# AMP 2022

## ANNUAL MEETING & EXPO

November 2, 2022 | Phoenix, AZ

# Corporate Workshop Program

Phoenix Convention Center

AMP Association for Molecular Pathology

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# WELCOME TO AMP 2022 WORKSHOP DAY!

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**Agilent Technologies***

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Arc Bio LLC

Arima Genomics

**AstraZeneca***

**Asuragen***

ATCC

Biocartis

Biolyph

Bionano Genomics

**Bio-Rad Laboratories, Inc***

Blueprint Medicines

Canexia Health

Caris Life Sciences

**Cepheid***

Codexis, Inc.

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**Eli Lilly and Company***

Fabric Genomics

**Illumina***

Integrated DNA Technologies

Invivoscribe

LGC, Biosearch Technologies

LGC Clinical Diagnostics

Meridian BioScience Inc.

MiRXES Corporation

Mission Bio

NanoString Technologies

OGT

Oxford Nanopore Technologies Ltd.

Paragon Genomics, Inc.

PerkinElmer

Personal Genome Diagnostics

**Pierian***

Pillar Biosciences Inc.

Promega Corporation

Purigen Biosystems, Inc.

QIAGEN

**Roche***

Seegene Technologies

**SOPHiA GENETICS***

STEMCELL Technologies, Inc.

Tecan

**Thermo Fisher Scientific***

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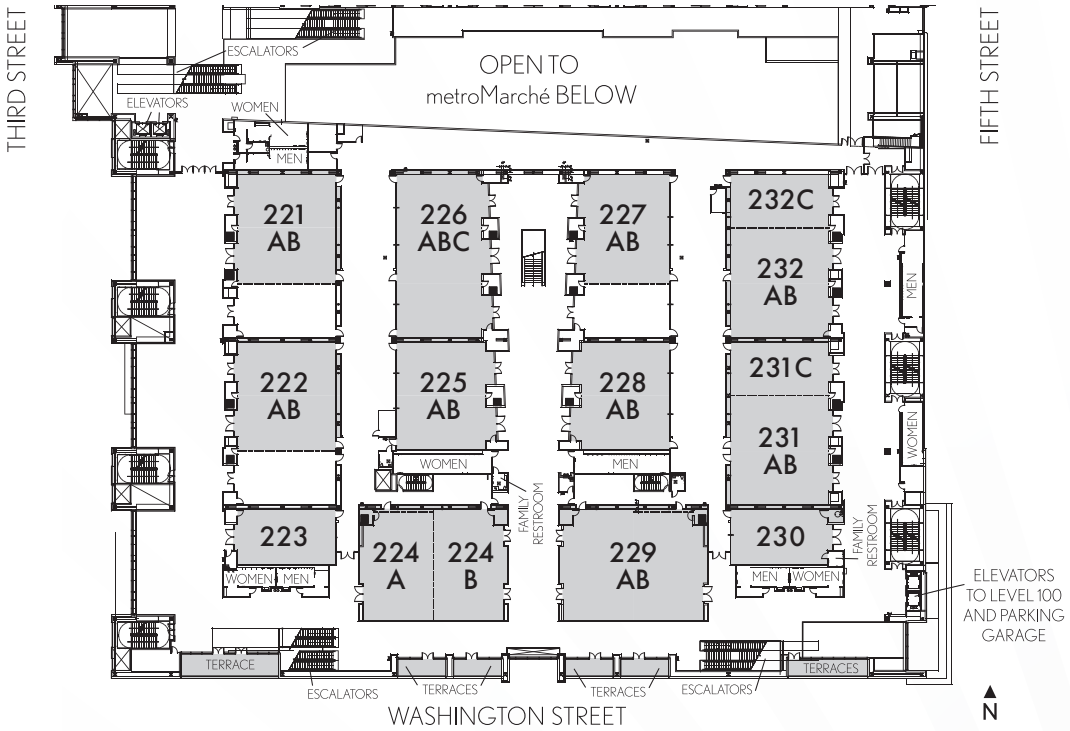
# CORPORATE WORKSHOPS

## PHOENIX CONVENTION CENTER, NORTH BUILDING



## AMP 2022 CORPORATE WORKSHOP DAY SCHEDULE AT A GLANCE

| START | END | TITLE | HOST | ROOM |
|---|---|---|---|---|
| **8:00 AM** | | | | |
| 8:00 AM | 8:50 AM | **Advancement of Pharmacogenomic (PGx) Testing: Development of Evidence-Based Guidelines and the Ongoing Effort to Drive Alignment with Regulatory Bodies** | Agena Bioscience | 221AB |
| 8:00 AM | 8:50 AM | **Companion Diagnostic Use of DNA Mismatch Repair Immunohistochemistry (MMR IHC) in Solid Tumors** | Roche | 230 |
| 8:00 AM | 8:50 AM | **Implementing an FDA Cleared Comprehensive Genomic Profiling (CGP) Solution with a Path to Reimbursement** | Personal Genome Diagnostics | 228AB |
| 8:00 AM | 8:50 AM | **Performance of the FDA-Cleared OncoMate™ MSI Dx Analysis System** | Promega Corporation | 232C |
| 8:00 AM | 8:50 AM | **Spatial Biology Innovations Pathway to the Clinic (Session 1 of 2)** | NanoString Technologies | 222AB |
| 8:00 AM | 8:50 AM | **Transplant Standardization: How Labs Can Help Shape Patient Care** | Roche | 231C |
| 8:00 AM | 8:50 AM | **Use of a Novel Blood Biomarker Test as an Aid in the Detection of Gastric Cancer** | MiRXES Corporation | 226ABC |
| **9:00 AM** | | | | |
| 9:00 AM | 9:50 AM | **Comparative Analysis of Testing Methods Used for the Detection of Internal Tandem Duplications in the KMT2A/MLL Gene; Comparison of Mutation Profiles in MDS and AML: A Single Site Experience** | OGT | 231AB |
| 9:00 AM | 9:50 AM | **Decision Medicine™: Helping Pathologists and Oncologists Obtain Individualized, Actionable and Highly Accurate Genomic Data in as Little as 48 Hours** | Pillar Biosciences Inc. | 232AB |
| 9:00 AM | 9:50 AM | **Development of High-Throughput Assays for Gene Editing Program** | Promega Corporation | 232C |
| 9:00 AM | 9:50 AM | **Fast NGS for Targeted and Comprehensive Cancer Genomic Profiling** | Thermo Fisher Scientific | 224B |
| 9:00 AM | 9:50 AM | **Liquid Biopsy—Improving Patient Access to Precision Oncology Through Centralized Services and Decentralized Kitted Solutions** | Personal Genome Diagnostics | 228AB |

## AMP 2022 CORPORATE WORKSHOP DAY SCHEDULE AT A GLANCE

| START | END | TITLE | HOST | ROOM |
|---|---|---|---|---|
| **9:00 AM (CONTINUED)** | | | | |
| 9:00 AM | 9:50 AM | **Maximizing Detection of Pathogenic Structural Variants Across Hematological Malignancies with Optical Genome Mapping** | Bionano Genomics | 229AB |
| 9:00 AM | 9:50 AM | **Post-Pandemic Molecular Diagnostics: Opportunity, Strategy, and Mechanisms** | Thermo Fisher Scientific | 224A |
| 9:00 AM | 9:50 AM | **Rethinking Solid Tumor Profiling: How the Massarray Complements NGS to Optimize Testing Throughout the Treatment Journey** | Agena Bioscience | 221AB |
| 9:00 AM | 9:50 AM | **Spatial Biology Innovations Pathway to the Clinic (Session 2 of 2)** | NanoString Technologies | 222AB |
| 9:00 AM | 9:50 AM | **Start One-Step Ahead: Roche Custombiotech Glycerol-Free Reagents in High Concentration Designed for Use in Dried-Down Assays** | Roche | 231C |
| 9:00 AM | 9:50 AM | **Frontline Multiplex Panel Testing and Reimbursement Challenges—From Respiratory to Gastrointestinal** | Applied BioCode, Inc. | 227BC |
| **10:00 AM** | | | | |
| 10:00 AM | 10:50 AM | **Advanced NGS Methods for Molecular Testing in Hematological Malignances** | Thermo Fisher Scientific | 224B |
| 10:00 AM | 10:50 AM | **An Extraction Free Method for the Semi-Quantitative Identification of Uropathogens from Urine and Kidney Stones** | Integrated DNA Technologies | 226ABC |
| 10:00 AM | 10:50 AM | **Comprehensive Assessment of HRD from Next-Generation Sequencing and Optical Genome Mapping** | Bionano Genomics | 229AB |
| 10:00 AM | 10:50 AM | **Demonstrating the Clinical Utility of Long Mononucleotide Repeats Through Collaborative Clinical Research Program** | Promega Corporation | 232C |
| 10:00 AM | 10:50 AM | **Improve Clinical Outcomes with Precision Oncology by Testing for All Actionable Biomarkers Before Treatment Selection** | Eli Lilly and Company | 230 |
| 10:00 AM | 10:50 AM | **Lymph2Cx/Lymph3Cx from Bench to Clinic—Developing Genomic Tests that Guide DLBCL Diagnosis and Treatment Using the nCounter Platform** | NanoString Technologies | 222AB |

