

8th International Conference

SAMPLE PREP east

**System Integration,
Techniques &
Applications**

December 9-10, 2013
Cambridge, MA USA



KNOWLEDGE FOUNDATION

TECHNOLOGY COMMERCIALIZATION ALLIANCE

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Conference Overview & Call for Speakers

The SAMPLE PREP east Conference, a 8th meeting in the Knowledge Foundation's Sample Prep Conference Series - an internationally recognized meeting for experts in sample preparation technologies for detection, identification, diagnostics and analysis of biomedical, biological and chemical agents, substances and threats in point-of-care, laboratory and field settings will explore the latest R&D developments, ready-to-market technologies, and their applications by exploring the following topical areas:

- Robust methodologies for sample collection, (pre-)concentration, lysis, and target extraction
- Critical role of sample prep in early diagnostics
- Rapid sample-to-sequence techniques
- Point-of-care sampling, detection and analysis
- Sample preparation with microfluidics
- Sample prep-on-a-chip
- Robust sampling methodologies (automation, high-throughput, combinatorial approach in sample prep)
- Alternative amplification techniques for sensitive sample prep
- Sample preparation as a separate system vs. an integrated module approach
- End-user prospective for biodetection and sampling technologies and devices
- Alternative and disruptive approaches to sample preparation and applications
- Field-ready devices: compatibility/reliability/scalability

Novel robust sampling and bioforensic techniques will be reviewed as applicable to biodefense, field & point-of-care biomedical & clinical applications, food & water testing, and environmental & agricultural sampling. Our group of leading experts from government, academia and industry will address the following discussion issues and areas of focused technology development and implementation:

- Target enrichment and background depletion techniques
- Isolation of dilute objects on cell and molecular levels
- Immiscible phase purification
- Novel methods of extraction from tough (non-filterable) matrices
- Nucleic acid and protein based sample prep for next generation sequencing
- Nanotechnology and miniaturization challenges for sample preparation
- New assay and sequencing technologies for sample preparation, detection and analysis
- Standardization and regulatory issues in sample preparation across different applications



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SPONSORSHIP AND EXHIBIT OPPORTUNITIES

Attendees at this event represent the very top industry, government and academic researchers from around the world and provide an extremely targeted and well-qualified audience for exhibitors and sponsors. Your participation as an exhibitor or sponsor is the most cost effective way to gain high quality, focused exposure to these industry leaders. Among other benefits, sponsorship packages include your logo on marketing materials to promote your participation and expose your company to 10's of thousands of prospects prior to the program - in addition to the highly targeted audience we deliver at the event itself.

CONFERENCE SPONSORSHIPS

A variety of conference sponsorships are available which offer incremental levels of visibility to conference delegates at the event — as well as opportunities for marketing exposure prior to the event. Taking advantage of pre-conference options has the added benefit of getting your organization's name out to a large group of interested decision makers.

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These "mini" sponsorships offer representatives of your organization a dedicated opportunity to network with conference delegates — with your organization clearly recognized as the host of the event.

- Cocktail Receptions
- Luncheons
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- Hospitality Suites

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Your company may sponsor an instructional workshop (subject to approval) for delegates in conjunction with the conference. Highlight your organization's expertise! Delegate feedback indicates that these scientific/technical vehicles enhance retention of your organization's presence in their minds — increasing the potential for drawing customers long after the conference is over. Call Ron Trznadel at (617) 232-7400 ext. 208 or email rtrznadel@knowledgefoundation.com today for pricing information and customization options.

COMPREHENSIVE DOCUMENTATION AVAILABLE

Nothing can substitute the benefits derived from attending **Sample Prep east**. But if your schedule prevents you from attending, this invaluable resource is available to you. Please allow 2-3 weeks after the conference date for delivery. *Note: Documentation is included with conference fee for registered delegates*



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Conference Agenda

Monday, December 9, 2013

8:00 *Registration, Exhibit Viewing/Poster Setup, Coffee and Pastries*

8:50 **Organizer's Welcome and Opening Remarks**

9:00 **Sample Preparation Approaches for Orthogonal Data in Field Forward Diagnostics**

Richard Allen, PhD, Senior Scientist, Biodefense and Food Safety, Luminex Corporation

Accurate assessments of complex infectious and chronic disease states present a unique instrumentation and assay challenge. Often the clinical presentation of an illness is the product of, or is impacted by, multiple competing factors that require widely differing analysis and preparation techniques to access. We are developing a digital microfluidic sample-to-answer system to address this limitation. For example, a key aspect of this technology is the ability to identify a pathogen through molecular techniques and simultaneously quantify host biomarkers over the infection time course via affinity capture reagents. Currently, portable systems provide one-dimensional data (e.g. sequence, biomarker). Our approach, combining multiple measurement modes from one sample has previously only been available to larger lab facilities. While we are only combining two types of tests (PCR assays and Immunoassays) in initial prototypes, this capability is unique in the current POC field and, in a field forward setting, these data will yield a more accurate and timely treatment, leading to better clinical outcomes than either test alone.

