

AMP CORPORATE WORKSHOP DAY PROGRAM

Wednesday, November 16, 2011 from 8:00 am – 5:00 pm
Gaylord Texan Hotel & Convention Center, Level 3

8:00 – 9:00 AM

QIAGEN Leadership in Personalized Healthcare and Companion Diagnostics

Hosted by: QIAGEN

Room: Grapevine B

QIAGEN is a market leader in the field of Personalized Healthcare with a broad range of assays for the detection of mutations in *KRAS*, *EGFR*, *BRAF* and other predictive biomarkers. These assays are being co-developed with companion drugs through pharma partnerships in order to obtain FDA approval as companion diagnostic tests for these drugs. QIAGEN is launching the 1st FDA approved *KRAS* companion diagnostic test in the US. The goal of this panel discussion is to understand the perspective of a lab director, an oncologist and a pathologist on the unique opportunities, challenges and benefits that companion diagnostic testing is bringing to the clinic.

Join the Cytogenetics Resolution Revolution: High-Density SNP Arrays for Cancer and Constitutional Cytogenetic Research

Hosted by: Affymetrix

Room: Grapevine C

Affymetrix invites you to learn how high-density SNP arrays are revolutionizing cancer and constitutional cytogenetic research for our customers. This workshop will provide an overview of the new CytoScan™ HD Cytogenetics Solution, with examples illustrating why a SNP-based technology with a gene-centric design is able to catch more chromosome aberrations in cytogenetically-relevant regions than any other technology. Hear from an Affymetrix customer about the benefits of a single array with both constitutional and cancer gene coverage for hematological cancer studies, and the convenience of a single array, single assay, and stable and consistent design. Please join us or visit www.affymetrix.com.

Update on Cologuard - A Novel Patient-Friendly Test for the Early Detection and Prevention of Colorectal Cancer

Hosted by: Exact Sciences

Room: Texas 1

Colorectal cancer (CRC) is the second leading cause of cancer deaths in the United States, yet it is potentially the most treatable and preventable cancer with effective screening. Multi-biomarker testing offers a noninvasive, accurate, and user-friendly approach to achieve effective detection of both colorectal cancer and precancerous adenomas. Exact Sciences is developing Cologuard, a CRC screening test that incorporates detection of methylated DNA, DNA mutations, and hemoglobin. Please join us for an update of development progress including presentation of recent data and the final biomarker panel for the Cologuard test.

Cervista® HPV Automation Options – TWO HOURS (8:00 – 10:00 AM)

Hosted by: Hologic

Room: Texas 2

Cervista® HTA is currently in development for automating the Cervista® HR assay. In order to meet the needs of increased HPV testing in laboratories, Hologic is developing a high throughput automation platform to automate the Cervista® HR test. A description of the platform and workflow will be reviewed.

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Blood Based Gene Expression Profiling as a Powerful Tool for Biomarker Development

Hosted by: PreAnalytix

Room: Texas 5

Genome-wide transcriptome analysis using microarrays is an attractive tool for discovering disease-associated gene expression patterns, refining diagnosis, targeting therapy, and predicting outcome. Peripheral blood is preferred for transcriptome analysis since it is easily accessible and represents an archive of all ongoing conditions in the body. The application of gene expression profiling of peripheral blood in routine clinical settings, however, requires consideration of the influence of pre-analytical variables on gene expression profiles. Here we highlight development of a robust specimen handling guideline for gene expression studies and demonstrate the use of stabilized peripheral blood for routine diagnosis and biomarker development.

Novel Multiplexed Molecular Testing for Gastroenteritis with xTAG® GPP: A European Perspective

Hosted by: Luminex

Room: Texas C

Join us for an informative discussion about the innovative new diagnostic assay from Luminex that tests for the top 15 pathogenic causes of gastroenteritis, including viruses, bacteria and parasites that is now available in Europe. A large European hospital will provide an overview of results from the European clinical trials, and their evaluation and implementation of the xTAG® GPP assay that shifted their paradigm for gastroenteritis testing.

Growing Importance of 2C19 Testing in Cardiovascular Patient Management

Hosted by: AutoGenomics, Inc.