## AMP 2022 CORPORATE WORKSHOP DAY SCHEDULE AT A GLANCE

| START | END | TITLE | HOST | ROOM |
|---|---|---|---|---|
| **10:00 AM (CONTINUED)** | | | | |
| 10:00 AM | 10:50 AM | **MAKO Medical Expands Surveillance Testing Menu to Include Monkeypox** | Thermo Fisher Scientific | 224A |
| 10:00 AM | 10:50 AM | **Navigating Gold Standard Testing This Respiratory Season** | Roche | 231C |
| 10:00 AM | 10:50 AM | **Optimizing FFPE Extraction for Methylation Array and Sequencing Assays** | Purigen Biosystems, Inc. | 225AB |
| 10:00 AM | 10:50 AM | **Utilization of Unity Data Management Solutions for Assessment of Quality Control of Viral Load Assays Based on Clinical Decision-Making Needs** | Bio-Rad Laboratories, Inc. | 223 |
| **11:00 AM** | | | | |
| 11:00 AM | 11:50 AM | **Advancing the Digital PCR Impact on Liquid Biopsy and Clinical Applications** | Thermo Fisher Scientific | 224B |
| 11:00 AM | 11:50 AM | **Comprehensive Genomic Profiling (CGP) from Liquid Biopsy Samples—Clinical Utility in Academic and Community Oncology Practices** | Illumina | 231AB |
| 11:00 AM | 11:50 AM | **Democratizing NGS Sample Prep—How to Achieve Reliable, Robust, and Scalable Automation** | Tecan | 227BC |
| 11:00 AM | 11:50 AM | **Enhanced Sensitivity to Detect Advanced Adenomas with a Novel Blood-based CRC Test** | DiaCarta | 221AB |
| 11:00 AM | 11:50 AM | **Evaluation of the AVENIO Tumor Tissue Comprehensive Genomic Profiling (CGP) Kit** | Roche | 231C |
| 11:00 AM | 11:50 AM | **Genomic Data Quality: Connecting the Dots Between Bioinformatics and Physical Materials** | ATCC | 232AB |
| 11:00 AM | 11:50 AM | **Monkeypox Outbreak Preparedness and Response** | Thermo Fisher Scientific | 224A |
| 11:00 AM | 11:50 AM | **New Normal: Surveillance and Epidemiology of Severe Acute Respiratory Pathogens Using Seegene Novaplex™ Respiratory Multiplex PCR** | Seegene Technologies | 228AB |
| **12:00 PM** | | | | |
| 12:00 PM | 12:50 PM | **A Multidisciplinary Perspective on the Latest Advancements in Precision Medicine—HER2 Mutations in Metastatic NSCLC** | AstraZeneca | 230 |

## AMP 2022 CORPORATE WORKSHOP DAY SCHEDULE AT A GLANCE

| START | END | TITLE | HOST | ROOM |
|---|---|---|---|---|
| **12:00 PM (CONTINUED)** | | | | |
| 12:00 PM | 12:50 PM | **Custom NGS Panels: From Wastewater Surveillance to Pharmacogenomics (PGx) Applications—Our Distinguished Panel Discusses How They Have Utilized Streamlined Workflows to Improve Their Research** | Paragon Genomics, Inc. | 226ABC |
| 12:00 PM | 12:50 PM | **Data Derived from Genomics in Practice: AI, ML, Rules Engine, Data for Lab Efficiency Mgmt, Data for Clinical Insights** | Pierian | 222AB |
| 12:00 PM | 12:50 PM | **Do More with Less: Better Genetic Answers in a Streamlined Analysis Workflow** | Asuragen, a Bio-Techne Brand | 223 |
| 12:00 PM | 12:50 PM | **Enabling In-House Comprehensive Genomic Profiling to Meet Increasingly Clinical Oncology Needs** | Illumina | 231AB |
| 12:00 PM | 12:50 PM | **It Is Time to Take a Leap Forward in Digital PCR Technology with Roche's Digital Lightcycler® System** | Roche | 231C |
| 12:00 PM | 12:50 PM | **See What You Couldn't See Before: Multi-Dimensional Genomics Tools for Oncology and Infectious Disease Research** | Cantata Bio | 225AB |
| 12:00 PM | 12:50 PM | **Streamlined Workflows for CML and ALL Monitoring and Research** | Cepheid | 232C |
| **1:00 PM** | | | | |
| 1:00 PM | 1:50 PM | **Accelerating NGS Workflows in Oncology Clinical Research: From Genomic Data to Insights** | SOPHiA GENETICS | 228AB |
| 1:00 PM | 1:50 PM | **Application of NGS in Microbiology; Where Are We Now and Where Are We Going?** | Thermo Fisher Scientific | 224B |
| 1:00 PM | 1:50 PM | **Biomarker Testing in Advanced Prostate Cancer to Help Inform Clinical Decisions** | AstraZeneca | 230 |
| 1:00 PM | 1:50 PM | **Comprehensive Genomic Profiling for Tumor Micro-Environment Assessment and Liquid Biopsy Analysis** | Agilent Technologies | 229AB |
| 1:00 PM | 1:50 PM | **Foundational Efforts to Drive High Quality, Efficient NGS Programs: Assay Selection, Lab Workflows, CLIO Services** | Pierian | 222AB |
| 1:00 PM | 1:50 PM | **Guidance® UTI Improves Patient Outcomes and Reduces Healthcare Resource Utilization in Complicated UTI Cases** | Thermo Fisher Scientific | 224A |

## AMP 2022 CORPORATE WORKSHOP DAY SCHEDULE AT A GLANCE

| START | END | TITLE | HOST | ROOM |
|---|---|---|---|---|
| **1:00 PM (CONTINUED)** | | | | |
| 1:00 PM | 1:50 PM | **High-Throughput Sequencing of T-Cell Receptor Gene Rearrangements as a Useful Tool for Identifying and Tracking Minimal/Measurable Residual Disease (MRD) in Lymphoid Neoplasms** | Invivoscribe | 227BC |
| 1:00 PM | 1:50 PM | **Improving Access to Precision Oncology Through In-House Plasma Biopsy Testing** | Canexia Health | 232AB |
| 1:00 PM | 1:50 PM | **Maximizing MDx: Performance, Quality, Stability, and Ease of Use** | Biolyph | 221AB |
| 1:00 PM | 1:50 PM | **Molecular Controls for Emerging Diseases: The Need for Rapid Development and Harmonization** | Asuragen, a Bio-Techne Brand | 223 |
| **2:00 PM** | | | | |
| 2:00 PM | 2:50 PM | **A New Frontier in Biomarker Discovery—How the 3D Genome Reveals Novel Disease Mechanisms and Therapeutic Targets Missed by Other Technologies** | Arima Genomics | 231C |
| 2:00 PM | 2:50 PM | **Applied Biosystems Quantstudio Real Time PCR Ecosystem, Thermo Fisher Scientific's Commitment for Innovation** | Thermo Fisher Scientific | 224A |
| 2:00 PM | 2:50 PM | **Bringing Rapid Molecular Testing In-House: How to Set Up a No-Hassle Workflow** | Biocartis | 226ABC |
| 2:00 PM | 2:50 PM | **Custom Bioinformatics Software Pipeline Solutions to Bring High-Throughput Sequencing In-House** | Invivoscribe | 227BC |
| 2:00 PM | 2:50 PM | **Developing the 5 Minutes Point-of-Care PCR Test: A Technology Revolutionizing Molecular Diagnostics** | LGC, Biosearch Technologies | 225AB |
| 2:00 PM | 2:50 PM | **Expanding Utility of Pharmacogenomics; An Opportunity to Improve Outcomes Through Personalized Perioperative Medicine** | Thermo Fisher Scientific | 224B |
| 2:00 PM | 2:50 PM | **Optimizing Comprehensive Genomic Profiling Pathways with Reflex Testing** | AstraZeneca | 231AB |
| 2:00 PM | 2:50 PM | **Streamlining Diagnostic Testing Workflows for Solid Tumor(s) with Insightful Rapid Clinical Reporting** | Fabric Genomics | 232C |

## AMP 2022 CORPORATE WORKSHOP DAY SCHEDULE AT A GLANCE

| START | END | TITLE | HOST | ROOM |
|---|---|---|---|---|
| **3:00 PM** | | | | |
| 3:00 PM | 3:50 PM | **A Novel Molecular Signature to Detect, Predict and Monitor Bladder Cancer** | DiaCarta | 221AB |
| 3:00 PM | 3:50 PM | **AML Single-Cell Multi-Omics MRD (scMRD) and the Horizon of Clinical Utility** | Mission Bio | 230 |
| 3:00 PM | 3:50 PM | **Breakthrough Approach for Ultra-Fast Molecular Assay Development** | Meridian BioScience Inc. | 222AB |
| 3:00 PM | 3:50 PM | **On the Road to Accurate and Precise ctDNA Testing for Cancer Patient Management: A Panel Discussion** | LGC Clinical Diagnostics | 229AB |
| 3:00 PM | 3:50 PM | **QIAGEN Digital Insights: Mitigating Variability in Somatic Variant Interpretation** | QIAGEN | 223 |
| 3:00 PM | 3:50 PM | **Reimagine Enzymes: Enzymes Engineered to Overcome Complex Challenges in Assay Development** | Codexis, Inc. | 232AB |
| **4:00 PM** | | | | |
| 4:00 PM | 4:50 PM | **Cytovale Presents: Intellisep®: Pioneering a New Pathway in Rapid Sepsis Risk Stratification** | Cytovale | 226ABC |
| 4:00 PM | 4:50 PM | **Demystifying End-to-End DNA Sequencing Solutions** | Twist Bioscience | 225AB |
| 4:00 PM | 4:50 PM | **Digital Pathology & AI-Driven Cancer Type Similarity Assessment for Cancer of Unknown Primary (CUP) Cases—MI GPSai (with Q&A)** | Caris Life Sciences | 227BC |
| 4:00 PM | 4:50 PM | **Keeping Your Lab Relevant** | PerkinElmer | 231C |
| 4:00 PM | 4:50 PM | **Advances in Syndromic Testing** | QIAGEN | 223 |
| 4:00 PM | 4:50 PM | **Sample Preparation for Next Generation Diagnostic Assays: Tools for the High-Throughput Isolation of Extracellular Vesicles** | STEMCELL Technologies, Inc. | 232C |
| 4:00 PM | 4:50 PM | **Systemic Mastocytosis: Overview of Disease and Diagnosis for Pathologists** | Blueprint Medicines | 231AB |
| 4:00 PM | 4:50 PM | **The Most Comprehensive View of the Genome at the Scale and Flexibility You Need** | Oxford Nanopore Technologies | 228AB |

