented at this symposium.

**Guidelines for the Interpretation and Reporting of Sequence Variants in Cancer**

*Room: 214C  Time: 12:00 PM-12:50 PM  Hosted by: PierianDx*

Broader adoption of next-generation sequencing-based cancer testing reveals the challenges associated with variant interpretation and underscores the need to standardize results across molecular pathology labs. In this informative workshop, we review the guidelines developed by the Association for Molecular Pathology (AMP) and describe how to put them into practice using real clinical cases.

**Evaluating NGS Liquid Biopsy and Tumor Tissue Assays**

*Room: 221CD  Time: 12:00 PM-12:50 PM  Hosted by: Roche*

Workshop attendees will learn about the capabilities of three new RUO next-gen sequencing kits for Tumor Tissue and their concordance with the existing AVENIO ctDNA Analysis Kits. First a Roche speaker will introduce the three new kits and present internally generated research data on FFPET samples. In the second half of the workshop, Dr. Shelly Gunn, Chief Medical Officer of ResearchDx, will describe her experience evaluating the new Tumor Tissue Kits in her laboratory, which has already validated the AVENIO ctDNA Analysis Kits.

**Detecting HCV Genotypic Resistances, Genotypes and Subtypes using the Vela Sentosa “Sample to Answer” Next Generation Sequencing System for Clinical Research**

*Room: 303C  Time: 12:00 PM-12:50 PM  Hosted by: Vela Diagnostics*

Detecting HCV Genotypic Resistances, Genotypes and Subtypes using the Vela Sentosa “Sample to Answer” Next Generation Sequencing System for Clinical Research.

**1:00 PM – 1:50 PM**

**Implementation of a Comprehensive NGS Panel at a Community Cancer Center**

*Room: 302A  Time: 1:00 PM-1:50 PM  Hosted by: Beckman Coulter Life Sciences*

Qi Wei, Ph.D.
Director, Genomics Laboratory Service
Miami Cancer Institute

Cancer is a disease of the genome. In the management of cancer patients, actionable mutations in cancer-associated genes are critical in the selection of the therapies. Next-generation sequencing (NGS) of tumor samples DNA can guide clinical management by providing diagnostic and prognostics insight to facilitate the identification of potential treatment regiments, such as targeted and immune therapies. Here we present our experience on the selection and implementation of a comprehensive NGS cancer panel (Illumina TruSight Tumor 170) in a community cancer center.

**Genomic Landscape of Meningioma**

Adriana Olar, M.D.
Assistant Professor of Pathology and Laboratory Medicine and Neurosurgery
Medical University of South Carolina & Hollings Cancer Center
Evaluation of Quantitative EBV and BKV LDT Implementation on the Open, Automated NeuMoDx 288 Molecular System

Room: 304C  Time: 1:00 PM-1:50 PM  Hosted by: NeuMoDx Molecular

NeuMoDx Molecular has developed a ‘sample to result’ platform capable of enabling rapid implementation of real-time PCR based LDTs resulting in significantly increased automation and improved flexibility.

In this workshop, Steve Young, Ph.D. Director of Research and Clinical Trials at TriCore Reference Laboratories will present results of implementing quantitative LDTs for EBV and BKV targets in plasma specimens on the open, automated NeuMoDx™ 288 molecular system. Steve will share TriCore’s experiences in implementing the assays as well as review various performance characteristics of both assays.

Rapid Prediction of Antibiotic Resistance Using OpGen’s Acuitas® AMR Gene Panel u5.47 (RUO) and Acuitas Lighthouse®

Room: 301C  Time: 1:00 PM-1:50 PM  Hosted by: OpGen, Inc.

Effective, targeted antimicrobial treatment is of critical importance in patients with complicated urinary tract infection (cUTI) as the emergence and spread of antimicrobial resistant pathogens increase. OpGen has developed a rapid molecular test for research use only that detects 5 pathogens and 47 resistance genes covering 9 antibiotic classes direct from urine specimens and isolates. When used with complementary analytics (Acuitas Lighthouse®), the RUO assay is the first to quickly predict resistance for 15 antibiotics. Please join us for an overview and update on preliminary performance data.