Room: Texas D

The integration of personalized medicine testing into clinical practice is now providing clinicians with the critical tools they require to assess the risks and benefits associated with the optimal prescribing of medications. The most recent example has been the FDA's Black Box warning of Clopidogrel to suggest 2C19 genetic testing prior to dosing. Recent publications have highlighted the direct impact of 2C19 on the increased risk of cardiovascular events and specifically stent thrombosis. Further, such testing is now being reimbursed by insurance companies that consider genotyping of 2C19 medically necessary for persons who have been prescribed Clopidogrel. This workshop will thus highlight the growing importance of 2C19 testing in patient management.

9:00 – 10:00 AM

Melanoma: a Molecular Diagnostic Update

Hosted by: Cleveland Clinic Laboratories

Room: Grapevine 1

The molecular biology of malignant melanoma is beginning to become apparent and available for evaluation in paraffin tissue. This workshop will review the current outline of the molecular biology and morphology for how the dysplasia-melanoma sequence works and what can be applied via immunohistology and *in situ* hybridization. A birds-eye-view of common melanomas and Reed's paramelanomas will be used for orientation purposes.

Automated Nucleic Acid Extraction from Challenging Sample Types

Hosted by: Promega Corporation

Room: Grapevine 5

Automated nucleic acid extraction has an increased presence in the molecular pathology laboratory. A growing challenge is the ability to obtain consistently high quality DNA from challenging sample types that perform well in a broad range of down-stream assays. In this workshop, we will look at several new applications on the Maxwell® 16 system, including extraction of RNA from blood and FFPE tissue. This will include assessments of quantity, purity, and performance in down-stream assays.

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The Value of Molecular Diagnostics: Risk-Based Classification of Leukemias and BCR-ABL Monitoring on the IS TWO HOURS (9:00 – 11:00 AM)

Hosted by: Asuragen

Room: Grapevine A

This workshop will illustrate how rapid multiplex molecular tools contribute to the optimal management of leukemia patients from risk-based classification at initial diagnosis to monitoring of residual disease with an emphasis on:

- Development and evaluation of multiplex panels for the detection of fusion transcripts associated with childhood ALL
- The utility of key biomarkers in managing AML patients, including AML fusion transcripts, NPM1 mutations and novel miRNA surrogates
- Implementing advanced molecular methods for the quantitative measurement of BCR-ABL expression in Ph+ CML
- The reporting of BCR-ABL results on the International Scale, (IS) in a large private reference laboratory

Cervista® HPV Automation Options, continued

Hosted by: Hologic

Room: Texas 2

Refer to 8:00 AM schedule above for description

Recent Advances in Cancer Research

Hosted by: RainDance Technologies

Room: Texas 4

RainDance Technologies is pioneering digital biology and powering ground-breaking human health and life science research with its novel droplet-based technologies. Our core RainStorm™ technology generates millions of discrete droplets that can encapsulate a single molecule, single cell or reaction and be digitally analyzed and sorted one at a time. The power, precision and simplicity of microdroplets enable researchers to answer complex questions with unprecedented sensitivity and quantitation. Join us for our presentation and learn about how our digital PCR technology will revolutionize cancer research.

BD MAX™: Now the Power of Choice is Yours! – TWO HOURS (9:00 – 11:00 AM)

Hosted by: BD Diagnostics

Room: Texas A

BD Diagnostics is redefining molecular diagnostic testing with the BD MAX™ System, a fully automated platform that gives you the power to consolidate and standardize a broad range of molecular tests. In this workshop you will hear real-world perspectives on clinically relevant molecular assays and learn about BD's planned content-rich menu that will provide clinicians the best information to make critical treatment & management decisions. Explore how the combination of versatility and simplicity of BD MAX will enable laboratories to offer a broad range of molecular tests to build programs that meet both their current and future clinical needs.

10:00 – 11:00 AM

Enhance Sensitivity of FISH Analysis with Highly Purified Multiple Myeloma Cells with RoboSep™, the Fully Automated Cell Separator

Hosted by: STEMCELL Technologies Inc.

Room: Grapevine 2

Speaker: Benoit Guilbault, PhD, Field Application Scientist, STEMCELL Technologies Inc.

