



**OEM Lecture Series
(As of July 25, 2014)**

TUESDAY, JULY 29

Progress in Point-of-Care Lipid and HbA1c Testing

Sponsored by Chek Diagnostics

Time: 11:00am – 11:20am

Session Abstract

To describe recent updates in performance based POC testing for lipids and glycosylated hemoglobin in relation to diabetes and cardiovascular disease.

The attendees will learn:

1. Overview of POC lipid panel monitoring
2. Role of POC Monitoring of HbA1c for long term diabetes control

SPEAKER

Keith Moskowitz, PhD, Chek Diagnostics, Indianapolis, IN

A Novel Chemiluminescent Multiplex ELISA Assay for Accurate and Reproducible Allergy Testing

Sponsored by Arlington Scientific, Inc.

Time: 11:30pm – 11:50pm

SESSION OVERVIEW

In this session Arlington Scientific, Inc. (ASI) will present the first ever in *vitro* multiplex enzyme immunoassay for the simultaneous, but separate, detection and quantification of various common allergens in human serum or plasma.

The ASI Allergy Nano System is capable of measuring up to 25 distinct allergens per patient sample in each microtiter plate well. Multiplex ELISA's maximize data generation from each sample, and provide a low cost per allergen. The test results are > 98% in correlation with other commercial allergy tests. Results are generated in as little as 2.5 hours. The system allows for simultaneous testing of up to 2400 allergens per run.

Panels can be easily customized allowing region specific allergen selection. The microplate-based multiplex system provides an accurate, efficient, and low cost alternative to conducting multiple traditional ELISA experiments.

TUESDAY, JULY 29 (continued)

Distributors outside of the USA, researchers and laboratorians are invited. Participant discussion is welcomed as time allows.

SPEAKER

Himanshu Mody, PhD, Arlington Scientific, Inc. (ASI), Springville, UT

EIA Test for Detection of Non-Treponemal Antibodies in the Serum of Patients with Syphilis

Sponsored by Arlington Scientific, Inc.

Time: 1:00pm – 1:20pm

SESSION OVERVIEW

In this session Arlington Scientific, Inc. (ASI) will present the world's first nontreponemal enzyme linked immunoassay (EIA) test for the detection of non-treponemal antibody in serum. This assay is ideal for the automation of high throughput screening of sera from patients with syphilis utilizing traditional algorithm recommended by the CDC. The introduction and clinical significance and application of automated RPR EIA IGG and IGM will be presented.

The ASI IgG and IgM quantitative EIA involves the determining IgG and IgM antibody concentration separately in patients' sample which indicates actual disease stage of patient and monitors drug response. ASI Non-trep IgG quantitative and IgM quantitative EIA can be very useful for clinical study and in clinical application separately and in tandem.

Manufactures of EIA analyzers, researchers, laboratorians, and concerned HCT/P individuals should attend to understand the future of syphilis testing and prepare for this technologic advance. Questions and participant discussion are welcomed as time allows.

SPEAKER

Himanshu Mody, PhD, Arlington Scientific, Inc. (ASI), Springville, UT

POCT One-Step Molecular Diagnostic System Bring Complex Clinical Testing Directly to the Patient

Sponsored by Coyote Bioscience Company

Time: 1:30pm – 1:50pm

SESSION OVERVIEW

Coyote Bioscience is dedicated to making break-through innovations in molecular diagnostics that brings complex clinical testing directly to the patient. We would like to introduce both of our lab-in-a-box instrumentation system based one PCR technology and our novel method of one-step gene test without nucleic acids extraction. You will see the first portable system for molecular diagnostics with general 0.2mL PCR tube capacity.

