21st International Conference

Biodetection Technologies 2013

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Technological Advances in Detection & Identification of Biological Threats

June 18-19, 2013 • Alexandria, VA USA

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COMPREHENSIVE DOCUMENTATION AVAILABLE

Nothing can substitute the benefits derived from attending **Biodetection Technologies 2013**. But if your schedule prevents you from attending, this invaluable resource is available to you. Please allow 5-7 days after the conference date for delivery. *Note: Documentation is included with conference fee for registered delegates*

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Tuesday, June 18, 2013

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

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

9:00 **DTRA/JSTO's 24 Month Diagnostic Challenge - Phase II**

Bradley R. Ringeisen, PhD, Lead, 24 Month Diagnostics Challenge, Science & Technology Manager, Diagnostics and Disease Surveillance Division, Joint Science and Technology Office (JSTO), U.S. Defense Threat Reduction Agency (DTRA)

DTRA/JSTO will present a progress report on the 24 Month Diagnostic Challenge. Initial Phase I evaluation of 12 diagnostic technologies is complete, with 4 technologies selected to move forward into Phase II development and evaluation. The assay development includes pathogen targets for antigen detection of dengue, malaria, melioidosis and plague. Two technologies will move forward for a clinical demonstration in 2014.

9:30 **Deep-Ultraviolet, Multi-Wavelength, Resonance-Raman Detection of Bacteria**

Jacob Grun, PhD, Chief, Special Projects, Laser Plasma Branch, Naval Research Laboratory*

A study of bacterial resonance-Raman signatures at multiple wavelengths in the deep-ultraviolet (210nm to 260nm) is presented. Some of the bacteria are genetically similar to a degree greater than 97% as measured by the bacteria's 16SRNA sequences. Others are less genetically similar. The signatures are measured in the bacteria's rapid-growth log phase as well as in the stationary phase, when bacterial growth slows as nutrients are depleted and bacterial growth is balanced by death. Also, signatures of bacteria grown in poor, average, and rich media are measured. Our ability to identify the bacteria from these signatures will be discussed. This presentation is supported by DTRA and the NRL Base Program. **In collaboration with: P.Kunapareddy, Research Support Instruments; and R.Lunsford, NRL*

10:00 **When is a Trace Detection "Significant"?**

Steve Velsko, PhD, Senior Scientist and Associate Program Leader, Lawrence Livermore National Laboratory

We will discuss how to apply statistical significance testing to the detection of trace quantities of pathogen nucleic acids by PCR based techniques, and the utility of such tests in forensic investigations.

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

11:00 **The LabTube Platform – Disposable Cartridges for Automated Processing of Biochemical Assays in Standard Laboratory Centrifuges**

Felix von Stetten, PhD, Head of the Lab-on-a-Chip Division, HSG-IMIT; Laboratory for MEMS Applications, Dept of Microsystems Engineering (IMTEK), University of Freiburg, Germany*

A laboratory centrifuge can be applied to automate biochemical assays for point-of-care diagnostics or sample preparation such as DNA or protein extraction. Key innovation is integration of liquid handling into a 50 ml centrifuge tube. This "LabTube" harbors three revolvers which are stepwise rotated against each other by a g-force operated ball pen mechanics. The first revolver sequentially releases pre-stored reagents into the second revolver which is equipped with a mixing chamber and a solid phase column. Fractions of processed liquids are collected by the third revolver. Automated LabTube based DNA-extractions showed comparable yields to manual reference extractions. **In collaboration with: A.Kloke, L.Drechsel, S.Zhang, A.Fiebach, R.Zengerle, N.Paust, HSG-IMIT; and J.Steigert, Robert Bosch GmbH*

11:30 **Multiplex Detection in Blood and Plasma with a Resequencing Microarray**

Robert Duncan, PhD, Staff Scientist, Lab of Emerging Pathogens, FDA Center for Biologics Evaluation and Research, U.S. Food and Drug Administration

Detection of pathogens in blood is required for donor screening and diagnostics. To stay ahead of emerging agents and make the process more efficient and flexible we are evaluating multiplex testing strategies. We have tested the Blood Borne Pathogen Resequencing Pathogen Microarray developed in collaboration with TessArae, LLC. Data will be presented showing optimization and final testing with coded spiked specimens and the limits of detection in the multiplex assay.