Detection and quantification of CD138⁺ plasma cells in the bone marrow is typically the first laboratory method of diagnosis and prognostic evaluation of the disease. However, conventional cytogenetic techniques such as FISH can fail to detect chromosomal abnormalities due to the paucity of plasma cells in patient samples. Enrichment of plasma cells by CD138 positive selection prior to downstream FISH analysis greatly enhances sensitivity of FISH, reducing bone marrow sample sizes and consuming less reagent. This workshop will show how RoboSep™, the fully automated cell separator, is being used in many multiple myeloma labs to standardize the isolation of CD138⁺ cells, increase the efficiency of sample processing and enhance the sensitivity of FISH analysis.

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The MassARRAY® System: Key Genetic Applications for Translational and Clinical Research Laboratories

Hosted by: Sequenom

Room: Grapevine 3 & 4

Next gen sequencing is facilitating the discovery of a large and growing number of biomarkers for oncology and translational research applications. To move from basic to clinical research, these findings require interrogation against a larger, more diverse sample cohort and/or focus on more comprehensive gene-based pathway screening. The MassARRAY® system provides a high-throughput method and flexible assay development to accommodate these expanding needs. The workshop will feature speakers who have successfully confirmed markers to transition from genome-wide association studies & sequencing efforts to laboratory developed tests.

The Value of Molecular Diagnostics: Risk-Based Classification of Leukemias and BCR-ABL Monitoring on the IS, continued

Hosted by: Asuragen

Room: Grapevine A

Refer to 9:00 AM schedule above for description

The Big V's: Verification and Validation of Viral Load Assays

Hosted by: EraGen Biosciences, a Luminex Company

Room: Grapevine B

Donna Wolk, Ph.D., D(ABMM) of the University of Arizona, will be presenting with the following session objectives: 1) Overview of CLIA and CAP requirements for verification of viral assays. 2) Review examples of statistical analysis of viral load data that you can perform with simple spreadsheets. 3) Summarizing data for your CAP inspector. EraGen Biosciences, a Luminex company, is pleased to host this event.

Creating Standards for Tissue Sample Collection and Quality in a Biorepository Setting: Maximizing the Utility for Pathological and Molecular Genetic Analyses

Hosted by: PreAnalytix

Room: Texas 1

Many challenges accompany managing a full service biorepository program. Among them is the desire to provide investigators with tools that help preserve the primary clinical sample from the time of collection through archival. The collection of solid tissues presents unique challenges for molecular genetic analyses. Histological preparation while preserving DNA and RNA is crucial for archiving study-specific and prospectively collected samples. This presentation will discuss the implementation of the PAXgene® Tissue System in a large biobank. Data on histology, DNA and RNA analyses will be presented as well as a discussion on operational challenges of archiving large numbers of samples.

Simplexa™ Direct Detection and Molecular Menu Expansion Beyond Infectious Diseases

Hosted by: Focus Diagnostics

Room: Texas 5

Bringing molecular testing closer to the patient is becoming the new standard of care for many routine tests. Focus Diagnostics is meeting this demand with the introduction of Simplexa Direct chemistry, sample to answer molecular assays, which do not require nucleic acid extraction and can be performed in less than 60 minutes. Further enhancing the menu offering available for the 3M Integrated Cyclor and expand beyond infectious diseases, Focus Diagnostics will be introducing in this session a set of molecular genetics assays.

BD MAX™: Now the Power of Choice is Yours!, continued

Hosted by: BD Diagnostics

Room: Texas A

Refer to 9:00 AM schedule above for description

Advances in HCV Viral Load Testing

Hosted by: Abbott Molecular

Room: Texas C

Review of Abbott Realtime HCV viral load testing technology, assay design and impact on patient monitoring.

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11:00 AM – 12:00 PM

Robust Multiplexed Detection of Balanced Translocations in Hematologic Disorders by Array CGH

Hosted by: Signature Genomics from PerkinElmer, Inc. *Room:* Grapevine 2

Microarray-based comparative genomic hybridization (aCGH) is a powerful technique, but the standard method cannot detect balanced translocations. We have developed a microarray-based technology coupled with linear DNA amplification [translocation-CGH (tCGH)] that detects balanced translocations, while multiplexed into disease-specific panels that detect as many as 128 different translocations in a single test. The ability of this technology to simultaneously detect traditional copy gain and loss data as well as clinically relevant balanced translocations for hematologic disease will be demonstrated. We anticipate that tCGH will have a profound impact on the diagnosis, prognosis, and treatment of individuals with hematologic and other malignancies.