9:30 **Automated Field Sample Preparation**

Michael Connolly, PhD, CEO, Integrated Nano-Technologies

INT has developed the Palladium biological identification system for field use. It automates all steps of sample preparation, nucleic acid amplification and identification into a single disposable cartridge. Assays have been developed for pathogens in blood, sputum, insect vectors and environmental samples. The system can be used for identification and diagnostics or to prepare nucleic acids for analysis on other platforms such as DNA sequencers.

10:00 **Rapid and Simple Procedure to Detect the Presence of Viruses and Mycoplasma in Cell Cultures Used in the Manufacture of Biotherapeutics**

Kathleen Souza, Senior Research Scientist, EMD Millipore Corporation, a division of Merck KGaA*

Mammalian cell cultures used as a substrate in the production of biotherapeutics need to be free of

contaminants in order to ensure product purity and safety. Many biotherapeutics are produced in rodent cells with raw materials of biological origin so they are susceptible to virus and mycoplasma contamination. Current cell-based methods for biocontaminant detection require days to weeks to obtain results. We have developed a sample preparation and detection procedure to capture contaminants, extract nucleic acids in order to detect a specific set of viruses and mycoplasma contained in CHO cells culture samples with a time to result of 4h, and a hands on time of 30 min. The combination of virus and mycoplasma detection in a single sample decrease the overall time from days to hours. **In collaboration with: Manjula Aysola, Celine Rofel, Jonathan Broe, Nolwenn Marques, Bodo Holtkamp, Frédéric Marc*

10:30 *Networking Refreshment Break, Exhibit/Poster Viewing*

11:00 **Universal Multiplexed Blood Screening Platform with a Robotic System**

Vincent Gau, PhD, President, GeneFluidics, Inc.

A 96-well frame plate capable of housing eight universal blood testing strips, multiplexed electrochemical sensor array, EK manipulation, two stage focusing flow channel and a blood cell counter with the robotic lab automation system is being developed. By leveraging established robotic and microfluidic expertise, we can utilize the superior accuracy and throughput of the robotic system and the parallel microfluidics channels of the point-of-care system. This hybrid robotic-microfluidics system can minimize human operation and potential contamination in an enclosed system that interfaces with microfluidic modules precisely handling blood samples of just a few μL .

11:30 **Neutrophil Chemotaxis Assay from One Drop of Blood**

Daniel Irimia, PhD, MD, Assistant Professor, Harvard Medical School

While the absolute neutrophil count is the most common blood tests in the clinic, it implicitly assumes that all neutrophils are normal and does not account for transient alterations of function. To estimate the risk for infections more accurately in patients with burn injuries, we designed a microfluidic device that measures neutrophil chemotaxis directly from one droplet of blood and employed it to identify interventions that restore normal neutrophil functions.

12:00 **Presentation title to be confirmed**

Please visit www.KnowledgeFoundation.com for the latest Program updates.

12:30 *Luncheon Sponsored by the Knowledge Foundation Membership Program*

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2:00 **Automated Sample Prep for Personalized Medicine**

Richard A. Montagna, PhD, Senior Vice President, Rheonix, Inc.

The presentation will focus on the challenges associated with providing cost-effective molecular diagnostics for personalized medicine and companion diagnostics in a manner that meets the needs of all stakeholders. The challenges facing clinical laboratories include the ability to simplify and streamline complex sample preparation steps and achieving actionable results in a timely manner. In addition, due to new molecular diagnostic reimbursement guidelines issued by CMS, it is imperative that cost-effective methods designed to meet the needs of all stakeholders be implemented. A fully automated molecular diagnostic platform will be described.

2:30 **Sample Preparation for Molecular Diagnostics of Sexually Transmitted Infections**

Wamadeva Balachandran, PhD, Depart of Systems Engineering, Brunel University, United Kingdom

An integrated microengineered platform is under development for automated DNA extraction, isothermal amplification and detection of sexually transmitted infections (STIs). Complex sample preparation techniques have inhibited the production of a true "sample-in answer-out" point of care test. This work aims to reduce the complexity associated with sample preparation by simplifying sample collection and nucleic acid extraction. Urine samples are collected and fed into a sample purification device with passive mixing of the lysis/binding buffer. DNA is extracted on a chitosan impregnated organic membrane within the microfluidic device. Chitosan has been shown to adsorb DNA in microfluidic devices by anion exchange. This method significantly reduces complexity associated with nucleic acid extraction; DNA is bound to the membrane under acidic conditions and eluted in alkaline conditions.

3:00 **Presentation title to be confirmed**

Please visit www.KnowledgeFoundation.com for the latest Program updates.

3:30 *Networking Refreshment Break, Exhibit/Poster Viewing*

4:00 **CyPlex: A Novel Platform for Multi-Analyte Immunoassays**

Rajiv Pande, PhD, Vice President, CyVek Inc.