12:00 **Development of Treatment Guiding Multiplexed Molecular Diagnostics for Drug Resistant *Burkholderia maleii* and *pseudomaleii***

R. Paul Schaudies, PhD, Chief Executive Officer, GenArraytion Inc., and

COL Bret Purcell, Deputy Chief, Bacteriology Division, USAMRIID

Burkholderia mallei is a gram-negative bipolar aerobic bacterium causing the disease Glanders in humans. *Burkholderia pseudomallei* is the causative agent for melioidosis in animals and humans. USAMRIID and GenArraytion have teamed to develop a multiplexed molecular diagnostic to identify both species independently and to provide treatment guiding information of the individual isolates. USAMRIID has an extensive collection

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Conference Agenda

of both *Burkholderia mallei* and *pseudomallei*. Antibiotic resistance profiles for individual isolates will be determined at USAMRIID and the extracted DNA analyzed by GenArraytion to correlate genotypic signatures with both the organisms as well as the antibiotic resistance elements. Multiplexed assays will be developed on both the Luminex and ABI PCR based platforms. Both of these platforms have FDA approved molecular diagnostics which will facilitate the development of a FDA approved molecular diagnostic.

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

2:00 **SAFETY Act: Risk Management for Providers of Anti-Terrorism Technologies**

Bruce Davidson, Director, Office of SAFETY Act Implementation, U.S. Department of Homeland Security Science & Technology Directorate

The SAFETY Act may limit the legal liability of companies that manufacture or sell technologies and services that have anti-terrorism capabilities. The "Safety" in SAFETY Act stands for "Support Anti-Terrorism by Fostering Effective Technologies". This law was enacted by Congress as a direct result of 9/11 and as part of the Homeland Security Act of 2002 (Title VII, Subtitle G). By capping liability, the law promotes the creation, deployment and use of anti-terrorism technologies. Its ultimate goal is to protect the homeland and save lives.

2:30 **Sepsis, MRSA, VAP: Molecular Pathogen and Antibiotic Resistance Detection in a Single Tube Multiplex LATE-PCR Assay**

Arthur H. Reis, Jr, PhD, Professor, Department of Biology, Brandeis University

LATE-PCR is a form of asymmetric PCR generating large amounts of single stranded DNA that can now be probed over a large temperature space using molecular beacon probes and our newly designed Lights-On/Lights-Off probes. Background introductions to each of the bacterial infections and complexities of antibiotic resistance will be presented. The MRSA multiplex assay detects and identifies each SCCmec type as well PVL toxin and vanA resistance, and discriminates versus coag negative staph. The Sepsis multiplex assay is constructed in two ways to detect over 20 bacterial and fungal species in a single tube by targeting individual genes or the 16S rRNA gene for bacteria and a specific gene for candida species using our Lights-On/ Lights-Off approach. The VAP multiplex assay is a quantitative endpoint LATE-PCR assay using combinations of the MRSA and Sepsis gene specific assays.

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3:00 **Modeling an Approach to Define Sensitivity of Viral Detection in Sample Matrices Relevant to Biopharmaceutical Manufacturing – Examples with Microarray Readout**

Szi-Fei Feng, PhD, Associated Principal Scientist, Vaccine Analytical Development, Merck and Co., Inc.

Advances in viral detection technologies have the potential to increase the safety assurance of medicines produced in biological production systems. However, taking full advantage of these technological advances in the regulated testing environment will require establishing protocols for standardization and performance testing. The most essential performance characteristics of detection methods for these applications include sensitivity, breadth of detection, and consistency. We have evaluated an approach to establishing the suitability of nucleic-acid-based detection systems, and have demonstrated it using a novel microarray-based viral detection system. Our approach is based on selection of the relevant challenge viruses, their preparation and characterization, their application to a robust sample preparation workflow, and quantitation of recovery by an independent means. This approach helps us evaluate the suitability of the workflow for handling diverse sample matrices, and also suggests a means by which technology users, developers and regulators can standardize the evaluation of critical performance attributes of novel detection technologies.