Solutions for the Molecular Pathology Workflow: From Extraction to Final Analysis

Hosted by: Promega Corporation *Room:* Grapevine 5

With more complex down-stream assays being implemented in molecular pathology laboratories, the quality of all reagents and systems used, as well as their ability to be integrated into a complete solution, become a critical consideration. You will hear how laboratories have incorporated solutions from Promega into their workflow, including DNA extraction from FFPE tissue samples, the new GoTaq MDx, and the Micro Satellite Instability (MSI) Analysis system. In addition, find out how the next generation DNA extraction instrument will make Maxwell® 16 a great partner for your diagnostic needs.

Next Generation Molecular Techniques in Quantitative PCR and Tools for Validating Assays

Hosted by: Life Technologies *Room:* Grapevine C

Attend our workshop and gain insight on new techniques and platforms for molecular testing. Specific topics will include:

- New castPCR™ based TaqMan® Mutation Detection Assays - Highly sensitive detection of mutations in cancer specimens.
- New Digital PCR directly measures the amount of nucleic acid in limited samples and provides a more precise quantitative answer than traditional qPCR without the need for reference standards or internal controls.
- The EZValidation™ Online Tool - A web based tool to assist in validation of quantitative assays, applying regulatory guidelines.

Infectious Disease Testing on the Verigene System – TWO HOURS (11:00 AM – 12:50 PM)

Hosted by: Nanosphere, Inc. *Room:* Grapevine D

Nanosphere's Verigene System uses the power of nanotechnology to bring multiplex molecular diagnostics to the clinical laboratory. The Verigene Processor SP's sample-to-result test processing capabilities allow for rapid, on-demand infectious disease testing in a CLIA Moderate Complexity platform. This workshop will feature presentations of clinical data and study results from Verigene System users and an update on the Verigene System's quickly expanding infectious disease test menu, with a focus on applications in clinical microbiology and respiratory viruses.

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The QIASymphony RGQ as a Platform for Lab Developed Tests

Hosted by: QIAGEN, Inc.

Room: Texas 3

Jim Mahony Ph.D., F.A.A.M., F.C.C.M., Head, Regional Virology & Chlamydiology Laboratory at St. Joseph's Healthcare Hamilton is presenting evaluation results on the QIASymphony RGQ platform running lab developed tests (LDTs). First, an LDT was adapted for the identification and subtyping of influenza virus data will be presented on test performance and compatibility with the QIASymphony RGQ. Second, an oseltamivir resistance test for influenza virus for the discrimination of resistant and susceptible genotypes will be presented with preliminary data on this Rotor-Gene Q assay. Third, laboratory developed assays for the detection of enteric viruses (Norovirus, Rotavirus, Adenovirus) and will present preliminary development and early stage validation.

Simple & Cost Effective Nucleic Acid Tests with BioHelix's Isothermal HDA Technology

Hosted by: BioHelix Corporation

Room: Texas A

BioHelix develops and commercializes simple and cost-effective molecular diagnostic tests based on its proprietary isothermal Helicase Dependent Amplification (HDA) technology. The workshop will present current and next generation HDA technology, including (1) the clinical evaluation of BioHelix's IsoAmp® HSV Assay, which utilizes HDA to amplify an HSV-specific sequence with detection on a disposable handheld device and (2) new developments for isothermal amplification including advances in amplification speed for rapid point-of-care tests and new assays based on detection with a fluorescence analyzer.

The Utility of FISH Analysis in Chronic Lymphocytic Leukemia Patient Management

Hosted by: Abbott Molecular

Room: Texas C

Fluorescence *in situ* Hybridization (FISH) has improved the detection of genomic aberrations in Chronic Lymphocytic Leukemia patients. Topics covered in the presentation will include a discussion of the prognostic implications of chromosomal abnormalities including 17p deletion (TP53), 11q deletion (ATM), 13q14 deletion and Trisomy 12. Speaker: Dr. Nyla Heerema.