Rapid Cancer Testing as an Integral Part of Precision Oncology

Room: 301A  Time: 1:00 PM-1:50 PM  Hosted by: Promega

Next Generation Sequencing (NGS) plays a critical role for comprehensive assessment of relevant mutations in cancer. However, turnaround times for NGS – in some settings – are still too slow (e.g., acute leukemia, aggressive end-stage NSCLC). In this presentation, Dr. Dias-Santagata will describe the development of several rapid cancer testing workflows for sample preparation to deliver timely, comprehensive NGS data. As an additional function of the workflow development, streamlined machine-learning powered NGS results in improved reporting times and integrated data analytics.

Complementary Detection of Somatic Variants from Tissue and Plasma Samples Using the AVENIO Family of NGS Oncology Assays

Room: 221CD  Time: 1:00 PM-1:50 PM  Hosted by: Roche

Workshop attendees will hear about a lab’s experiences in evaluating and adopting the AVENIO ctDNA Analysis Kits for the evaluation of liquid biopsy samples. An overview of the lab’s validation process will also be presented, and performance data will be shown. Come ask questions about the results and implementation of these liquid biopsy-based kits.

Achieving Better ctDNA Assay Sensitivity – Laboratory Perspectives

Room: 304AB  Time: 1:00 PM-1:50 PM  Hosted by: SeraCare Life Sciences, Inc.

Non-invasive ctDNA testing of cancer patients for treatment decisions and monitoring is a major advance towards precision diagnostics. One of the greatest challenges for ctDNA assays is to achieve assay sensitivities required for clinical applications while preserving specificity and overall assay performance. At this session, two perspectives will be presented. Tony Godfrey, PhD, Boston University Medical Center, will discuss the highly sensitive SiMSen-Seq assay that is being optimized to achieve 0.05% variant allelic fractions and Bob Daber, PhD, Gnosisity Consults, will discuss his experience optimizing highly sensitive ctDNA assays for routine use in clinical laboratories.
Obtaining Clinically Relevant Sequencing Readout from Single Cells and Cell Free DNA

Room: 214B   Time: 1:00 PM-1:50 PM   Hosted by: Takara Bio USA

In this workshop, we will present data using novel library preparation workflows that enable NGS from single cells, trophoblasts, cell-free DNA, FFPE, fine needle aspirates, and other challenging sample types. These methods allow researchers and clinicians to obtain clinically relevant information from their sequencing data such as CNV, SNV, indels, and other genomic aberrations. Incorporation of unique molecular tags to enhance sensitivity will be described. The simple, single-tube workflows are easily portable to a wide array of automation platforms for high-throughput sample processing. A broad range of indexes, including unique dual indexes (UDIs) can also be used to increase read assignment confidence.

Next Generation Sequencing meets Next Generation Automation

Room: 214D   Time: 1:00 PM-1:50 PM   Hosted by: Tecan

Next Generation Sequencing technologies are adapting at a very fast pace due to the new demands from users: shorter and more simple protocols, with reduced hands-on time, that give top quality and reproducible results. Kits are evolving following these trends and so are the automation technologies. Tecan has been developing solutions to offer users longer walk-away times and a friendlier and more intuitive user-experience.

Driving down the Cost of Microbial Testing Through Flexible-content Syndromic Panels - Leveraging Nanofluidic and Microfluidic Form-factors on Real-time PCR Platforms

Room: 217A   Time: 1:00 PM-1:50 PM   Hosted by: Thermo Fisher Scientific

The development of commercially available, panel-based molecular pathogen detection tests has provided many benefits to laboratories. Some challenges still exist – including scalability in throughput, decreasing cost per sample, and increasing content flexibility to meet the ever-changing needs for detecting pathogenic targets. Join our workshop to learn how laboratories can drive down the cost of microbial testing with the utilization of nanofluidic and microfluidic solutions. Hear from laboratories that have implemented this technology, selected their own pathogen targets, all while minimizing the cost of testing using real-time PCR technology. This workshop will focus on respiratory, vaginal, and urinary tract microbiota detection.

Vela Diagnostics’ Microbiology Workshop

Room: 303C   Time: 1:00 PM-1:50 PM   Hosted by: Vela Diagnostics

Molecular Diagnostic testing: overcoming cost and ease-of-use challenges in Near-Patient Testing.