# 8:00 AM – 8:50 AM

SESSION INFORMATION

## Advancement of Pharmacogenomic (PGx) Testing: Development of Evidence-Based Guidelines and the Ongoing Effort to Drive Alignment with Regulatory Bodies

***Room: 221AB*** ***Time: 8:00 AM – 8:50 AM*** ***Hosted by: Agena Bioscience***

CPIC Co-PI and Director Dr. Kelly Caudle has been at the forefront of the changing landscape of pharmacogenomic testing. As the rapidly evolving science and supporting evidence have outpaced regulatory guidance, the medical community has looked to thought-leading organizations such as CPIC to translate evidence of drug-gene interactions into actionable guidelines for care providers. In this workshop Dr. Caudle will discuss the process and considerations behind CPIC guideline development and their ongoing work to continually evolve the list of drug-gene interactions recognized by the FDA. Attendees will gain insights into evidence-based guidelines and other resources to consider when developing and maintaining pharmacogenetic testing panels.

## Companion Diagnostic Use of DNA Mismatch Repair Immunohistochemistry (MMR IHC) in Solid Tumors

***Room: 230*** ***Time: 8:00 AM – 8:50 AM*** ***Hosted by: Roche***

See the value of MMR IHC as a prognostic and predictive biomarker for immunotherapy in solid tumors, with a discussion of interpretation, advantages for your laboratory, role in Lynch Syndrome testing, and clinical impact using real cases. Participants should come away from the workshop with a better understanding of how an FDA-approved MMR IHC companion diagnostic assay can integrate with molecular testing for Microsatellite Instability (MSI) in clinical applications.

## Implementing an FDA Cleared Comprehensive Genomic Profiling (CGP) Solution with a Path to Reimbursement

***Room: 228AB*** ***Time: 8:00 AM – 8:50 AM*** ***Hosted by: Personal Genome Diagnostics***

**Guest Speakers:** Eli S. Williams, PhD, Associate Professor of Pathology, Director of Genomics and Cytogenomics, School of Medicine, University of Virginia; Lawrence J Jennings, MD, PhD, Associate Professor of Pathology, Director of Genomic Pathology, Feinberg School of Medicine, Northwestern University

Clinical next-generation sequencing (NGS) has continued to advance precision oncology by enabling physicians to identify actionable biomarkers in cancer patients to aid in personalized therapy selection. Access to this specialized testing modality, however, remains a challenge with only 20% of advanced cancer patients receiving molecular profiling to help tailor their treatment path. To address this gap, PGDx has developed a FDA-cleared CGP tissue kit paired with best-in-class bioinformatics to empower local laboratories to implement clinical NGS in house, thereby reducing turnaround time to result and benefitting from payer coverage to help offset costs.

**Performance of the FDA-Cleared OncoMate™ MSI Dx Analysis System**

*Room: 232C Time: 8:00 AM – 8:50 AM Hosted by: Promega Corporation*

Screening cancer patients for microsatellite instability (MSI) can provide pathologists, oncologists, and patients with valuable biomarker information to inform care decisions. With the growing demand for MSI testing and recognition of its value, the need for a reliable and cost-effective MSI test has increased. In this workshop, Ms. Oostdik will discuss the new OncoMate™ MSI Dx Analysis System, the first FDA-cleared PCR-based MSI kit. The system uses the most sensitive panel of markers for MSI status detection, as included in multiple clinical guidelines. Topics will include assay design, and clinical performance of OncoMate™ MSI along with its automated analysis software.

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**Spatial Biology Innovations Pathway to the Clinic (Session 1 of 2)**

*Room: 222AB Time: 8:00 AM – 8:50 AM Hosted by: NanoString Technologies*

Join us for the first of two informative sessions to learn about the latest innovations in Spatial Biology and the path to clinical utility. Session one will deliver an overview of spatial biology from whole transcriptomics and high-plex spatial proteomics to multiomic, single-cell and subcellular resolution spatial imaging. Joseph Beechem will highlight NanoString's entire spatial ecosystem, the GeoMx Digital Spatial Profiler, CosMx Spatial Molecular Imager, and AtoMx Spatial Informatics Platform. In closing, Dr Grant Kolar, St Louis University, will present his study of Diabetic Kidney disease using both GeoMx DSP and CosMx SMI spatial technologies.

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**Transplant Standardization: How Labs Can Help Shape Patient Care**

*Room: 231C Time: 8:00 AM – 8:50 AM Hosted by: Roche*

This workshop will follow a transplant patient's journey and address the evolution and importance of standardization in quality of transplant care, recent advances in testing procedures for BK and EBV, and establishing hospital and laboratory best practices in care for transplant patients leading to improved quality of care.

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**Use of a Novel Blood Biomarker Test as an Aid in the Detection of Gastric Cancer**

*Room: 226ABC Time: 8:00 AM – 8:50 AM Hosted by: MiRXES Corporation*

Gastric cancer is the fifth most common cancer worldwide representing 5.7% of all new cancer diagnosis and contributing to over 800,000 deaths every year. Early detection remains key to survival. MiRXES has developed a blood-based test that detects and quantifies 12 miRNAs associated with gastric cancer utilizing RT-qPCR. These results are used to aid in the detection of gastric cancer and inform patient diagnoses for the best possible outcomes. This workshop will review the clinical development of the test as well as how it is being used in practice.

# 9:00 AM – 9:50 AM

SESSION INFORMATION

**Comparative Analysis of Testing Methods Used for the Detection of Internal Tandem Duplications in the KMT2A/MLL Gene; Comparison of Mutation Profiles in MDS and AML: A Single Site Experience**

***Room: 231AB*** ***Time: 9:00 AM – 9:50 AM*** ***Hosted by: OGT***

We evaluated the ability of three technologies to detect partial tandem duplications in the KMT2A gene: 1) OGT's RUO Next Generation Sequencing panel with KMT2A specific probes, 2) an MLPA assay covering exons 4 and 36 of KMT2A, and 3) Optical Genome Mapping; Mutation profiles in AML/MDS patients from a large Southern Ontario cohort will be examined. Comparison of observed mutation frequencies to those in the literature highlight the utility of this measurement as an important quality control marker. Exceptional cases further emphasize the complexity of myeloid neoplasia biology and leukomeogenic processes.

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**Decision Medicine™: Helping Pathologists and Oncologists Obtain Individualized, Actionable and Highly Accurate Genomic Data in as Little as 48 Hours**

***Room: 232AB*** ***Time: 9:00 AM – 9:50 AM*** ***Hosted by: Pillar Biosciences Inc.***

Multiple clinical advantages exist by localizing NGS testing. In this workshop, Helen Fernandes, PhD, Professor of Pathology at Columbia University Medical Center will lead the discussion on how Pillar's oncoReveal™ NGS products and simple workflows provide accurate and actionable results to allow clinicians to make timely and informed therapeutic decisions. The presentations from this workshop cover the rigorous evaluation and clinical validation of Pillar's NGS products, and how Pillar's Decision Medicine™ solutions can enable better, more informed outcomes to for everyone, everywhere.

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**Development of High-Throughput Assays for Gene Editing Program**

***Room: 232C*** ***Time: 9:00 AM – 9:50 AM*** ***Hosted by: Promega Corporation***

**Speaker:** Jiankun Wu, Vertex Pharmaceuticals

For gene therapy programs, biological specimens are collected to evaluate critical endpoints such as vector genome and transgene expression levels. Prior to analysis, workflows including nucleic acid extraction, clean-up, concentration quantitation, and normalization are time-consuming, labor-intensive, and error-prone when performed manually. This presentation will focus on our optimization process which implements high-throughput and automated strategies including Promega Maxwell®, Promega Glomax® plate reader, 384-plate based real-time PCR system, and Hamilton Vantage liquid handling platform. This updated workflow will significantly increase the efficiency, robustness, and accuracy of the analysis by eliminating repetitive and error-prone manual steps.

### Fast NGS for Targeted and Comprehensive Cancer Genomic Profiling

*Room: 224B* *Time: 9:00 AM – 9:50 AM* *Hosted by: Thermo Fisher Scientific*

NGS implementation barriers including turnaround time and level of automation are being addressed. Join our workshop to hear how the Ion Torrent Genexus System enables labs to offer fast results, excellent sample success, and a true end-to-end workflow with integrated bioinformatics. With a growing menu of assays, the Genexus System can generate results in as little as 24 hrs for a targeted panel, and less than 48 hrs for a comprehensive panel with complex biomarkers including a genomic instability metric.