12:00 – 1:00 PM

Ion Torrent Semiconductor Sequencing Technology

Hosted by: Ion Torrent by Life Technologies

Room: Grapevine C

Ion Torrent's semiconductor sequencing technology and native chemistry make sequencing faster, simpler and more scalable than ever before. Less than a year after launching, people in more than 50 countries have adopted the Ion PGM™ sequencer, making it the fastest-selling sequencer in the world. Throughput has increased tenfold to 100 Mb since launch and will jump another tenfold to 1 Gb by the end of this year. The Ion PGM is also easy to use, with the fastest workflow of any next-generation sequencer, at under eight hours. Stop by our workshop and hear firsthand from customers about the Ion PGM.

Infectious Disease Testing on the Verigene System, continued

Hosted by: Nanosphere, Inc.

Room: Grapevine D

Refer to 11:00 AM schedule above for description

Quidel Molecular

Hosted by: Quidel Corporation

Room: Texas 2

Quidel Molecular will introduce its suite of RT-PCR and non-instrumented molecular assays for infectious disease. The presentation will include a discussion of the results generated by our clinical collaborators when compared to currently approved systems.

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Advances in Clinical Applications Using Illumina Technologies – 1 ½ HOURS (12:00 – 1:30 PM)

Hosted by: Illumina

Room: Texas 4

As next-generation sequencing is increasingly considered for use in diagnostics and to guide treatment, physicians and researchers are faced with an array of challenges in incorporating the technology into the clinical setting. In addition to the platforms and reagents available through Illumina, the company has been offering whole-genome sequencing in its CLIA-certified CAP-accredited laboratory since 2009. The Illumina Corporate Workshop will focus on technical advancements using the Illumina microarray and sequencing technologies.

ALK Rearrangement and Lung Cancer

Hosted by: Abbott Molecular

Room: Texas C

Rearrangement of the *ALK* gene (2p23) has been identified as a cytogenetic abnormality in both lymphoma and non-small cell lung cancer patients (NSCLC). Recent therapeutic advances have been made targeting the tyrosine kinase domain of the *ALK* fusion protein in NSCLC patients. A review of the role of *ALK* diagnostic testing and clinical therapy for NSCLC will be presented. Speaker: Dr. Marileila Varella-Garcia.

Advancing Oncology and Personalized Medicine – TWO HOURS (12:00 – 2:00 PM)

Hosted by: Roche

Room: Texas D

Based on the advances achieved through translational research and companion diagnostics, Roche is dedicated to help lead the fight against cancer. This workshop will discuss the latest information on the complexity of cervical cancer screening and how Roche is committed to helping improve patient care with the Cobas® HPV Test. There will be information about breakthrough discoveries in cancer research utilizing the GS Junior sequencer. In addition, this workshop will cover the role of *BRAF* mutation testing in metastatic melanoma and how the INFORM *HER2* Dual ISH FDA approved test is continuing to advance *HER2* breast cancer companion diagnostics.

1:00 – 2:00 PM

Localize and Quantify mRNA with Stellaris™ FISH Probes

Hosted by: Biosearch Technologies

Room: Grapevine 2

Are you keeping up with the latest developments in molecular pathology? Biosearch Technologies invites you to learn how to easily localize mRNA transcripts *in situ* using our new Stellaris FISH technology. This novel approach requires minimal prep work and produces strong signal to noise for simple, accurate, and fast imaging of mRNA transcripts in fixed cells and tissue. Each transcript is resolved as a single diffraction limited spot, producing compelling and intuitive images which clearly illustrate the quantity and location of mRNA *in situ*. Join Dr. Arturo Orjalo for an in depth look at the technology and its applications.

The Film Array Respiratory Panel and Blood Cultured ID Panel

Hosted by: Idaho Technology

Room: Grapevine 3 & 4

The FilmArray is quickly becoming known for its ease of use and comprehensive multiplex PCR testing capabilities. This remarkable system requires only 2 minutes of hands-on time and a complete run-time of about one hour. This workshop will focus on two FilmArray studies. In the first, the results of an evaluation of the FilmArray Respiratory Panel performed at the Cleveland Clinic will be reviewed. The second focuses on a beta study of the FilmArray Blood Culture ID panel currently underway at Tampa General Hospital. Both presentations will highlight the diagnostic capabilities of the FilmArray and its ability to improve laboratory workflow. Come see how easy multiplex PCR can be!