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

4:00 **The Microfluidic Bioagent Autonomous Networked Detector (M-BAND) - Fully Integrated, Automated, and Networked Field Identification of Airborne Pathogens**

Kimothy L. Smith, DVM, PhD, Chief Technology Advisor, Positive ID - Microfluidic Systems*

We describe a fully automated and autonomous air-borne biothreat detection system for biosurveillance applications. The system, including the nucleic-acid-based detection assay, was designed, built and shipped by Microfluidic Systems (MFS), a wholly owned subsidiary of PositiveID Corporation (PSID). Our findings demonstrate that the system and assay unequivocally identify pathogenic strains of *Bacillus anthracis, Yersinia pestis, Francisella tularensis, Burkholderia mallei,* and *Burkholderia pseudomallei*. In order to assess the assay's ability to detect unknown samples, our team also challenged it against a series of blind samples provided by the Department of Homeland Security (DHS). These samples included natural occurring isolated strains, near-neighbor isolates, and environmental samples. Our results indicate that the multiplex assay was specific and produced no false positives when challenged with in house gDNA collections and DHS provided panels. Here we present another analytical tool for the rapid

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identification of nine Centers for Disease Control and Prevention category A and B biothreat organisms. **In collaboration with: M.Sanchez, L.Probst, E.Blazevic, B.Nakao*

4:30 **Enabling Tool for Lab-On-A-Chip Immunoassays: Development System for Pathogen Detection Devices**

Claudia Gärtner, PhD, CEO, microfluidic ChipShop GmbH, Germany

The detection of biological pathogens on immunological and serological level is widely used. The transfer of this technology on lab-on-a-chip devices as detection tool for various kinds of pathogenic targets is of utmost interest, since this allows for a lab-independent analytical tool, to be used at the point of interest. In order to enable the quick development of such lab-on-a-chip platforms, to look at sensitivity, cross-reactivity etc. of such assays, a generic platform to establish immunological and serological assay modules has been created. In all application cases, the assays are based on immobilized probes located in microfluidic channels. Therefore a microfluidic chip and the respective bread-board instrument were realized, containing a set of three individually addressable channels, not only for detection of the sample itself but also to have a set of references for a quantitative analysis. The technical approach as well as sample applications will be presented.

5:00 *Exhibitor/Sponsor Showcase Presentations – I / Concluding Discussion*

5:45 *End of Day One*

Wednesday, June 19, 2013

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

9:00 **Deconstructing the Fear of Responding to a Biological Threat (title to be confirmed)**

Christopher J. Cowen, Hazardous Materials Response Team, United States Capitol Police

Abstract is not available at time of publishing. Please visit www.KnowledgeFoundation.com for the latest Program updates.

9:30 **Point of Care Magnetorotation Assay for Ultra-Fast Drug Sensitivity Determination of Unidentified Bacteria**

Raoul Kopelman, PhD, Professor of Chemistry, Physics, Applied Physics, Biophysics, Biomedical Engineering and Chemical Biology, The University of Michigan

Bacterial antibiotic resistance is one of the top concerns of modern healthcare worldwide, and the development of rapid growth based diagnostics is a key in addressing this problem. Faster diagnostic tests will reduce inappropriate antibiotic use, decrease health care costs, reduce the prevalence of antimicrobial resistance, and lower mortality rates. Here we introduce self-assembled AMBR biosensors for antibiotic susceptibility testing (AST), specifically in measuring the minimum inhibitory concentration (MIC) value, and demonstrate a prototype that can monitor multiple such biosensors simultaneously and measure bacterial growth within two hours. We rapidly measured the MIC for uropathogenic *Escherichia coli* isolate using the self-assembled AMBR biosensors. Reducing the time and cost required to determine the drug sensitivity of unidentified bacteria will have an important clinical impact, and may play a major role in pathogenic biodetection.

10:00 **Novel Strategies for Point-Of-Care Diagnostics**

Harshini Mukundan, PhD, Principal Investigator, Chemistry Division, Los Alamos National Laboratory

The talk will present recent work from LANL for the development of novel strategies for the rapid detection of pathogen biomarkers in patient samples with unprecedented sensitivity. This work resulted in the discovery of association of biomarkers with host lipoprotein carriers, a critical finding not only in the design of diagnostic assays, but also in our understanding of host immunity. In addition, we will also discuss new research from our team demonstrating the use of bacterial siderophores for the selective detection of only live bacteria in complex samples.

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

11:00 **Development of the Integrated Diagnostic Nano- and Microsystems (title to be confirmed)**

Frank Bier, Prof Dr, Dept Nanobiotechnology and Nanomedicine, Fraunhofer Institute for Biomedical Engineering IBMT, Germany

Abstract is not available at time of publishing. Please visit www.KnowledgeFoundation.com for the latest Program updates.