2:00 PM – 2:50 PM

Avoid the Compromise: How the Agena MassARRAY System Uniquely Addresses Multiple Challenges in Routine Solid Tumor and Liquid Biopsy Testing

Room: 217BC   Time: 2:00 PM-2:50 PM   Hosted by: Agena Bioscience

When implementing solid tumor and liquid biopsy testing, there are many challenges that need to be considered such as cost, turnaround time, sample input, and limit of detection. Clinical labs are often forced to settle on addressing only one or two of these challenges as most technologies are limited to a few enabling features. In this session, Dr. Doug Demetrick from Calgary Lab Services and Dr. Pierre-Jean Lamy from Imagenome will demonstrate how the Agena MassARRAY System uniquely addresses these challenges compared to other technologies such as digital droplet PCR and Next Generation Sequencing.
Implementing NGS to Quantify Human and Pathogen Tumor Markers in Plasma and Tissue

Room: 302C  Time: 2:00 PM-2:50 PM  Hosted by: ArcherDx

Margaret Gulley, MD from the UNC School of Medicine describes her group’s method to quantify cancer mutations alongside tumor-related viral and bacterial pathogens in plasma and FFPE tissue using modified off-the-shelf Archer NGS reagents combined with Archer Analysis bioinformatics. She will discuss analytic and clinical interpretation criteria and the value of molecular barcodes and noise reduction algorithms in patient and control DNA. Dr. Gulley will be introduced by Aaron Garnett, PhD, Assay Development Group Lead at ArcherDx.

Multidisciplinary Approach to Optimal and Timely Testing in Lung Cancer

Room: 217D  Time: 2:00 PM-2:50 PM  Hosted by: AstraZeneca

Optimal management of patients with advanced/metastatic NSCLC with targetable mutations depends heavily on comprehensive biomarker testing results. Establishing good communication among the various medical disciplines involved in patient care is essential for optimal testing and treatment decisions resulting in the most appropriate administration of therapy and improved patient care. This workshop, led by a medical oncologist and a pathologist, will illustrate the importance of coordinated care through a multidisciplinary approach to ensure the timely implementation of evolving testing and treatment guidelines.

Current and Emerging Biomarkers: Science, Technologies, and Practicalities

Room: 301B  Time: 2:00 PM-2:50 PM  Hosted by: Bristol-Myers Squibb

At Bristol-Myers Squibb, we recognize pathologists play a crucial role in furthering advancements that may help predict which patients are likely to benefit from immuno-oncology therapies. Join us as we explore one of the hottest topics in molecular pathology: immuno-oncology biomarkers. Light refreshments will be provided.

A Novel Solution to FFPE Extraction Challenges for Downstream Clinical Assays

Room: 302B  Time: 2:00 PM-2:50 PM  Hosted by: Covaris, Inc.

Extracting nucleic acids from FFPE samples for downstream clinical assays including Next-Generation Sequencing (NGS) is a labor-intensive process that is highly variable depending on the sample and extraction method. Covaris has developed a novel solution to address these extraction challenges. Using Adaptive Focused Acoustics® (AFA®), Covaris truXTRAC FFPE enables high throughput, reproducible extraction of high yield, NGS-grade nucleic acids from FFPE, reducing QNS rates. This session explores how truXTRAC FFPE enabled OmniSeq, Inc., a CAP accredited molecular diagnostic laboratory, to improve overall comprehensive molecular and immune profiling of patient tumors using a novel process for automated DNA and RNA extraction.

The Global Explosion of Resistant Pathogens: What Can Be Done?

Room: 214A  Time: 2:00 PM-2:50 PM  Hosted by: GenePOC

Carbapenem-resistant Gram-negative organisms (CROs), such as carbapenem resistant Enterobacteriaceae (CRE), are an emerging threat due to multidrug resistance and limited discovery of new antibiotics. The global spread of CRE has been fostered by the lack of pre-emptive screening of patients in healthcare facilities that could prevent patient-to-patient transmission. In the USA, CRE alone have been estimated to cause 9,000 infections and 600 deaths per year (CDC). While traditional methods such as chromogenic culture and antimicrobial susceptibility testing are important in phenotypic detection of CROs, molecular testing is the gold standard for rapid detection of carbapenemases genes in patient samples.
Real-life Applications using NEXTFLEX® Amplicon Panels to Better Understand Infertility and Inherited Diseases

Well-designed amplicon NGS panels represent efficient tools to target significant variants and minimize sequencing costs. We discuss real-life applications and performance of a custom NEXTFLEX® amplicon panel that interrogates key variants clinically recognized in infertility and inherited disorders for clinical research. This research is intended to improve reproductive health and decrease the odds of the inheritance of single gene disorders. We describe challenges associated with amplicon design and laboratory workflows, and we ultimately offer potential solutions for routine laboratory environments.