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Exome Sequencing and Other Developments Shape Sequencing's Future in the Lab

Hosted by: Life Technologies

Room: Grapevine C

DNA Sequencing's evolution in molecular laboratories has continuously challenged clinical researchers to stay on top of the latest capabilities and tools. Come and hear how exome sequencing and other developments may shape the future of your laboratory. Discussion will include the new TargetSeq™ Exome Enrichment kit in addition to new developments on capillary electrophoresis systems.

QIAGEN's Digene HPV Test: Proven Methods in Cervical Cancer Screening

Hosted by: QIAGEN, Inc.

Room: Texas 3

QIAGEN is the market leader in molecular testing for cervical cancer. The Digene HPV Test is the most robust, validated HPV test available, with over 1 million women studied in over 300 peer-reviewed publications worldwide. The Digene HC2 High-Risk HPV DNA Test's unsurpassed clinical performance is built on its detection of the entire HPV genome with full length probes. The goal of this session is to compare the results of this unique assay design to other region-specific assays, and explore complimentary testing methods, including HPV genotyping.

Advances in Clinical Applications Using Illumina Technologies, continued

Hosted by: Illumina

Room: Texas 4

Refer to 12:00 PM schedule above for description.

Next-generation Genomics through High-throughput Microfluidics

Hosted by: Fluidigm

Room: Texas 5

Fluidigm technology enables the rapid, efficient, highly parallel, and reproducible analysis of tens-to-hundreds of genetic markers, across hundreds-or-thousands of DNA samples, in hours instead of days or weeks. Fluidigm's technology supports genomics-based applications such as single-cell gene expression, high sample throughput SNP genotyping and ground-breaking capabilities such as digital PCR and automated target enrichment for next-generation sequencing. Join us for a workshop featuring talks that focus on high-throughput screening for cancer mutations as well as target amplification for next-generation sequencing studies. Rajyalakshmi Luthra, PhD, MD Anderson Cancer Center, and Andrew May, PhD, Fluidigm Corporation.

Advancing Oncology and Personalized Medicine, continued

Hosted by: Roche

Room: Texas D

Refer to 12:00 PM schedule above for description

2:00 – 3:00 PM

Case Report: A Live Walkthrough of a Successful LIMS Implementation at Axial Biotech

Hosted by: UNICConnect

Room: Grapevine 1

Axial Biotech, will take attendees through a "live" walk-through of its molecular diagnostic LIMS. The end-to-end solution starting with sample accessioning, every phase of testing (including side discussions of what can go wrong and how to fix it) and ultimate report generation of the patient result will be demonstrated. Axial has had multiple audits and inspections resulting in zero deficiencies. Auditors regularly comment on how impressed they are with the Axial LIMS because it is a true reflection of the work being done at the bench. This workshop will show lab managers how the right LIMS can accelerate their science.

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Needle-in-Haystack Detection of Drug Resistant Pathogens Using the Light Scanner

Hosted by: Idaho Technology

Room: Grapevine 5

Come to the source of melting analysis where you'll learn about several novel high resolution melting advancements and applications including: applying mutant enrichment techniques simultaneously with high resolution melting to enable ultralow levels of mutant detection, rapid analysis of infectious disease sequence variation, as well a demonstration of Umelt, the suite of novel melting prediction tools freely available that allows you to take melting analysis to the next level with direct predicted vs. empirical melting curves generated right before your eyes!

Complex Array-Based Test Development: Updates by Affymetrix' Partners

Hosted by: Affymetrix

Room: Grapevine A

Affymetrix invites you to a discussion of novel molecular diagnostic assays and applications for detecting complex diseases that are being developed utilizing the GeneChip® platform. Our Powered by Affymetrix™ partners will discuss the development process of their signatures, clinical utility, workflow, test validation, and how they are bringing their tests to market. They will also share experiences in the development of innovative array-based molecular diagnostic tests. Please join us to learn more about these exciting new products and applications using GeneChip® technology and our new IVD Gene Profiling Reagents.

C. difficile Disease: Why is it so Important and Why is it so Hard to Diagnose?

Hosted by: Meridian Bioscience, Inc.

Room: Grapevine B

This presentation will feature insights into the large issues that HAI and *C. difficile* represent to the hospital, patients, and staff as well as the challenges in treating, preventing and diagnosing this disease. The current test methods will be reviewed, including the advantages and disadvantages of each, and the current ASM guidelines will be discussed.