### Liquid Biopsy—Improving Patient Access to Precision Oncology Through Centralized Services and Decentralized Kitted Solutions

*Room: 228AB* *Time: 9:00 AM – 9:50 AM* *Hosted by: Personal Genome Diagnostics*

**Guest Speaker:** Gang Zheng, MD, PhD, Associate Professor of Laboratory Medicine and Pathology, Mayo Clinic

Over the last decade liquid biopsy has rapidly evolved both as a research strategy for biodiscovery purposes and as a clinical tool to accompany tissue-based genomic profiling for precision oncology. Liquid biopsy offers several advantages over tissue testing including reduced turnaround time to result minimized risk and cost greater sensitivity and better representation of tumor heterogeneity. From identification of new biomarkers for future drug development to directing patients to clinical trials and targeted therapies this testing strategy can be widely applied throughout the patient care continuum.

### Maximizing Detection of Pathogenic Structural Variants Across Hematological Malignancies with Optical Genome Mapping

*Room: 229AB* *Time: 9:00 AM – 9:50 AM* *Hosted by: Bionano Genomics*

**Chair:** Alka Chaubey, PhD, FACMG, Chief Medical Officer, Bionano Genomics
**Presenters:** Nikhil Sahajpal, PhD, Laboratory Genetics and Genomics Fellow, Greenwood Genetic Center, USA; Rashmi Kanagal-Shamanna, MD, Director, Molecular Diagnostic Lab, Hematopathology Department, MD Anderson Cancer Center, USA; Adam Smith, PhD, FCCMG, FACMG, Director, Cancer Cytogenetic Laboratory and Clinician Investigator, University Health Network, Canada

Combining OGM and Next-Generation Sequencing (NGS) has proven to be a powerful solution to detect alterations across the variant continuum—from SNVs and small indels to all classes and sizes of SVs—in hematological samples. During this workshop, the panelists will review studies with multiple types of hematological malignancies, compare results generated from OGM as compared to traditional cytogenetics, and highlight the benefits of combining OGM with NGS for maximizing actionable results.

**Post-Pandemic Molecular Diagnostics: Opportunity, Strategy, and Mechanisms**

*Room: 224A Time: 9:00 AM – 9:50 AM Hosted by: Thermo Fisher Scientific*

The COVID-19 pandemic underscored the importance of molecular diagnostics and compelled laboratories to quickly validate new methods and increase testing capacity. Aegis Sciences Corporation has performed over 13.8M COVID-19 tests and has a capacity over 100,000 tests/day, servicing a broad network of physicians, urgent care centers, nursing homes, public schools, departments of health, and retail pharmacies across the United States. As the virus moves towards an endemic state and testing demand decreases, Aegis leveraged the partnerships, technologies, and infrastructure developed during the COVID-19 surge for new diagnostic offerings and strategies to expand molecular testing and prepare for future public health needs.

**Rethinking Solid Tumor Profiling: How the Massarray Complements NGS to Optimize Testing Throughout the Treatment Journey**

*Room: 221AB Time: 9:00 AM – 9:50 AM Hosted by: Agena Bioscience*

Characterizing the genetic profile of solid tumors upon initial diagnosis is a critical step in determining the appropriate treatment plan. While NGS provides a unique ability to perform broad genetic profiling, it often does not generate the results required to initiate treatment quickly enough. Additionally, sample input challenges may cause the analysis to fail entirely. Many times, this delayed or unavailable genetic information results in sub-optimal treatment. This session will discuss how the MassARRAY technology provides the targeted genetic results specified by treatment guidelines in a timely and reliable manner, even in the presence of limited and/or poor-quality samples. Dr. Adrian Box of Alberta Precision Laboratories will share how this technology is used to optimize solid tumor profiling at all stages of the treatment journey.

**Spatial Biology Innovations Pathway to the Clinic (Session 2 of 2)**

*Room: 222AB Time: 9:00 AM – 9:50 AM Hosted by: NanoString Technologies*

Immediately following Session 1, you will hear from Dr Jodi Carter, University of Alberta, formerly of Mayo Clinic. Dr Carter has been working with OHSU to develop a high-plex, spatial proteomic solution on GeoMx DSP while making novel single cell discoveries with CosMx SMI. Following, you will hear from Dr Tae Hyun Hwang, Florida Department of Health and Mayo Clinic, who has been studying Gastric cancers and uses various analytical tools from his digital pathology toolbox. Finally, we will wrap up our sessions with a panel discussion with all our speakers and provide Q&A with the audience.

**Start One-Step Ahead: Roche Custombiotech Glycerol-Free Reagents in High Concentration Designed for Use in Dried-Down Assays**

*Room: 231C Time: 9:00 AM – 9:50 AM Hosted by: Roche*

The need for rapid Point-of-care (POC) testing has never been greater. To address diagnostic manufacturing needs, Roche CustomBiotech offers a wide portfolio of glycerol-free and high concentration reagents designed for speed and use in dried-down assays. Join our talk, and learn how working with CustomBiotech enzymes can reduce your development time and decrease your overall assay time with our latest KAPA3G DNA Polymerase and NxtScript Reverse Transcriptase family of products.

**Frontline Multiplex Panel Testing and Reimbursement Challenges—From Respiratory to Gastrointestinal**

*Room: 227BC Time: 9:00 AM – 9:50 AM Hosted by: Applied BioCode, Inc.*

Molecular testing is an ever-evolving world for the most common infectious diseases, including respiratory and gastrointestinal pathogens detection. While microbiology laboratories are pivotal in the detection and identification of infectious diseases, the microbiology lab environment is rapidly changing. Conventional methods are being reevaluated as innovative test methodologies emerge. The challenges for conventional methods include inability to detect some coinfections, delay time to results, and false negatives due to poor sensitivity. A molecular approach that uses the PCR technology has the potential to increase the specificity and sensitivity of pathogen detection in polymicrobial samples.

# 10:00 AM – 10:50 AM

SESSION INFORMATION

## Advanced NGS Methods for Molecular Testing in Hematological Malignances

*Room: 224B* *Time: 10:00 AM – 10:50 AM* *Hosted by: Thermo Fisher Scientific*

Next-generation sequencing (NGS) is becoming a critical component of molecular testing in both myeloid and lymphoproliferative neoplasms. During this workshop, hear from experts on the latest advances in the application of fast NGS for myeloid genomic profiling, myeloid measurable residual disease (MRD), and B-cell and T-cell sequencing applications for clonality assessment and detection of low-frequency residual clones. Talks will feature our latest NGS testing solutions, including the Ion Torrent Genexus System, which offers a fully complete end-to-end workflow capable of delivering results in just 1–2 days. See how these groundbreaking testing methods are helping to advance research in hemato-oncology care.

## An Extraction Free Method for the Semi-Quantitative Identification of Uropathogens from Urine and Kidney Stones

*Room: 226ABC* *Time: 10:00 AM – 10:50 AM* *Hosted by: Integrated DNA Technologies*

## Comprehensive Assessment of HRD from Next-Generation Sequencing and Optical Genome Mapping

*Room: 229AB* *Time: 10:00 AM – 10:50 AM* *Hosted by: Bionano Genomics*

**Chair:** Alka Chaubey, PhD, FACMG, Chief Medical Officer, Bionano Genomics
**Presenters:** Christopher Lum, PhD, Medical Director, Molecular Diagnostics, Diagnostic Laboratory Services, Inc. USA; Ravindra Kolhe, MD, PhD, FCAP, Professor and Interim Chair, Dept of Pathology, Augusta University; Rashmi Kanagal-Shamanna, MD, Director, Molecular Diagnostic Lab, Hematopathology Department, MD Anderson Cancer Center, USA

During this workshop, we will discuss common and innovative methodologies for HRD assessment, such as NGS, microarray and Optical Genome Mapping, and bioinformatics approaches for analysis of data, across solid tumors and hematological malignancies. Case studies and results will be overviewed across three presentations provided by speakers from leading institutions.

**Demonstrating the Clinical Utility of Long Mononucleotide Repeats Through Collaborative Clinical Research Program**

*Room: 232C Time: 10:00 AM – 10:50 AM Hosted by: Promega Corporation*

As the understanding of cancer biology increases and biomarker targets for treatment become more specific, establishing the clinical utility of molecular diagnostic tests continues to be important. The global Promega Clinical Research Program (PCRP) supports physicians and researchers interested in collaborating to demonstrate the clinical utility of our technologies. In this workshop, we share an overview of the PCRP program and opportunities to partner. We will also discuss a completed PCRP study, conducted in collaboration with Johns Hopkins University researchers, which sought out improved detection of MSI-H in non-colorectal cancers using the LMR MSI Analysis System.

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**Improve Clinical Outcomes with Precision Oncology by Testing for All Actionable Biomarkers Before Treatment Selection**

*Room: 230 Time: 10:00 AM – 10:50 AM Hosted by: Eli Lilly and Company*

Precision oncology may lead to an improvement in clinical outcomes for certain patients. There are several important factors when considering treatment options, such as efficacy and safety data, evidence-based guidelines, staging, comorbidities, patient preference, and a patient's biomarker status. This program reinforces that testing for all actionable biomarkers is an important factor to patient care and may improve clinical outcomes for some patients.

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**Lymph2Cx/Lymph3Cx from Bench to Clinic—Developing Genomic Tests that Guide DLBCL Diagnosis and Treatment Using the nCounter Platform**

*Room: 222AB Time: 10:00 AM – 10:50 AM Hosted by: NanoString Technologies*

Diffuse large B cell lymphoma (DLBCL) is a heterogeneous disease that includes distinct cell of origin subtypes which can have significantly different prognoses and survival rates. Primary mediastinal B cell lymphoma (PMBCL) can be difficult to distinguish from DLBCL on clinicopathologic features alone. Join us as colleagues from the Mayo clinic share how they used digital gene expression profiling on the nCounter® platform to develop and validate a cell of origin assay to molecularly subtype DLBCL as well as an assay to differentiate it from PMBCL. Hear their experiences establishing a CAP/CLIA-certified molecular laboratory to offer the tests to patients.