Join us to learn about the speaker’s experience with NEXTFLEX® panels as a comprehensive and cost-efficient library preparation solution.

Tumor Mutational Burden (TMB) Analysis Across Multiple Genomic Platforms with Considerations for Sample Type Utility and Effects on Numerical Representation

Learn about the impact of molecular endpoints for facilitating therapeutic selection with considerations to the patient’s immune response. Determining the tumor mutational burden (TMB) has increased in adoption as a biomarker, but how it is determined and implications on interpretation are not standardized.

Discover conventions for TMB calculation plus algorithm approaches and effects across matched samples tested with Exome, targeted panels, independent of normal samples. Using colorectal cancer specimens, we will demonstrate utility for extending traditional biomarker testing of FFPE into liquid biopsy inclusive of TMB calculation. Finally, we will review updates enhancing algorithms calling TMB with tumor tissue only, showing high linearity concordance to paired calls with high reproducibility and RNA-Sequencing.

Expanding Applications on the Genereader NGS System to Address Unmet Needs in Cancer Testing

As cancer genetics evolves and new clinical trials and data emerge, it has become increasingly critical to capture complete tumor molecular profiles. Examples of such applications include measuring TMB, detecting CNVs in susceptibility genes BRCA1/2, and capturing fusion events in lung cancer. NGS serves as an important tool for such interrogations, but major gaps remain in performance robustness and workflow standardization. The GeneReader NGS System adds an expanded menu with integrated solutions to specifically address these unmet needs and technical challenges. Join us in this workshop to find out how any lab can start their journey to Precision Medicine.


As healthcare costs continue to rise, health delivery systems and providers are under increasing pressure to deliver quality care with decreasing resources. This workshop will describe a medication management framework that utilizes pharmacogenetic (PGx) testing as a component of a holistic medication management strategy; and as such, provides one of the clearest opportunities for health systems to remain competitive and reduce costs while improving patient outcome. Join our workshop to hear how programs around the world use PGx testing to improve financial and health outcomes – and the impact on healthcare program ROI metrics.
Validation and Implementation of a Custom Hematologic Neoplasm NGS Panel

Room: 302C  Time: 3:00 PM-3:50 PM  Hosted by: ArcherDx

Jay Brock, PhD from Cleveland Clinic describes his group's experience validating and bringing up a custom DNA-based Archer® myeloid NGS assay combined with the Archer Analysis bioinformatics platform for use in their institution. Dr. Brock will be introduced by Katie Moore, PhD, Assay Development Group Lead at ArcherDX.

Update: The Latest in Molecular Testing for P. jirovecii and Group B Strep

Room: 214B  Time: 3:00 PM-3:50 PM  Hosted by: DiaSorin Molecular

Molecular testing is quickly becoming the gold standard for many infectious diseases. The latest in molecular testing for P. jirovecii and Group B Strep will be presented. In this workshop, Dr. Wallace Greene from Penn State College of Medicine, Hershey Medical Center will discuss converting Pneumocystis jirovecii testing from DFA to molecular. Dr. Raquel Martinez from Geisinger Medical Laboratories will discuss Group B Strep diagnostics and results from the clinical study for Simplexa Group B Strep Direct.

Clinical Application of Methylated DNA for Early Detection of Cancer

Room: 302A  Time: 3:00 PM-3:50 PM  Hosted by: Epigenomics, Inc.

Epigenomics will be presenting on further advancement of the US Commercial product, Epi proColon, with respect to pre-analytical automation and clinical studies/applications. Guest speakers/partners will share their experiences with performance and outreach to urban and rural communities. The clinical studies team will share status on investigator lead studies and PDA-approved post approval studies. Speakers will also discuss recent advancements methylated DNA in liver cancer detection.

