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BIODEFENSE WORLD SUMMIT 2015

Cover

Biodetection Technologies:
Pathogen and Biothreat
Detection

Biodetection Technologies:
Point-of-Care for
Biodefense

Biosurveillance Integration:
Integrated Management
of Threats

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The Knowledge Foundation's

BIODEFENSE WORLD SUMMIT 2015

June 22-26, 2015
HYATT REGENCY BETHESDA
BETHESDA, MD

Empowering the defense community to recognize, assess and act on biological threats while preparing for the *unknown unknowns*

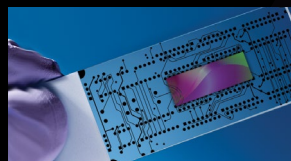


23RD INTERNATIONAL

Biodetection Technologies: PATHOGEN AND BIOTHREAT DETECTION

**COVERAGE
INCLUDES**

- Strategies & Practical Case Studies for Identification & Management of Pathogens of Bioterrorism
- Rapid and Future Technologies for Biodetection
- Application of Nucleic Acid Technologies, Biomarkers and Immunotechnologies for Pathogen Detection



23RD INTERNATIONAL

Biodetection Technologies: POINT-OF-CARE FOR BIODEFENSE

**COVERAGE
INCLUDES**

- Creation and Validation of Rapid Point-of-Care Detection and Diagnostic Assays
- Tools to Enhance Situational Awareness in Disease Surveillance
- Rapid Aberration Detection Research and Development to Drive Incident Preparedness



4TH ANNUAL

Biosurveillance Integration: INTEGRATED MANAGEMENT OF THREATS

**COVERAGE
INCLUDES**

- Risk Anticipation Strategies that Permit the Prediction of Impending Natural or Intentional Incidents
- Rapid Threat Identification & Accurate Characterization
- Information Integration, Real-Time Analysis and Sharing To First Responders and Healthcare Providers

KEYNOTE SPEAKERS

Steve Bennett, Ph.D.,



Executive Director, National
Biosurveillance Integration
Center, U.S. Department of
Homeland Security

Charles Chiu, M.D., Ph.D.,



Associate Professor, Laboratory
of Medicine, Infectious
Diseases, UCSF School of
Medicine, University of
California, San Francisco

Peter Emanuel, Ph.D.,



ECBC BioSciences Division
Chief & JPEO-CBD JUPITR
ATD Lead, Aberdeen Proving
Grounds

Gerald Epstein,



Deputy Assistant Secretary
for Chemical, Biological,
Radiological, and Nuclear Policy,
U.S. Department of
Homeland Security

Matthew J. Shaw,



Vice President,
CBRNE Defense,
Battelle

Michael A. Smith, M.Phil., Ph.D.,



PMP, Director, Critical Reagents
Program, Medical
Countermeasure Systems,
JPEO, U.S. Department of
Defense

CO-LOCATED EVENTS

• **Sample Prep Technologies**

• **Rapid Detection for Food Safety**

• **Next Gen Drones**

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Workshops

TUESDAY, JUNE 23 | 5:45 - 8:45 PM

RAPID SAMPLE PREPARATION FOR PATHOGEN DETECTION

This workshop will discuss sample preparation technologies for detection, identification and analysis of biomedical, biological and chemical agents, biothreats in point-of-care, laboratory and field settings. It will review the novel and rapid technologies for sample preparation, application of analytical strategies and automation in biodetection.

Instructors:

Dave Alburty, CEO, InnovaPrep LLC

Anubhav Tripathi, Ph.D., Professor of Engineering, Professor of Molecular Pharmacology, Physiology and Biotechnology, Director of Biomedical Engineering, Brown University

THURSDAY, JUNE 25 | 5:30 - 8:30 PM

HOW TO LAUNCH A LABORATORY TEST: EVERYTHING YOU WANTED TO KNOW BUT WERE AFRAID TO ASK

The workshop is designed to give a clear and complete overview/guidance for any company or researcher who is planning to bring a molecular test on the market. In this session, the instructors will begin with a discussion covering FDA approval pathways, recent updates to molecular diagnostics regulations, the different levels of evidence that drive FDA approval and payer coverage, reimbursement fundamentals and the latest coding updates and laws that will impact coverage and payment across the diagnostics industry.