Overview of CLIA vs FDA Proposed Regulation of LDTs

Hosted by: EraGen Biosciences, a Luminex Company

Room: Grapevine D

EraGen Biosciences, a Luminex company, invites you to join us at a workshop where Mya Thomae of Myraqa will discuss the FDA's interest in regulating CLIA tests and the major differences between CLIA oversight and FDA regulation. Mya will cover how FDA tests are cleared and approved as well as share information on the differences between CLIA documentation requirements and the FDA's Quality System Regulation (QSR).

The GenMark Customer Experience: Using the eSensor® XT-8 for HCV Genotyping and RVP Testing

Hosted by: GenMark Diagnostics

Room: Texas 2

GenMark is committed to providing patient-focused solutions to diagnose disease and aid in therapy selection and dosing decisions. Together with clinical laboratory partners, GenMark is improving patient care with its innovative eSensor® XT-8 molecular diagnostics system and an expanding menu of multiplex tests that deliver fast, accurate results. In this informative 1-hour workshop, you will hear about the Respiratory Virus Panel (RVP) and HCV Genotyping Test from a customer perspective, as well as an update on GenMark's progress in 2011 and pipeline for 2012.

Risk Analysis QC Plans for LDT's, by Dr. James Westgard

Hosted by: SeraCare Life Sciences Inc.

Room: Texas A

SeraCare is pleased to host Professor James Westgard, developer of Westgard Rules and founder of Westgard QC. He will describe the approach in his new book, *Six Sigma Risk Analysis: Designing Analytic QC Plans for the Medical Laboratory*, which integrates the CLSI EP23 guidance with the JC Proactive Risk Reduction methodology. Westgard will discuss applications for traditional and molecular analytical methods and the advantages and limitations of different control mechanisms. Real world scenarios, including use of an online peer review program to aid data analysis will also be featured. Bring your copy of Westgard's book for a complimentary book signing.

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Next Gen PCR in the Clinical Labs from Pathogen Detection to Oncology

Hosted by: PrimeraDx

Room: Texas C

PrimeraDx, The Multiplex PCR Company, invites you to join us in a workshop showcasing the next generation of molecular testing. The workshop will highlight research performed by our collaborators using the ICEPlex Platform, a high performance instrument that simplifies and automates multiplex qPCR. In particular, multiplex viral load and multiplex EML4-ALK variant detection will be presented.

3:00 – 4:00 PM

Standardization of BCR-ABL MbcR Results on the International Scale (IS): A North American Multicentric Study TWO HOURS (3:00 – 5:00 PM)

Hosted by: IPSOGEN

Room: Grapevine 2

Standardization and high-level analytical performance are essential for consistent interpretation of results across time and geography. BCR-ABL reference materials have been recently validated by the World Health Organization. Ipsogen has integrated a RNA sample calibrated on the 0.1% reference sample in its new BCR-ABL IS-MMR kit. A European multicenter study has demonstrated that this IS-MMR calibrator allows for an easy and accurate IS conversion (EHA 2011, poster 133). In this symposium, results from a multicenter North American study involving 37 laboratories will be presented. *In North America, Ipsogen products are not for diagnostic use but for Research Use Only (RUO).

Multiplexed Panels for Rapid Solid Tumor Profiling

Hosted by: Sequenom

Room: Grapevine 3 & 4

The Sequenom MassARRAY® system, based on MALDI-TOF mass spectrometry, has been utilized by a number of leading cancer institutes and clinical research centers for the development of multiplexed panels designed to interrogate somatic mutations, insertions, and deletions implicated in a number of druggable pathways. The workshop will feature speakers from at least two of these institutes and how each has accomplished high-throughput validation of putative targets to accelerate clinical research trials using highly sensitive and accurate methods. The MassARRAY® system is for Research Use Only. Not For Use in Diagnostic Procedures

C. difficile: The UCLA Experience

Hosted by: Meridian Biosciences, Inc.

Room: Grapevine B

This presentation will be a review of the *illumigene*® C. difficile system and assay to familiarize the audience with the basic features. Along with this, data will be presented describing UCLA's implementation of the *illumigene*® C. difficile assay including their validation protocol, validation results, training, lessons learned, and benefits realized.