Transforming Targeted NGS Panels through AI-Driven Analysis and Reporting

Room: 303C  Time: 3:00 PM-3:50 PM  Hosted by: Fabric Genomics

Advances in NGS coupled with decreased costs and growing reimbursements are opening the door for broader use of panels for hereditary and somatic cancers and pediatric, rare, cardiovascular, and neurological diseases. In this workshop, learn how Fabric Genomics provides diagnostic labs with flexible tools to quickly interpret and report genomic data while minimizing turnaround time, using step-by-step workflows and dashboards.

Dale Hedges, Ph.D., Senior Clinical Bioinformatics Scientist, St. Jude Children's Research Hospital, will present pediatric cancer cases, including retinoblastoma, medulloblastoma, and recurrent rhabdomyosarcoma, using Fabric Enterprise in their targeted sequencing panel workflows for variant annotation and classification.

MH Guide – A Streamlined Workflow for Variant Interpretation and Reporting

Room: 304C  Time: 3:00 PM-3:50 PM  Hosted by: Molecular Health

MH Guide was built and optimized to streamline and simplify the interpretation and reporting of variants in somatic testing. MH Guide provides pre-curated variant interpretations based on AMP classification system. All pre-curated variant interpretations are reviewed and approved by molecular pathologists and oncologists and updated regularly. The high-quality annotations and optimized workflow standardize the preparation of clinical reports in an efficient manner to shorten your turn-around times and exceed customers’ expectations.

This workshop will provide an introduction to our technology and a short demo of MH Guide, followed by a hands-on session for you to work through cases.
Molecular Profiling of Malignancies by NGS and FISH

Room: 301A          Time: 3:00 PM-3:50 PM          Hosted by: Oxford Gene Technology

This two part presentation demonstrates: 1) the effectiveness of NGS in determining the mutational status of hematologic malignancies samples 2) a novel approach integrating different technologies, including FISH, to identify immunotherapy biomarkers in a wide spectrum of solid tumors.

I. A custom NGS Panel for the analysis of hematological malignancies: the approach in Ontario (Speaker: José-Mario Capo-Chichi PhD, FACMG, FCCMG, Clinical Molecular Geneticist, University Health Network, Toronto)

II. PD-L1/2 amplification in solid tumors and response to checkpoint inhibitors (Speaker: Dr. Carl Morrison, President and Chief Medical Officer, Omniseg Inc. and Professor of Pathology, Roswell Park Comprehensive Cancer Center)

Supporting NGS-Based IVD Assays with the Most Accurate, Comprehensive and Clinically Robust KnowledgeBase

Room: 214D          Time: 3:00 PM-3:50 PM          Hosted by: PierianDx

Clinical NGS has been widely adopted as Laboratory Derived Tests (LDTs). NGS-based in vitro diagnostics (IVD) recently gained FDA approval with many others now in process. These IVD assays facilitate broad, widespread adoption of NGS-based testing globally in cancer and other complex conditions that require timely, accurate diagnoses and treatment. To support comprehensive interpretation of these assays, we have developed the PierianDx KnowledgeBase. Driven by the richest set of curated and rationalized content of medical interpretations, clinical practice guidelines, FDA therapeutics and clinical trials, the PierianDx KnowledgeBase offers the most well-vetted interpretations and classifications of genomic variants for IVD use.

Why Microsatellite Instability (MSI) Characterization of Tumors by PCR Is Still the Gold Standard in a World of NGS

Room: 221CD          Time: 3:00 PM-3:50 PM          Hosted by: Promega

AMP, CAP and the NCI have recognized the prognostic utility of MSI characterization for decades. In 2017, the FDA named MSI as a tumor biomarker for immunotherapeutic treatment of all cancers types, thus extending the utility of this trusted biomarker for an exciting new indication in the selection of patients with unresectable or metastatic MSI-High solid tumors.

This presentation will cover both basic and advanced topics of characterizing MSI status of tumor tissue using PCR and capillary electrophoresis and why this method is still the gold standard globally and likely to remain so into the future.