### MAKO Medical Expands Surveillance Testing Menu to Include Monkeypox

*Room: 224A Time: 10:00 AM – 10:50 AM Hosted by: Thermo Fisher Scientific*

MAKO Medical Laboratories, a national reference laboratory and leader in SARS-CoV-2 testing is now one of fewer than 100 laboratories across the country capable of performing surveillance testing for monkeypox research. Mako Medical has developed a workflow for monkeypox surveillance testing to support health state department in furthering the research of monkeypox viral epidemiology. The MAKO Medical team shares their journey of responding to the need for more surveillance testing capacity in the United States for monkeypox research. Gain insights from a question-and-answer discussion format of the team's decision on their workflow, including sample types, automation, reagents, and throughput.

### Navigating Gold Standard Testing This Respiratory Season

*Room: 231C Time: 10:00 AM – 10:50 AM Hosted by: Roche*

Identify why PCR is considered the Gold Standard for respiratory testing. Differentiate when PCR testing appropriate, discussing the applicability and value of both antigen and syndromic panels. Illustrate at risk patient populations, impact of delayed diagnosis for clinical decision making and available treatment. Demonstrate settings for high throughput, POC and syndromic panels describing various use case.

### Optimizing FFPE Extraction for Methylation Array and Sequencing Assays

*Room: 225AB Time: 10:00 AM – 10:50 AM Hosted by: Purigen Biosystems, Inc.*

Analysis of the methylation state of cancer samples is a powerful new tool for research and clinical applications. Ensuring high-quality high-yield DNA extraction from tiny FFPE samples is essential to optimize clinical testing. Here we describe best practices for extraction of DNA from FFPE to support downstream applications including methylation arrays and sequencing. A case study comparing extraction methods for methylation array profiling will be presented.

### Utilization of Unity Data Management Solutions for Assessment of Quality Control of Viral Load Assays Based on Clinical Decision-Making Needs

*Room: 223 Time: 10:00 AM – 10:50 AM Hosted by: Bio-Rad Laboratories, Inc.*

Quality control rules (Westgard rules) balance the benefit of error detection with the cost of false rejection. This workshop will discuss the clinical utility of different viral load assays, how to determine allowable error (clinical thresholds) for a test, and how to use Unity QC data management solutions to choose and implement rules that strike the right balance between error detection and false rejection.

# 11:00 AM – 11:50 AM

SESSION INFORMATION

## Advancing the Digital PCR Impact on Liquid Biopsy and Clinical Applications

*Room: 224B* *Time: 11:00 AM – 11:50 AM* *Hosted by: Thermo Fisher Scientific*

From monitoring tumor biomarkers that inform treatment selection to tracking viral outbreaks using wastewater surveillance, dPCR enables clinical researchers and public health labs to quantitate nucleic acid targets reliably. The powerfully simple Absolute Q dPCR MAP technology enables less than 2% dead volume to help ensure rare target quantitation and detection are precise. Learn how a flexible workflow with 5-minute setup and 90-minute runs can expand the capabilities of your lab, and explore our latest innovations, including verified liquid biopsy assays, an optimized SARS-CoV-2 wastewater kit, and a custom assay design tool powered by more than 40 years of expertise.

## Comprehensive Genomic Profiling (CGP) from Liquid Biopsy Samples—Clinical Utility in Academic and Community Oncology Practices

*Room: 231AB* *Time: 11:00 AM – 11:50 AM* *Hosted by: Illumina*

With the increasing number, complexity, and diversity of biomarkers to be tested in support of precision medicine approaches, limited tissue availability and patient health status can be barriers to genomic testing. Liquid biopsies provide an alternative to invasive tissue sample collection to match patients with appropriate therapies based on their genomic profile. In this workshop, we will discuss the rationale and drivers for the implementation of a CGP liquid biopsy assay to better support molecular testing and therapy matching. We will also highlight real-world evidence that demonstrates the clinical utility of including liquid biopsies in biomarker testing algorithms in both academic and community oncology practices.

## Democratizing NGS Sample Prep—How to Achieve Reliable, Robust, and Scalable Automation

*Room: 227BC* *Time: 11:00 AM – 11:50 AM* *Hosted by: Tecan*

In NGS workflows sample preparation remains complex and laborious. Robust and reliable NGS automation starts with a purpose-built chemistry paired with purpose-built automation. In this workshop learn about Tecan's MagicPrep™ NGS system which combines hardware engineering with expert NGS chemistry to offer NGS sample prep That Just Works™. Tecan's NGS sample prep systems range from low throughput MagicPrep systems to high throughput DreamPrep™ systems. The expertise that Tecan has built in the area of NGS sample prep can also be made available to OEM partners through flexible bespoke developments.

### Enhanced Sensitivity to Detect Advanced Adenomas with a Novel Blood-based CRC Test

*Room: 221AB Time: 11:00 AM – 11:50 AM Hosted by: DiaCarta*

**Speaker:** Paul Okunieff, MD, Professor, University of Florida, Gainesville, FL

ColoScape™ Colorectal Cancer Detection Test is a novel highly-sensitive in vitro diagnostic assay using the qPCR-based multigene panel for the qualitative detection of colorectal cancer-associated gene mutations in liquid biopsy samples. The test targets 61 mutations in 8 genes and 7 methylation markers mostly associated with colorectal cancer utilizing our XNA technology which leverages a sequence-specific clamp made by xeno-nucleic acid (XNA) Target Genes: APC (1309 1367 1450) CTNNB1 (41 45) KRAS (12 13) BRAF 600 TP53 (R273H R175H R248Q) SMAD4 (R361C) PIK3CA (E545K) NRAS G12D Sensitivity for CRC: 88.9% 62.5% for Advanced adenoma Specificity 96%.

### Evaluation of the AVENIO Tumor Tissue Comprehensive Genomic Profiling (CGP) Kit

*Room: 231C Time: 11:00 AM – 11:50 AM Hosted by: Roche*

AVENIO Tumor Tissue CGP is a manual, distributable, and research-use-only kit. Tissue samples were tested using the AVENIO Tumor Tissue CGP Kit, and the approved FoundationOne CDx assay (F1CDx; Foundation Medicine, Inc., Cambridge, MA, USA) was used to determine the true nature of the samples. The AVENIO Tumor Tissue CGP Kit utilizes different chemistry, molecule barcoding, and bioinformatical procedures. We aimed to assess agreement of genomic variants between the AVENIO Tumor Tissue CGP Kit and F1CDx. The AVENIO Tumor Tissue CGP Kit was performed at Signature Diagnostics GmbH (Potsdam, Germany), according to manufacturer instructions, and F1CDx at Foundation Medicine GmbH (Penzberg, Germany). Overall percent agreement (OPA), weighted kappa (WK), and 95% confidence intervals (95% CI) were calculated. We observed a high degree of agreement between the AVENIO Tumor Tissue CGP Kit and F1CDx for all genomic variants and the genomic signatures TMB, MSI, and gLOH. MSA only, not for commercial use. Approved for AMP use only under SCAP.

### Genomic Data Quality: Connecting the Dots Between Bioinformatics and Physical Materials

*Room: 232AB Time: 11:00 AM – 11:50 AM Hosted by: ATCC*

Breaks in the data provenance between biological source materials and genomics data are challenges for scientific reproducibility as errors or omissions in both the metadata and the sequence data end up hampering accurate interpretation of results. To address this issue ATCC is working toward 100% data provenance for all biological materials in our collection. The ATCC Genome Portal represents the first genomic data repository where whole-genome sequencing assembly and genome annotation are being consistently applied under a quality assurance program that requires all data and procedures are fully authenticated and traceable back to physical biological materials in our culture collection.

### Monkeypox Outbreak Preparedness and Response

*Room: 224A Time: 11:00 AM – 11:50 AM Hosted by: Thermo Fisher Scientific*

Molecular testing infrastructure is critical for laboratories to rapidly respond during public health emergencies. Partnerships with public and private sector entities to expand resources, innovation, and capabilities support these efforts and limit the spread of health risks within the community. The lessons learned from COVID-19 can be directly applied to the Monkeypox virus outbreak to improve preparedness, response, and community engagement for detection and prevention. Utilizing previously developed networks has dramatically reduced the response time to an emerging public health threat. Maintaining national laboratory capacity and infrastructure is a hedge against an increasingly interconnected world of transmissible pathogens.

### New Normal: Surveillance and Epidemiology of Severe Acute Respiratory Pathogens Using Seegene Novaplex™ Respiratory Multiplex PCR

*Room: 228AB Time: 11:00 AM – 11:50 AM Hosted by: Seegene Technologies*

**Speakers:** Dr. Sara Vetter, Assistant Laboratory Director & CLIA Director, Minnesota Department of Health; Dr. Anna Strain, Infectious Disease Laboratory Manager, Minnesota Department of Health

Circulating respiratory viruses represent infectious disease challenges. Multiplex PCR options offer advantages of testing for seasonal viruses in single-tube reactions needed for ongoing surveillance and clinical testing needs. Drs Anna Strain and Sara Vetter will discuss Seegene's innovative technology that enables the detection of multiple gene targets with Individual Ct values in a single channel without melting curve analysis while speaking to the role of ongoing respiratory surveillance within public health initiatives.