SPEAKER

Sabrina Li, Coyote Bioscience Company, Beijing, China

TUESDAY, JULY 29 (continued)

Distributor Executive Perspectives – New Realities in the Laboratory & Diagnostics Market

Sponsored by Health Industry Distributors Association (HIDA)

Time: 3:00pm – 4:00pm

SESSION OVERVIEW

This session will feature leading healthcare distributor executives answering some key supply chain questions currently facing lab & diagnostics providers, including:

- How is distribution adapting to changing lab provider needs?
- How is consolidation among both providers and distributors impacting the lab market?
- How can distribution help manufacturers reach diverse diagnostics markets, including reference facilities, physician office labs, and hospital laboratories?
- How do distributors expect testing locations and volume to shift as a result of healthcare reform?
- What do the most effective manufacturer partners do to get sales support from distributors to reach lab/diagnostics markets?

SPEAKERS

Ian Fardy, HIDA, Alexandria, VA

Mark Zacur, Fisher HealthCare, Houston, TX

Dan Eckert, LABSCO, Louisville, KY

Andy Wright, Mercedes Medical, Sarasota, FL

WEDNESDAY, JULY 30

What's the Point? Meeting Evolving Challenges in Consumer-Driven Healthcare

Sponsored by Stratos Product Development LLC

Time: 10:00am – 10:20am

SESSION OVERVIEW

We all know that putting some degree of healthcare into the hands of consumers is imperative for future success. The next wave of consumer zed health and wellness technologies is on our doorstep. In the past couple of years, we have seen a proliferation of health, wellness and fitness devices as consumers have ubiquitous connectivity and mobile apps are now the status quo. Recently, however, the market has been saturated with devices offering a rather pedestrian set of capabilities. These capabilities have been around for decades (heart-rate monitoring, pedometer, activity-sensing devices etc), but advances in miniaturization, system-on-chip solutions, and processing power improvement - along with some slick marketing - have made all these recycled capabilities desirable once again. But at this moment, consumer users are asking: "what's the point?" The current climate has created a race between medical device and consumer electronics OEM's to see who can create the best solutions first. But, the approach taken by these two vastly different industries is what will make the difference between products that have real promise for users and those that will prove to be nothing more than glorified pedometers. What is your organization's approach to meeting this trend? Will you succeed in the race to win consumers' trust and loyalty in this critical space? How do you create these hybrid solutions that have clinical relevance but deliver on expectations for consumer usability and price points?

WEDNESDAY, JULY 30 (continued)

Attend this webinar and you will learn:

- Overview of current state of the marketplace and how to meet emerging trends for future success
- Case-study: Medamonitor Tone, a sensor-based device designed to detect a person's fat burning state via exhaled breath

SPEAKER

Sean Macleod , Stratos Product Development LLC, Seattle, WA

Multiplexed Protein and Nucleic Acid Microarray Platforms for Research and Commercial Applications

Sponsored by InDevR, Inc.

Time: 10:30am– 10:50am

SESSION OVERVIEW

With InDevR's multiplexed microarray platform, traditional protein and nucleic acid assays may be modernized while utilizing reagents proven in your existing products or research. Take content from traditional assay techniques and migrate to multiplexed microarrays in a variety of forms including well slides or 96-well plates to accommodate both high and low throughput needs. Successful implementations of multiplexed microarray technology include: quantifying viral protein in a vaccine sample, genotyping Shiga Toxin-Producing Escherichia coli and identifying/ differentiating influenza viruses. This talk will present data from example applications to help illustrate the wide variety of potential ways our partners may choose to create an assay. We will also include a detailed general discussion about microarrays including assay design, challenges with the platform and data analysis.

SPEAKER

Steve Smith, PhD, InDevR, Inc., Boulder, CO

Custom Solutions for Clinical Immunochemical Analysis

Sponsored by EXBIO Praha, a.s.

Time: 11:00am – 11:20am

SESSION OVERVIEW

Our R&D activities are directed towards the optimization of technological processes that further lead to the fast and effective design and development of products for clinical immunochemical analysis. Examples of conducted studies are presented. 1) Our successfully accomplished custom Antibody Reagent development project demonstrates all the steps of design and development of two reagent solutions for the customer's fully automated flow cytometry-based system for clinical cell analysis (patient immune status monitoring). Project included selection of antibodies, development of new fluorescent probes and specific antibody conjugation technology, optimization of antibody multi-color reagents, product stabilization and verification on human blood samples. 2) Our running collaborative project demonstrates