A new platform technology for multiplexed immunoassays is described. The technology combines a unique solid phase approach with innovative microfluidics to design test cartridges that can be configured in a variety of ways for

applications in life science research and in clinical diagnostics. A key feature of CyPlex™ is that each analyte, from every sample, is assayed individually in its own microenvironment. So, while the test is multi-analyte, each assay is performed with its own specific reagents: there are no reagent cocktails, and chances of cross-reactivity are greatly diminished. Assays are fully automated. CyPlex™ assays are sensitive (fM), robust (precise and accurate), rapid (1 hr time to result), and require very low sample volumes (2 µL per analyte).

4:30 **Development of a Cell Based Functional Assay for the Detection of Botulinum Neurotoxin Type A & E**

Shashi K. Sharma, Research Microbiologist, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration

The standard procedure for definitive detection of BoNT-producing *Clostridia* is a culture method combined with neurotoxin detection using a standard mouse bioassay. The mouse bioassay is highly sensitive and specific, but it is expensive and time-consuming and there are ethical concerns due to use of laboratory animals. Cell based assays provide an alternative for mouse bioassay in screening for BoNT-producing *Clostridia*. Here, we describe a cell-based assay utilizing a fluorescence reporter construct with full length SNAP-25 as the linker, expressed in a neuronal cell model, to study toxin activity in situ. Our data indicates that PC-12 cells have significant sensitivity to BoNT/A and E action and the assay can detect as little as 100 pM BoNT/A activity within living cells. Of the in vitro approaches published in the literature for BoNT detection, we believed that cell-based methods provide a model that more closely approximates the in vivo model and have a potential to at least reduce and refine animal assays if not replace it.

5:00 **Exhibitor/Sponsor Showcase Presentations**

5:45 *End of Day One*

Tuesday, December 10, 2013

8:00 *Exhibit/Poster Viewing, Coffee and Pastries*

9:00 **Biostabilization of Nucleic Acids for Next-Gen Sequencing**

Rolf Muller, PhD, CEO, Biomatrix

There is an increasing need for the development of technologies for handling human specimens in an all ambient workflow at point-of-care, laboratory and field settings without sacrificing the quality of molecular analytes contained in patient samples. We have developed biostabilization methods for patient samples that allow a

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complete ambient diagnostic workflow. We now demonstrate that such biostabilized nucleic acids retain near-native quality and quantity compared to fresh samples and can also be used to obtain comprehensive genomic data by Next-Gen Sequencing analysis.

9:30 **Electricity-Free, Hand-Held Chromatography Platform**

David R. Pawlowski, PhD, Senior Research Scientist, CUBRC

CUBRC has developed an electricity-free chromatography platform conceptually based on disposable transfer pipettes. Our platform encompasses a chromatography resin or sorbent built into a low-density polyethylene transfer pipette and held within by a high-density polyethylene frit. CUBRC has successfully demonstrated solid phase nucleic acid and protein extraction using silica as the sorbent and His-tagged protein purification using Talon® (Clontech) and His-bond® (Novagen) metal affinity resins. Our platform is designed to include other combinations such as antibody conjugates, aptamers, or nucleic acid oligomers. Custom combinations can also be built to suit a researcher's individual requirements. This platform is particularly well suited for use in austere environments, teaching laboratories or University settings.

10:00 **Presentation title to be confirmed**

Please visit www.KnowledgeFoundation.com for the latest Program updates.

10:30 *Networking Refreshment Break, Exhibit/Poster Viewing*

11:00 **Simplifying Sample Collection and Processing with Unique Device for Rapid POC Test**

John Zeis, President, Symbient Product Development

Client FABPulous came with a concept that had 6 sample

collection and processing steps. We helped them simplify it down to 2 steps. This unique device collects a blood sample, separates plasma from whole blood, adds a reagent, and finally delivers it to a lateral flow strip. The device already has a CE mark and since it is so intuitive, it should be approved by the FDA and CLIA-waived soon.

11:30 **Acquisition of High Quality Tissues to Support Genome Wide Association Studies**

Latarsha Carithers, PhD, Project Manager, Office of Biorepositories and Biospecimen Research, National Cancer Institute

The Genotype-Tissue Expression project is a NIH Common Fund study that is aimed at understanding how genetic variation influences gene expression in normal tissues. The purpose of this presentation is to describe a biospecimen collection platform that was developed to address the logistical challenges of acquiring a large collection of high-quality tissues from rapid autopsy and organ donors that was needed to support genome wide association analysis for this study.

12:00 **Thermostable Positive Controls**

Victor Bronshtein, PhD, President, Universal Stabilization Technologies, Inc.

Preservation by vaporization has been demonstrated to be effective and scalable technology for long-term stabilization of active proteins, viruses, and bacteria that could be used as positive controls in diagnostic kits after inactivation by irradiation in the dry state.

12:30 **Selected Oral Poster Highlights**

1:00 *Concluding Remarks, End of Conference*

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Discount Accommodations and Travel: A block of rooms has been allocated at a special reduced rate. Please make your reservations by November 18, 2013. When making reservations, please refer to the The Knowledge Foundation. Contact The Knowledge Foundation if you require assistance.

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