## 12:00 PM – 12:50 PM

### A Multidisciplinary Perspective on the Latest Advancements in Precision Medicine—HER2 Mutations in Metastatic NSCLC

*Room: 230 Time: 12:00 PM – 12:50 PM Hosted by: AstraZeneca*

During this workshop, the speakers will review the latest biomarker developments in non-small cell lung cancer (NSCLC), including emerging biomarkers, such as HER2 (ERBB2) mutations. The oncologist and pathologist speakers from the same institution will discuss bringing together their complementary practices to provide the best possible diagnostic and therapeutic approaches to each individual patient. They will address how implementing next generation sequencing technology in-house can enable rapid turnaround times to facilitate clinical decision making. They will share their best practices for implementing a collaborative molecular tumor board and strategies for working together towards individualized treatments for their patients.

**Custom NGS Panels: From Wastewater Surveillance to Pharmacogenomics (PGx) Applications—Our Distinguished Panel Discusses How They Have Utilized Streamlined Workflows to Improve Their Research**

*Room: 226ABC Time: 12:00 PM – 12:50 PM Hosted by: Paragon Genomics, Inc.*

Please Join us as our panel of speakers discuss their recent research: Edwin Oh, PhD, Associate Professor, Nevada Institute of Personalized Medicine, UNLV School of Medicine will present on the utilization of WGS tools to define the emergence and evolution of actionable pathogens (i.e. SARS-CoV-2, Influenza, monkeypox, and polio) from clinical and wastewater samples. Matthew Beckman, Director of Laboratory Services, GENETWORx, will discuss utilizing custom panels in different pharmacogenomics (PGx) applications.

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**Data Derived from Genomics in Practice: AI, ML, Rules Engine, Data for Lab Efficiency Mgmt, Data for Clinical Insights**

*Room: 222AB Time: 12:00 PM – 12:50 PM Hosted by: Pierian*

Empowered By Technology Pierian's advanced interpretation technology provides the insights and functionality you need to practice clinical genomics with confidence. Our adaptive learning algorithms connect more variants to relevant genomic data and help you deliver the most precise results. Our intuitive user interface enables you to modify templates, enter new interpretations, and build on preferences over time.

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**Do More with Less: Better Genetic Answers in a Streamlined Analysis Workflow**

*Room: 223 Time: 12:00 PM – 12:50 PM Hosted by: Asuragen, a Bio-Techne Brand*

Tech shortage? Tech burnout? Training new techs? Hear from Barbara Anderson, MS, MB(ASCP)CM, Analytical Specialist in the Division of Molecular Pathology, Genetics and Genomics at Duke University Health System about her experience implementing a new CFTR kit and using the AmplideX Trio workflow to streamline training and minimize tech time. Also hear how accessible, automated analysis software has made it easier for her lab leadership to review results. Learn how you can have a more streamlined lab while providing better genetic answers for three targets (CFTR, SMN1/2, and FMR1) in this workshop.

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**Enabling In-House Comprehensive Genomic Profiling to Meet Increasingly Clinical Oncology Needs**

*Room: 231AB Time: 12:00 PM – 12:50 PM Hosted by: Illumina*

Comprehensive Genomic Profiling (CGP) is becoming a critical component for evaluating treatment options in oncology patients. The ideal CGP assay provides information on both standard-of-care and emerging molecular biomarkers maximizes information obtained from limited biopsy samples and is straightforward to implement and operate in the pathology laboratory. Implementing CGP in-house using a hybrid capture-based CGP assay has made significant impact at various institutions.

### It Is Time to Take a Leap Forward in Digital PCR Technology with Roche's Digital Lightcycler® System

*Room: 231C Time: 12:00 PM – 12:50 PM Hosted by: Roche*

We will discuss the Digital LightCycler System, a digital system for DNA and RNA with 6-color capability for flexible, multiplexed biomarker detection. With advances in sensitivity, precision, flexibility, and integration, the Digital LightCycler System is a powerful digital PCR system that aims to help laboratories push the boundaries of clinical research forward. Three configurations of consumables are available to meet varied application needs, including high sample volume for cfDNA screening or greater number of partitions for high-resolution CNV analysis. We will present data that demonstrates the sensitive performance of the Digital LightCycler System as the powerful new addition to the Roche PCR ecosystem.

### See What You Couldn't See Before: Multi-Dimensional Genomics Tools for Oncology and Infectious Disease Research

*Room: 225AB Time: 12:00 PM – 12:50 PM Hosted by: Cantata Bio*

Join us to learn how researchers are using Cantata Bio's novel genomics analysis tools and solutions to unlock access to genomic epigenomic and metagenomic information at unprecedented levels. Cantata Bio offers leading-edge proprietary NGS workflows to help its customers solve complex problems including detection of small and large genomic variants haplotype phasing of difficult regions (such as HLA and PGx genes) and microbial detection and quantification. Applications for Cantata Bio's solutions span the fields of epigenetics cancer research infectious disease and more.

### Streamlined Workflows for CML and ALL Monitoring and Research

*Room: 232C Time: 12:00 PM – 12:50 PM Hosted by: Cepheid*

Traditional BCR-ABL monitoring assays involve complex methodologies implemented by highly skilled technologists. The outcome gets delayed which results in inefficient use of technologists' time. Cepheid's Xpert® BCR-ABL ULTRA p190 (RUO)[1] and Xpert® BCR-ABL Ultra[2] provide monitoring results directly from whole blood in less than 2.5 hours. The simplified cartridge design enables labs to run individual samples without batching, minimal hands-on time, and reduced risk of contamination. Learn more about how these products are enabling easier and faster CML and ALL monitoring. 1) For Research Use Only. Not for use in diagnostic procedures. 2) US-IVD. In Vitro Diagnostic Medical Device. May not be available in all countries.

# 1:00 PM – 1:50 PM

SESSION INFORMATION

### Accelerating NGS Workflows in Oncology Clinical Research: From Genomic Data to Insights

***Room: 228AB*** ***Time: 1:00 PM – 1:50 PM*** ***Hosted by: SOPHiA GENETICS***

Next-generation sequencing (NGS) has the potential to revolutionize cancer care but creates increasingly large and complex datasets for analysis. Without the right analytical technology pinpointing causative variants and obtaining actionable insights from NGS data requires specialist skills multiple resources and considerable time. During this workshop speakers will share their experience of overcoming the challenges of NGS and maximizing laboratory workflow efficiency with algorithm-powered solutions that offer high analytical performance intuitive interpretation features and flexible reporting. Join us to learn about how SOPHiA DDM™ can help your laboratory uncover genomic insights from solid tumor and hematology applications more quickly and confidently.

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### Application of NGS in Microbiology; Where Are We Now and Where Are We Going?

***Room: 224B*** ***Time: 1:00 PM – 1:50 PM*** ***Hosted by: Thermo Fisher Scientific***

The promise of unlocking new frontiers in microbiology using modern technologies like NGS has been at the forefront of discussion recently. With a significant increase in access to these technologies through pandemic response programs, we are now positioned to realize that promise through exploration and implementation of applications such as pathogen identification, tracking of AMR markers, and microbiome profiling. Limitations of cumbersome workflows, long turnaround times, and complex analyses have largely been removed, though there is still significant opportunity ahead of us in order to pivot many well-established culture-based approaches to newer molecular methods using NGS.

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### Biomarker Testing in Advanced Prostate Cancer to Help Inform Clinical Decisions

***Room: 230*** ***Time: 1:00 PM – 1:50 PM*** ***Hosted by: AstraZeneca***

This presentation reviews the clinical significance of biomarkers in advanced prostate cancer, including homologous recombination repair gene mutations. Additionally current guideline recommendations for molecular testing and other information to help guide testing, such as sample selection considerations, are presented.

**Comprehensive Genomic Profiling for Tumor Micro-Environment Assessment and Liquid Biopsy Analysis**

*Room: 229AB Time: 1:00 PM – 1:50 PM Hosted by: Agilent Technologies*

Tumor molecular characterization is key for precision oncology. Here we present case studies to show the flexible use of a new comprehensive genomic profiling (CGP) pan-cancer NGS assay targeting 650+ cancer-specific genes. The assay enables detection of key classes of somatic variants, including SNVs, small indels, CNVs, TLs, TMB, MSI, and RNA fusions. We will present preliminary results from two applications of the assay: 1) genomic profiling of cell-free DNA (cfDNA) for high sensitivity detection of somatic variants and 2) interrogation of the tumor immune micro-environment in prostate cancer. This work demonstrates the utility of a modular NGS panel for tumor characterization.

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**Foundational Efforts to Drive High Quality, Efficient NGS Programs: Assay Selection, Lab Workflows, CLIO Services**

*Room: 222AB Time: 1:00 PM – 1:50 PM Hosted by: Pierian*

Expert Guidance in Clinical Genomics Clinical genomics is complex and changing all the time. As committed partners, we share our expertise and educate you on all aspects of testing and reporting. In addition to proven tools and workflows, we provide services to support interpretation, validation, and reimbursement. With Pierian, you have what you need to stay informed and deliver the most relevant insights to guide patient care.

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**Guidance® UTI Improves Patient Outcomes and Reduces Healthcare Resource Utilization in Complicated UTI Cases**

*Room: 224A Time: 1:00 PM – 1:50 PM Hosted by: Thermo Fisher Scientific*

Complicated UTIs require rapid and accurate test results for pathogen identification and antibiotic susceptibility. Standard urine culture has significant shortcomings, including a long delay before results and negative or "mixed flora/contamination" results for clear cases of UTI. Guidance® UTI is a precision diagnostic providing the sensitivity of PCR plus Pooled Antibiotic Susceptibility (P-AST™) measuring antibiotic susceptibility against the pool of polymicrobial organisms. By providing rapid and actionable results to the clinician, Guidance® UTI is associated with improved patient outcomes, with a 67% reduction of inpatient admissions and an average $463 reduction per complicated UTI case in Medical Resource Utilization costs.