WEDNESDAY, JULY 30 (continued)

strong engagement in transfer of discovered technologies in practice. Project includes the development of new biomaterials and technologies that will be exploited for the assembly of new flow cytometry assays for measuring the cell immunity in chronic and persistent infections. Using model of CMV infection, recombinant molecules combining antigens, co-stimulatory molecules and the targeted delivery of this novel complex system to the antigen presenting cells is investigated. With the strong expertise and broad portfolio of key components, EXBIO is the reliable reagent partner for all manufactures of instruments for immunochemical analysis - from the point-of-care devices to the automated immunochemical analyzers.

SPEAKER

Miloslav Suchanek, EXBIO Praha, a.s., Vestec, Czech Republic

MedMira Rapid Vertical Flow Technology

Sponsored by MedMira, Inc.

Time: 11:30am – 11:50am

SESSION OVERVIEW

MedMira RVF Technology requires just three simple steps and a single drop of sample to obtain instant, multiplexed results. Using RVF Technology in clinical assays has been independently shown to produce assays that are more sensitive than lateral flow. This patented technology provides the simplest route to multiplexed assays, delivering up to five instant results simultaneously on a single cartridge.

Miriad RVF Toolkit equips developers with a platform to access MedMira RVF Technology in a way that enables assays to be built and run within 30 minutes of opening the box. There is no complex equipment required for producing, storing or running the assays, and results can be read easily by the naked eye or via commercially available readers. Developers using particle based assays have a rapid, simple model for scale up from the lab bench to commercialization using MedMira's more than 20 years of experience and in-depth knowledge.

Miriad provides a simple platform that can be used with almost any sample type, the only limitation being that large particles or cells are lysed or removed prior to application to the test cartridge. In all cases the test will run within minutes and in commercial assays has been shown to give minimum detection limits in the same order of magnitude as colorimetric ELISA.

The presentation will cover how RVF Technology works and how it can be used to produce multiplexed assays. Learn more about MedMira RVF Technology and the myriad of possibilities, visit www.medmira.com

SPEAKER

Kevin Jones, MedMira Inc., Halifax, NS Canada

WEDNESDAY, JULY 30 (continued)

Optimizing Stripwell-Based Enzyme-Linked Immunosorbent Assays (ELISA)

Sponsored by Corning Incorporated

Time: 1:00pm – 1:20pm

SESSION OVERVIEW

Today's tutorial will provide guidance on theory and practice of optimizing ELISA-based applications using the Corning's® Stripwell™ microplate. There are a number of methods for running ELISA-based applications, ranging from the standard absorbance-based to newer methods including Time Resolved Fluorescent-based assays (TRF). Each method requires careful optimization and an understanding of the options and choices for the various reagents required to run the assay, including the choice of microplate. Beyond assay optimization other topics to be discussed in the tutorial include:

- An overview of ELISA-based applications
- Choosing the correct Stripwell surface chemistry
- Important considerations of Liquid Handling
- The importance of choosing the correct instrumentation and settings to run your assay.

OUTCOMES

1. Understand the theory and practice of performing ELISA-based applications using Corning Stripwell Microplates.
2. Understand how to develop and troubleshoot ELISA-based applications using Corning Stripwell Microplates.

SPEAKER

Mark E. Rothenberg, Ph.D., Corning Incorporated, Corning, NY

Successful Fluid Sensing

Sponsored by Gems Sensors & Controls

Time: 1:30pm – 1:50pm

SESSION OVERVIEW

When choosing a sensor or control device for the product you are manufacturing you have many choices. Yet, anyone with experience knows that for ultimate long-term success, the attributes of an individual component are just the tip of the iceberg. This discussion will explain the different types of level sensing technologies, how they work and when you should use each type of fluid sensor. Some of the technology discussed will include pressure, capacitive and ultrasonic. Experience has taught us which technologies and product characteristics provide effective solutions in a variety of applications, we will be sharing this knowledge with attendees.

SPEAKER

Vincent Ellis, Gems Sensors & Controls, Plainville, CT