11:30 **From Viruses to Cells: Tuneable Resistive Pulse Sensors for High Resolution Nano-to-Micro Particle Characterization and Label-Free Biosensor Readout**

Darby Kozak, PhD, Chief Scientist, Izon Science US Ltd*

Tuneable resistive pulse sensors (TRPS) have the ability to accurately characterize the size, charge and concentration

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of nano to micro-scale particles. Measuring the properties of each particle as it passes through the TRPS provides high resolution analysis often beyond that of other techniques. Furthermore, the ability to simultaneously measure size and charge on a particle-by-particle basis provides a unique method to characterize and understand the role that these properties play. We present the fundamental principles behind TRPS and demonstrate how it has been used to improve particle characterization and as a label-free biosensor readout. **In collaboration with: W.Anderson, R.Vogel, U. Queensland (Austraalia); and M.F.Broom, Izon Science Ltd (New Zealand)*

12:00 **Novel Tools for Rapid Diagnosis in the Field Of Biomedicine: From Development to Applications**

Panagiotis Karanis, PhD, Professor, Medical School, University of Cologne, Germany

The purpose of this presentation is to call attention to the developments of new and useful molecular rapid assay technologies and specifically to address its development and applications in the field of infectious diseases considering its validation and evolution in the field of molecular diagnostics. The presentation will include a remarkably novel method (LAMP = loop mediated isothermal assay) for the elegantly specific and rapid replication of selected DNA sequences. Applicability of LAMP assays for rapid identification of amplicons as a part of molecular diagnostics is possible not only for the diagnosis of infectious diseases but also for specific purposes using clinical material in various fields of medicine. Research analysis referring original data with examples of pathogen monitoring will be presented.

12:30 *Lunch on Your Own*

2:00 **Electronic Solutions for Implementing, Tracking and Auditing EHS Programs**

Patty Olinger, RBP, Director of Environmental, Health and Safety Office (EHSO), Emory University & Elizabeth R. Griffin Research Foundation

This talk will review tools readily available for EHS data gathering and management that did not exist 5 years ago. Whether you are in the field gathering data using an iPad, or reviewing a "cloud" dashboard, monitoring progress of program implementation, today's technology can allow institutions to readily identify existing EHS program gaps. Allowing institutions to strategically focus resources where needed. While the examples discussed will focus on Biorisk Management the technology and methodology is applicable to any EHS discipline.

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2:30 **Biosurveillance System Enables Detecting Biohazardous Substances of Unknown Origin in Drinking Water**

Sergei Makarov, PhD, CEO, AttaGene, Inc.

To detect the presence of biohazardous activities in drinking water, we use AttaGene's proprietary reporter platform enabling simultaneous assessment of multiple signaling pathways within cells. By analyzing the pattern and amplitude of perturbations, induced by water sample in test cells, we can classify the hazardous substance and estimate the potential threat. A distinct advantage of our technology is that it affords detecting very broad range of biohazards of unknown origin.

3:00 *Networking Refreshment Break, Exhibit/Poster Viewing*

3:30 **Molecular Recognition Elements in Sensing Applications**

Letha J. Sooter, PhD, Assistant Professor, Dept of Basic Pharmaceutical Sciences, West Virginia University

Molecular Recognition Elements (MRE) are biomolecules with high affinity and specificity for a target. Of particular interest are single-stranded DNA (aptamer) and antibody fragment (scFv) MREs. Using conjugation chemistry these MREs may be incorporated into an array of sensing devices. MREs against pesticides and biowarfare agents have been isolated. Incorporation into optical sensing platforms has been achieved.

4:00 **Laser-Induced Breakdown Spectroscopy as a Rapid, In-situ Clinical Diagnostic**

Rosalie Multari, PhD, Senior Scientist, Applied Research Associates, Inc.*

Laser-Induced Breakdown Spectroscopy (LIBS) is an analytical technique in which light from a laser plasma is analyzed to provide information on sample identity and composition. Results analyses are available within seconds to minutes. Instruments can be operated with minimal training and be made portable. We have developed LIBS to detect bacteria, viruses, and parasites in the clinical matrices of human blood and cerebral spinal fluid. We will present results that demonstrate our analysis approach to the LIBS data permits differentiation of inoculation type and concentration in clinical matrices for *Staphylococcus aureus, Leishmania donovani,* and *Herpes simplex* virus. **In collaboration with: D.Cremers, ARA; R.Duncan, FDA; S.Young, TriCore Reference Labs*

4:30 **Exhibitors and Sponsors Showcase Presentations – II / Selected Oral Poster Highlights**

5:00 *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 May 17, 2013. When making reservations, please refer to the The Knowledge Foundation. Contact The Knowledge Foundation if you require assistance.

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