Identification of Inherited Genetic Risk Factors of Pancreatic Cancer Using a Targeted Sequencing Approach in a Large Cohort

Room: 221AB          Time: 3:00 PM-3:50 PM          Hosted by: QIAGEN

Pancreatic cancer has one of the worst survival outcomes for any type of cancer. Given the high fatality rates, identifying individuals at risk by testing for inherited susceptibility is crucial for improving outcomes. Join us in this workshop to hear Dr. Fergus Couch from the Mayo Clinic discuss his lab's study where 21 cancer predisposition genes were sequenced using a QIAseq targeted DNA panel to determine which ones were associated with an increased risk for pancreatic cancer. The study consisted of 3,030 cases and 123,136 controls and discovered genes independently associated with disease.

Modified Oligonucleotides: Core to Molecular Diagnostics, Therapeutics, Genomics, and Gene Editing

Room: 304AB          Time: 3:00 PM-3:50 PM          Hosted by: TriLink BioTechnologies

This presentation will provide a brief overview of current oligonucleotide synthesis methods that allow the production of highly modified oligonucleotides. The “tool-box” of base, sugar, and backbone modifications as well as conjugates will be reviewed, and the use of various constructs in target capture, amplification, detection, and other applications will be highlighted. Additionally, specific details related the Hybridization Protection Assay (HPA) assay that has been used clinically in hundreds of millions of assays for infectious disease detection, as well as the Switch-Blocker technology that enables the ultra-high sensitivity of detection of rare cancer associated mutations in patients, will be presented.
Chimerism Made Easy: How the ChimericID Panel for the MassARRAY System Simplifies Traditional STR-Based Chimerism Testing

Room: 217BC  Time: 4:00 PM-4:50 PM  Hosted by: Agena Bioscience

Current bone marrow engraftment chimerism testing requires time-intensive results interpretation by specialized staff. The SNP-based ChimericID panel for the MassARRAY System offers intuitive data analysis and efficient laboratory workflow. In this session, you will learn how implementing this panel reduces staff time and simplifies results reporting.

Integration of Archer Analysis into Clinical Reporting Platform

Room: 302C  Time: 4:00 PM-4:50 PM  Hosted by: ArcherDx

Archer® Analysis is a versatile bioinformatics platform that automates the processing of sequencing data generated from all Archer NGS assays. This versatility extends to the ability to integrate Analysis into various upstream data preparation and downstream reporting platforms. In this workshop, Aaron Berlin, Vice President of Bioinformatics and Commercial Development at ArcherDX, will introduce Archer Analysis and describe recent updates that improve accuracy in variant calling and integration. Then Bob Daber, PhD, DABMG, President and Chief Technology Officer at Genosity, will describe how his team integrated Archer Analysis into their clinical reporting software.

Powerfully Fast and Suitable for Any Lab – Fully-automated Molecular Testing with Idylla™

Room: 301B  Time: 4:00 PM-4:50 PM  Hosted by: Biocartis

Turnaround time remains a major issue in molecular biomarker testing. Learn how the fully-automated Idylla™ platform can help improve turnaround times in virtually any lab. Hear from Dr. Arcila, Director of the Diagnostic Molecular Pathology Laboratory at Memorial Sloan Kettering Cancer Center, on how they use Idylla™ as an ultra-rapid complement to their NGS platform.

Get firsthand perspectives on the first-ever fully-automated solution for MSI status determination – directly from FFPE tissue without the need of concurrent testing of a normal control. Dr. Nafa from Memorial Sloan Kettering Cancer Center, will share her experiences with the new Idylla™ MSI assay.

Expanding the use of Droplet Digital™ PCR for Clinical Applications

Room: 217D  Time: 4:00 PM-4:50 PM  Hosted by: Bio-Rad Laboratories

Layatories around the world are using Droplet Digital PCR (ddPCR) for a wide variety of clinical applications, from liquid biopsy analysis to minimal residual disease monitoring and newborn screening. Dr. Dobrovic will share his experience with clinical implementation of ddPCR for cancer diagnostics and screening. All information refers to use of laboratory developed tests (LDTs).