**High-Throughput Sequencing of T-Cell Receptor Gene Rearrangements as a Useful Tool for Identifying and Tracking Minimal/Measurable Residual Disease (MRD) in Lymphoid Neoplasms**

*Room: 227BC Time: 1:00 PM – 1:50 PM Hosted by: Invivoscribe*

High-throughput sequencing (HTS) of the T-cell receptor beta (TRB) and gamma (TRG) loci has become a valuable tool in the diagnostic workup for lymphoid neoplasms due to its high sensitivity specificity and versatility. Disease-specific clonosequences identified by diagnostic HTS assays can also serve as valuable biomarkers for detecting disease recurrence determining response to therapy guiding future management of patients and establishing endpoints for clinical trials. Although MRD monitoring by HTS presents unique advantages over other traditional methodologies important technical and bioinformatic considerations should be taken into account by clinical laboratories wanting to offer these services.

**Improving Access to Precision Oncology Through In-House Plasma Biopsy Testing**

*Room: 232AB Time: 1:00 PM – 1:50 PM Hosted by: Canexia Health*

Precision oncology has proven success in providing better treatment results and has helped in identifying mechanisms of drug resistance and disease progression. However, a small number of patients in local communities have access to molecular testing which is integral to offering targeted treatments. Dr. Anthony Magliocco of Protean Biodiagnostics explains how bringing testing capabilities in-house has helped his organization overcome challenges such as setting up bioinformatics capabilities, long turnaround time, clinical data management, and higher costs enabling his organization to facilitate access to precision oncology to local communities through a clinically actionable liquid biopsy panel.

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

*Room: 221AB Time: 1:00 PM – 1:50 PM 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's Lyophilization Technology & Services can maximize your MDx value proposition.

**Molecular Controls for Emerging Diseases: The Need for Rapid Development and Harmonization**

*Room: 223* *Time: 1:00 PM – 1:50 PM* *Hosted by: Asuragen, a Bio-Techne Brand*

The COVID-19 pandemic put a spotlight on the need for expedited development of molecular controls that can standardize results of the myriad tests created to accurately diagnose emerging diseases. Armored Molecular Controls are synthetic, non-infectious, non-biological, nuclease-resistant full process controls that can be quickly designed and scaled to meet global supply demands. Learn how Armored Molecular Controls have been deployed to harmonize SARS-CoV-2 assays and rapidly developed to address the Monkeypox outbreak, as well as their application in wastewater surveillance for emerging diseases.

# 2:00 PM – 2:50 PM

**A New Frontier in Biomarker Discovery—How the 3D Genome Reveals Novel Disease Mechanisms and Therapeutic Targets Missed by Other Technologies**

*Room: 231C* *Time: 2:00 PM – 2:50 PM* *Hosted by: Arima Genomics*

Arima Genomics provides 3D genomic technologies that enable scientists to uncover novel disease mechanisms and identify new therapeutic targets. Join us to learn how 3D genomics is enabling biomarker discovery, tumor classification, and patient stratification. In this session, Anthony Schmitt, PhD, SVP of Science at Arima Genomics, and Matija Snuderl, MD, Director of Molecular Pathology and Diagnostics at NYU Grossman School of Medicine, will share how 3D genomics is revealing genetic drivers of previously undiagnosed tumors, reshaping how we understand disease, and yielding exciting new opportunities in precision oncology.

**Applied Biosystems Quantstudio Real Time PCR Ecosystem, Thermo Fisher Scientific's Commitment for Innovation**

*Room: 224A* *Time: 2:00 PM – 2:50 PM* *Hosted by: Thermo Fisher Scientific*

As leader in RT-PCR, Thermo Fisher Scientific committed to provide innovative, and flexible systems needed for laboratories to expand their IVD testing capabilities. For over 10 years, Thermo Fisher Scientific developed high-performance RT PCR (qPCR) instruments for clinical laboratories across the world. Our innovative IVDR compliant qPCR instruments showcase built-in smart features, user-friendly interfaces, integrated, intuitive, and modular software solutions along with user support and training. As a leader in RT-PCR, Thermo Fisher Scientific's molecular diagnostics solutions enable actionale results accurately and quickly to meet your laboratory needs.

**Bringing Rapid Molecular Testing In-House: How to Set Up a No-Hassle Workflow**

*Room: 226ABC Time: 2:00 PM – 2:50 PM Hosted by: Biocartis*

Rick Ledding, Histology Supervisor at Benefis Health Systems, will share his experience implementing the Idylla™ platform in his laboratory and how it fits in his clinical practice.

**Custom Bioinformatics Software Pipeline Solutions to Bring High-Throughput Sequencing In-House**

*Room: 227BC Time: 2:00 PM – 2:50 PM Hosted by: Invivoscribe*

NGS-based clonality testing has become an essential component of pathologic evaluation of hematolymphoid proliferations. As hematopathology progresses high-throughput tests and bioinformatics analyses are needed for diagnosis prognosis and to monitor therapeutic response. In this workshop we will present one approach to build a robust highly automated pipeline bioinformatic software solution for clonality assessments.

**Developing the 5 Minutes Point-of-Care PCR Test: A Technology Revolutionizing Molecular Diagnostics**

*Room: 225AB Time: 2:00 PM – 2:50 PM Hosted by: LGC, Biosearch Technologies*

Never before have people around the world been impacted by rapid diagnostics as during the COVID pandemic. Many point-of-care solutions have been developed, though often compromising either time to result, complexity, sensitivity/specificity or cost in an effort to get to market quickly. In this workshop, LEX Diagnostics will give a unique insight into developing the low-cost, point-of-care PCR test that aims to diagnose SARS-COV-2 and Flu A/B in 5 minutes with high sensitivity and specificity. You will learn how a nearly 40-year-old technology that formed the cornerstone of human molecular diagnostics can be improved upon to revolutionize molecular diagnostics again.

**Expanding Utility of Pharmacogenomics; An Opportunity to Improve Outcomes Through Personalized Perioperative Medicine**

*Room: 224B Time: 2:00 PM – 2:50 PM Hosted by: Thermo Fisher Scientific*

Postoperative pain control remains a huge challenge for healthcare systems though there are currently no tools available to routinely select personalized medication. Multiple genes have been implicated in explaining some variation among postoperative response and studies indicate that single-gene pharmacogenetic analysis can improve postop outcomes. However, most professional guidelines only provide recommendations for single gene/drug interactions. Precision Genetics, in cooperation with MUSC Health System, is undertaking the PRospective Outcomes and Molecular Implementation Support Registry (PROMISRx) Study to better explain interpatient variability in response to perioperative treatment and lead to the creation of a tool for predicting postoperative outcomes.

### Optimizing Comprehensive Genomic Profiling Pathways with Reflex Testing

*Room: 231AB Time: 2:00 PM – 2:50 PM Hosted by: AstraZeneca*

Discuss the value of reflex testing and comprehensive genomic profiling provided by NGS and how to optimally combine them for full accurate and timely molecular characterization of NSCLC.

### Streamlining Diagnostic Testing Workflows for Solid Tumor(s) with Insightful Rapid Clinical Reporting

*Room: 232C Time: 2:00 PM – 2:50 PM Hosted by: Fabric Genomics*

**Speakers:** Shubhda Roy, Jim Lund, Erwin Frise, Fabric Genomics, Oakland, CA

Fabric Enterprise software offers a comprehensive pipeline for solid tumor genetic testing and customized clinical reporting. TSO500 assay provides coverage of exonic regions of relevant cancer genes for SNV/Indel and CNV. An RNA component detects fusions, MSI/TMB is also reported. A clinical breast cancer case study is presented, demonstrating the case workflow. The turnaround time from VCF to report is less than a day, with short and longer research reporting available, including variant classification, drug therapies, clinical trials, and API to integrate with LIMS/EHR. Where appropriate, patients can be reflexed to the hereditary BRCA HBOC panel supported by Fabric.

## 3:00 PM – 3:50 PM

### A Novel Molecular Signature to Detect, Predict and Monitor Bladder Cancer

*Room: 221AB Time: 3:00 PM – 3:50 PM Hosted by: DiaCarta*

**Speaker:** Charles Rosser, MD, Professor, Cedars Sinai Medical Center, Los Angeles, CA

Oncuria® is the first-of-its-kind multiplex protein-based immunoassay to provide early detection therapy choice and disease monitoring for bladder cancer. It has been developed for early detection of bladder cancer monitoring bladder cancer for recurrence and predicting whether patients with intermediate- to high-risk early-stage bladder cancer will respond to bacillus Calmette-Guérin (BCG) therapy. It has achieved a sensitivity of 93% for the detection of bladder cancer and achieved an accuracy of 82% in a diagnostic nomogram for predicting response to intravesical BCG therapy. Biomarkers: VEGF-A MMP-9 IL-8 ANG MMP-10 CA9 PAI-1 SERPIN E1 SDC1 APOE A1AT SERPIN A.

**AML Single-Cell Multi-Omics MRD (scMRD) and the Horizon of Clinical Utility**

*Room: 230 Time: 3:00 PM – 3:50 PM Hosted by: Mission Bio*

Join Mission Bio and our invited guest speakers as we discuss the tools and treatments shaping the battle to end cancer. The Tapestri Single-cell Multi-omics MRD (scMRD) Assay for AML provides institutions early access to our scMRD technology, which allows for MRD detection with unparalleled resolution, sensitivity, and specificity. Speakers will share leveraging the scMRD technology to improve the identification of residual disease and potential therapeutic strategies, including an overview of scMRD data. We'll also discuss opportunities for single-cell multi-omics in the clinic for MRD and beyond, and provide an insider look into our scMRD Early Access Program.