Multiplexing FFPE Samples in Your Lab and Achieving Meaningful Results – TWO HOURS (3:00 – 5:00 PM)

Hosted by: HTG Molecular

Room: Grapevine C

Learn how qNPA technology allows you to obtain significant data from FFPE tissue samples with minimal prep work and no extraction. The ability to quantitate multiple genes in a single well, along with the flexibility to use old or degraded samples, differentiates HTG Molecular's qNPA technology from traditional gene expression methods. Also hear from labs that are using qNPA today and how it has impacted their results.

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Improved Performance of Cervical Cancer Screening by Quantifying HPV E6 & E7 Measurement on a Cell-by-Cell Basis

Hosted by: IncellDx, Inc.

Room: Texas 3

Screening for HPV DNA has been used to help triage abnormal cytology specimens, especially ASCUS, however, these test are positive in >50% of ASCUS samples where <10% of ASCUS samples have CIN 2+. HPV DNA is also detected in >80% of LSIL cases yet <20% have CIN 2+ on biopsy. Better methods are needed to determine which cases warrant further attention. Cervical cancer screening can be improved by cellular quantification of HPV E6, E7 mRNA simultaneously with measures of cellular size and complexity. This can be performed using the HPV E6 & E7 mRNA reagents (IncellDx, Inc., Menlo Park, CA).

Delivering Actionable Results Using Next Generation Molecular Diagnostics – TWO HOURS (3:00 – 4:50 PM)

Hosted by: Cepheid

Room: Texas 5

The clinical utility of diagnostic information decreases over time. Providing clinicians with accurate and actionable information sooner facilitates better patient management whether it is in a clinic, Emergency Department, or other healthcare facility. This workshop will focus on Cepheid's GeneXpert advanced molecular diagnostic assays and the actionable information they are providing clinicians in a variety of settings. New next generation assays that will be highlighted are the Xpert *C. difficile* Epi test that has the capability to accurately detect *C. difficile* as well differentiate the epidemic strain (O27/NAP1/BI); Xpert Flu for the detection of Flu A and Flu B with 2009 H1N1 call out; and Xpert GBS the only *in vitro* diagnostic test to fully meet CDC criteria for rapid and accurate intrapartum Group B Strep testing. Come learn how clinicians have effectively implemented these tests to benefit their patients.

Evaluation and Implementation of xTAG® RVP Fast by TriCore Reference Laboratories

Hosted by: Luminex

Room: Texas D

Speaker: Dr. Karissa Culbreath, Manager, Infectious Diseases, TriCore Reference Laboratories. Dr. Culbreath will be discussing the evaluation of xTAG® RVP Fast at TriCore and their experience converting from traditional culture and DFA testing methods to this new respiratory viral panel.

4:00 – 5:00 PM

Cancer Microarrays

Hosted by: Baylor College of Medicine

Room: Grapevine A

Chromosome Microarray Analysis (CMA) has been used for several years in clinical laboratories for constitutional applications. Properly designed cancer microarrays can be used clinically to detect cancer associated genomic aberrations including copy number alterations (CNAs) and loss of heterozygosity (LOH). The Cancer Genetics Laboratory at Baylor College of Medicine offers cancer-specific high resolution CGH/SNP arrays and SNP-based arrays as one of the tools for cancer diagnosis and clinical research. Our experience has demonstrated that CMA can accurately detect pathogenic structural anomalies that not only are of diagnostic significance but also potential therapeutic implications.

Multiplexing FFPE Samples in Your Lab and Achieving Meaningful Results, continued

Hosted by: HTG Molecular

Room: Grapevine C

Refer to 3:00 PM schedule above for description

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Septin9: A Plasma Marker for Colo-rectal Cancer

Hosted by: Epigenomics, Inc.

Room: Texas 4

Epigenomics will provide an update on the status of the company and future plans. Our focus is on developing an improved plasma test for methylation of Septin9 as an aid in screening for colorectal cancer. Based on European market feedback and technology development, we are currently performing verification and validation studies for CE marking of the next version of the Septin9 test, as well as performing safety and effectiveness testing in support of a PMA submission for regulatory approval to commercialize the test in the US.

Delivering Actionable Results Using Next Generation Molecular Diagnostics, continued

Hosted by: Cepheid

Room: Texas 5

Refer to 3:00 PM schedule above for description

All Corporate Workshops will take place at the Grapevine Convention Center, Level 3...