Speaker: Associate Prof. Alexander Dobrovic PhD, Head, Translational Genomics & Epigenomics Laboratory
Olivia Newton-John Cancer Research Institute

Moving from Bulk NGS to Precision Sequencing with Single-Cell Genomics: Resolving Heterogeneity in Blood and Solid Tumors

Room: 214A  Time: 4:00 PM-4:50 PM  Hosted by: Mission Bio

The average read-out from conventional bulk (NGS) sequencing misses the rare events and underlying genetic diversity within and across cell populations. To improve patient stratification, therapy selection, and disease monitoring, we need insights into clonal evolution and mutation co-occurrence within every single cell. The Tapestry™ Precision Genomics Platform enables precision sequencing with the sensitive and unambiguous identification of multiple co-occurring mutations within subclones that drive disease and is not possible with bulk NGS measurements. In this workshop, hear from translational and pathology labs characterizing heterogeneity with mutational signatures at the single-cell level to move precision medicine forward.
### Making the Right Calls in Precision Oncology

**Room:** 303AB  
**Time:** 4:00 PM-4:50 PM  
**Hosted by:** N-of-One Inc

As the number of targetable alterations expands, and the pace of drug development quickens, oncologists seek solutions that can meet the new challenges this extensive body of data presents. Artificial Intelligence has made strides across several applications over the past few years, but it has struggled to find a successful place in precision oncology.

This panel will discuss the current status of AI in the field, the importance of expert curation and judgement to provide consistent and accurate clinical interpretation that is backed by defendable and transparent evidence, and where AI might appropriately fit as precision oncology continues to evolve.

### Ultra-High Multiplexed and Molecular-Barcoded NGS Panels to Enable Genomic-Based Healthcare and Science

**Room:** 214C  
**Time:** 4:00 PM-4:50 PM  
**Hosted by:** Paragon Genomics, Inc.

Establishing NGS tests with high accuracy, reproducibility, ease-of-use, and scalable content is essential to meeting the demands in translational research and molecular assay development. We have developed novel ultra-high multiplex PCR-based target enrichment technologies to overcome the limitations of existing methods. CleanPlex and CleanPlex UMI NGS panels provide a proven, rapid, flexible, customizable, and cost-effective solution to accelerate the development of NGS-based assays. In this workshop, we will showcase how we have helped researchers design custom NGS panels to advance their work. We will also present our new molecular barcoding technology developed for precise analysis of ctDNA from liquid biopsies.

### Delivering on the Promise of Fast Point-of-care Syndromic Testing with QIAstat-DX

**Room:** 221AB  
**Time:** 4:00 PM-4:50 PM  
**Hosted by:** QIAGEN

Acute respiratory tract infections are caused by a wide range of viral and bacterial pathogens, and may share similar clinical presentations. Syndromic testing with multiplex molecular panels allows clinical labs to quickly distinguish between a broad array of respiratory pathogens. The QIAstat-Dx offers detection of a range of respiratory pathogens in about an hour, with less than a minute of hands-on time. Join us in this workshop to find out how the next generation of syndromic insights will allow you to deliver diagnostic information with confidence, and facilitate fast therapeutic decision-making.

The QIAstat-Dx is not currently available in the US.

### How Can Labs Implement a Best-In-Class, Robust, and Compliant Next-Generation Sequencing QC Program?

**Room:** 302B  
**Time:** 4:00 PM-4:50 PM  
**Hosted by:** SeraCare Life Sciences, Inc.

Clinical laboratories face many challenges adopting new technologies into clinical testing. One of the most critical is achieving CAP CLIA regulatory compliance. Next-generation sequencing technology provides many challenges due to complex sample preparation, multi-step sequencing, and data analysis workflows. These challenges extend to the overall QC strategy. At this session, two scientific thought leaders in advanced molecular pathology - John Pfeifer, MD, Washington University School of Medicine and Greg Tsongalis, PhD, Dartmouth Hitchcock Medical Center - will discuss their experiences applying up-to-date quality control systems and standardization to NGS oncology assays in order to meet current guidelines and regulatory compliances.
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November 6

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At Bristol-Myers Squibb (BMS), we recognize pathologists play a crucial role in furthering advancements that may help predict which patients are likely to benefit from Immuno-Oncology (I-O) therapies.

Bristol-Myers Squibb is looking at multiple I-O biomarkers to help identify new ways to understand a patient’s immune response to a tumor. These biomarkers may have the potential to change how cancer is treated through personalized I-O therapy selection. BMS is dedicated to discovering predictive I-O biomarkers that can help pathologists support better patient outcomes.

To learn more, visit us at Booth 924 at the Association for Molecular Pathology Annual Meeting in San Antonio, November 1–3, 2018.

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