**Breakthrough Approach for Ultra-Fast Molecular Assay Development**

*Room: 222AB Time: 3:00 PM – 3:50 PM Hosted by: Meridian BioScience Inc.*

Molecular assay developers face complex challenges when developing tests that are highly sensitive, easy to use and provide quick time to results. In this session, you will learn about a breakthrough approach in overcoming inhibition from complex specimens in qPCR and LAMP assays. Our unique approach takes into consideration the need for ultra-fast assay development, the specimen type complexities, and requirements for ambient temperature storage and portability.

**On the Road to Accurate and Precise ctDNA Testing for Cancer Patient Management: A Panel Discussion**

*Room: 229AB Time: 3:00 PM – 3:50 PM Hosted by: LGC Clinical Diagnostics*

ctDNA assays have tremendous potential to advance genomics into routine clinical use. At the workshop, expert panelists will discuss the current state of ctDNA testing and the critical roles that standardization, proof testing through concordance studies, routine quality control, frequent proficiency testing and fit-for-purpose reference materials are playing to achieving our common goal of personalized molecular oncology testing.

### QIAGEN Digital Insights: Mitigating Variability in Somatic Variant Interpretation

*Room: 223* *Time: 3:00 PM – 3:50 PM* *Hosted by: QIAGEN*

As next-generation sequencing (NGS) panels are increasingly used in precision oncology, there's an industry-wide issue of standardization: a high degree of variability in variant interpretation exists across laboratories. During this session, we will explore causes of inter-laboratory inconsistencies in somatic variant interpretation and discuss how clinical decision support (CDS) software, such as QIAGEN Clinical Insight, can help mitigate variability. To further our discussion, we will examine a peer-reviewed study comparing the consistency of variant assessments from eight laboratories and a study conducted with Mayo Clinic examining oncogenic assessment guidelines.

### Reimagine Enzymes: Enzymes Engineered to Overcome Complex Challenges in Assay Development

*Room: 232AB* *Time: 3:00 PM – 3:50 PM* *Hosted by: Codexis, Inc.*

Join us to learn what engineered enzymes can do for life science assays. Showcasing two engineered enzymes—Codex® HiTemp Reverse Transcriptase and Codex® HiFi Hot Start DNA Polymerase, our scientists will discuss options for catalog enzymes as well as custom engineering. Codex® HiTemp Reverse Transcriptase is a highly sensitive and robust enzyme specifically engineered for thermostability and performance in challenging conditions. Codex® HiFi Hot Start DNA Polymerase delivers high-fidelity results when applications demand exceptionally accurate DNA sequences. Quantities and concentrations can be customized for seamless integration into your assays.

## 4:00 PM – 4:50 PM

### Cytovale Presents: Intellisep®: Pioneering a New Pathway in Rapid Sepsis Risk Stratification

*Room: 226ABC* *Time: 4:00 PM – 4:50 PM* *Hosted by: Cytovale*

As the no. 1 cause of death in U.S. hospitals, sepsis is often difficult to quickly and accurately diagnose as it presents with undifferentiated signs and symptoms. This workshop explores a new type of test and technology (currently under regulatory evaluation) that has been designed to evaluate the state of immune activation, the dysregulation of which makes sepsis a medical emergency, by measuring the biophysical properties of leukocytes from a routine blood sample. Designed for clinical laboratory use, the IntelliSep® host response assay provides a potential window into a patient's immune activation state and the associated potential risk for sepsis.

### Demystifying End-to-End DNA Sequencing Solutions

*Room: 225AB* *Time: 4:00 PM – 4:50 PM* *Hosted by: Twist Bioscience*

Join us as we discuss end-to-end next-generation sequencing solutions in greater detail with an emphasis on targeted DNA sequencing including custom targeted panels and whole exome sequencing solutions.

### Digital Pathology & AI-Driven Cancer Type Similarity Assessment for Cancer of Unknown Primary (CUP) Cases – MI GPSai (with Q&A)

*Room: 227AB* *Time: 4:00 PM – 4:50 PM* *Hosted by: Caris Life Sciences*

**Speaker:** Dr. Matthew Oberley, Executive Medical Director, Caris Pathology

Comprehensive genomic profiling has become standard of care in oncology to guide treatment; it also provides useful diagnostic information in most cases. We utilize the molecular results to help assign cancer lineage and provide quality control in our high capacity laboratory with careful oversight by pathologists and molecular geneticists. In this presentation, we will discuss the design, development, and clinical validation of a machine learning-based test that utilizes the DNA sequencing and RNA expression data to assign cancer lineage automatically.

### Keeping Your Lab Relevant

*Room: 231C* *Time: 4:00 PM – 4:50 PM* *Hosted by: PerkinElmer*

Some of the biggest challenges facing labs today include their need to stay relevant by keeping pace with technological innovations while reducing costs and working with fewer personal resources. In PerkinElmer's Corporate Workshop you will learn ways to overcome this inherent dichotomy with automation flexibility improved laboratory efficiency and creative new technologies keeping labs relevant. For research use only. Not for use in diagnostic procedures.

### Advances in Syndromic Testing

*Room: 223* *Time: 4:00 PM – 4:50 PM* *Hosted by: QIAGEN*

The QIAstat-Dx Analyzer, combined with QIAstat-Dx assay cartridges, uses real-time PCR to detect pathogen nucleic acids in human biological samples. The QIAstat-Dx Analyzer and cartridges are designed as a closed system that contains on board all necessary reagents, enabling hands-off sample preparation. Detected real-time amplification signals are interpreted by the integrated software and are reported via an intuitive user interface. Available panels utilize powerful QIAGEN sample and assay technologies, to deliver a true Sample to Insight solution.

**Sample Preparation for Next Generation Diagnostic Assays: Tools for the High-Throughput Isolation of Extracellular Vesicles**

*Room: 232C Time: 4:00 PM – 4:50 PM Hosted by: STEMCELL Technologies, Inc.*

Extracellular vesicles (EVs) are shed from cells all over the body, and EV phenotype and cargo reflects the physiological status of the tissue from which it derives. EVs isolated from biofluids have demonstrated utility as biomarkers for cancer and an array of other diseases. Traditional EV isolation methods involve ultracentrifugation protocols that require specialized equipment, training, and represent a barrier to workflow standardization across laboratories. Recent studies demonstrate the utility of STEMCELL's EasySep EV Isolation kits for the consistent isolation of high-purity EVs for cancer biomarker screening, and the feasibility of implementing this technology for EV-based testing in a diagnostic laboratory.

**Systemic Mastocytosis: Overview of Disease and Diagnosis for Pathologists**

*Room: 231AB Time: 4:00 PM – 4:50 PM Hosted by: Blueprint Medicines*

Systemic mastocytosis (SM) is a clonal mast cell neoplasm driven by KIT D816V in ~95% of cases. Patients can present with heterogenous symptoms due to infiltration of mast cells in the various organ systems including bone marrow GI tract skin liver and spleen making the diagnosis challenging which results in a delayed diagnosis for most patients. This program will provide a disease overview of SM including how the evaluation and diagnostic workup and will close with a discussion of the diagnostic challenges and recommendations for optimizing laboratory testing.

**The Most Comprehensive View of the Genome at the Scale and Flexibility You Need**

*Room: 228AB Time: 4:00 PM – 4:50 PM Hosted by: Oxford Nanopore Technologies*

Hear from top clinical researchers how nanopore sequencing is now ready for molecular pathology research. Learn about the latest developments and clinical research discoveries, shedding light on complex biomarkers like structural variants, copy number variants, and methylation, in addition to single nucleotide variants, all from the same assay, on the same device.


# Develop Your Assays with Confidence

**JOIN ATCC AT BOOTH #920 TO SEE HOW WE CAN COLLABORATE ON THE DEVELOPMENT OF YOUR NEXT MOLECULAR ASSAY.**

- Molecular Standards – Quantitative genomic and synthetic nucleic acids with diagnostic relevance
- NGS Standards – Whole-cell and nucleic acid mixes that enable the optimization of metagenomics workflows
- ATCC Genome Portal – Thousands of high-quality whole-genome sequences tied back to credible microbial strains
- Advanced Cancer Models – Patient-derived, next-generation cancer models provided with sequence data and clinical information if available
- Matched Normal and Cancer Cell Lines – Normal or metastatic cell lines from the same patient
- Quantitative Cell Line DNA – Purified, quantitative genomic DNA with known mutation allelic frequency and gene copy number

## Join us at booth #920

ATCC® | Credible leads to Incredible®

Cantata Bio

## Visit us at Booth #1014

*Wednesday, November 2, 2022 | 12:00 pm (Noon)*
*Phoenix Convention Center - Room 225AB*
*Lunch will be provided*

**See what you couldn't see before:**
Multi-dimensional genomics tools for oncology and infectious disease research

**Naissan Hussainzada, PhD**
VP Commercial Opperations
Cantata Bio

**See what you couldn't see before:**
Multi-dimensional genomics tools for oncology and infectious disease research

**Ahbijit Parolia, PhD**
Research Investigator
University of Michigan - Medical School

Join us to learn how researchers are using Cantata Bio's novel genomics analysis tools and solutions to unlock access to genomic, epigenomic, and metagenomic information at unprecedented levels.

Cantata Bio offers leading-edge proprietary NGS workflows to help its customers solve complex problems including detection of small and large genomic variants, haplotype phasing of difficult regions (such as HLA and PGx genes), and microbial detection and quantification. Applications for Cantata Bio's solutions span the fields of epigenetics, cancer research, infectious disease, and more.

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