Following the presentation will be an interactive case study activity for participants to exercise their new knowledge of regulatory and reimbursement considerations

for diagnostic tests. Participants will work together to determine whether diagnostic test cases would or would not have successful commercialization and why, and finally regroup to discuss the actual outcomes.

Instructors:

Steven Gutman, M.D., Strategic Advisor, NA, Myraqa, Inc.

Bruce Quinn, M.D., Ph.D., Senior Health Policy Specialist, Foley Hoag LLP

FRIDAY, JUNE 26 | 1:00 - 5:00 PM

RAPID VACCINE TECHNOLOGIES WORKSHOP – THERAPEUTICS FOR EMERGING AND RE-EMERGING INFECTIOUS DISEASES

The need for the rapid formulation of novel vaccines in response to emerging pathogens is critical to public health and safety. The vaccines developed should elicit protective immune responses and be unaffected by pre-existing immunity to vaccine components. In addition, these treatments should be amenable to combination and multi-agent formulation, and should be safe for all populations and the environment.

Instructors:

Willy Valdivia-Granda, Ph.D., CEO, Orion Integrated Biosciences

Matthew Coats, Program Manager, Office of University Programs, Science and Technology Directorate, U.S. Department of Homeland Security

Leslie Lobel, M.D., Ph.D., Department of Microbiology, Immunology and Genetics Faculty of Health Sciences, Ben Gurion University of the Negev, Israel

Darrell R. Galloway, Ph.D., Adjunct Professor of Pharmaceutical Chemistry, Department of Pharmaceutical Chemistry, University of Utah

HOTEL & TRAVEL INFORMATION

Conference Venue and Hotel:

Hyatt Regency Bethesda
One Bethesda Metro Center
Bethesda, MD 20814
Phone: 301-657-1234

Discounted Room Rate: \$225 s/d

Discounted Cut-off Date: May 22, 2015

RESERVATIONS: Go to the travel page of
BiodefenseWorldSummit.com for additional info



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Showcase your solutions to a guaranteed, targeted audience. Package includes a 15- or 30-minute podium presentation within the scientific agenda, exhibit space, on-site branding, access to cooperative marketing efforts by Knowledge Foundation, and more.

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Opportunity includes a 30-minute podium presentation. Boxed lunches are delivered into the main session room, which guarantees audience attendance and participation. A limited number of presentations are available for sponsorship and they will sell out quickly. Sign on early to secure your talk!

Invitation-Only VIP Dinner/Hospitality Suite

Sponsors will select their top prospects from the conference pre-registration list for an evening of networking at the hotel or at a choice local venue. Knowledge Foundation will extend invitations and deliver prospects, helping you to make the most out of this invaluable opportunity. Evening will be customized according to sponsor's objectives i.e.:

- Purely social
- Focus group
- Reception style
- Plated dinner with specific conversation focus

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Sherry Johnson

Business Development Manager
781-972-1359 | sjohnson@healthtech.com
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Bertin Technologies	Meso Scale Defense
Biosearch Technologies	NanoLogix
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MONDAY, JUNE 22

IDENTIFICATION & MANAGEMENT OF EMERGING AND REEMERGING PATHOGENS OF BIOTERRORISM

7:00 am Registration and Morning Coffee

8:25 Chairperson's Opening Remarks

Candice Warner, Field Application Scientist, Pall ForteBio LLC

» KEYNOTE PRESENTATIONS

8:30 Pan-Genomic Technologies for Molecular Detection of Viral Hemorrhagic Fever



*Charles Chiu, M.D., Ph.D., Associate Professor, Laboratory of
Medicine / Infectious Diseases, UCSF School of Medicine,
University of California, San Francisco*

Sensitive diagnosis of viral hemorrhagic fever (VHF), especially in the "eclipse" phase of pre-symptomatic/early illness, is key in promptly identifying infected patients for supportive treatment and preventing further spread of disease. Whole-genome sequencing of VHF agents using target-enriched next-generation sequencing and identification of gene expression classifiers to discriminate VHF patients from controls using global transcriptome profiling will be discussed.

9:00 Targeted Acquisition of Reference Materials Augmenting Capabilities (TARMAC)



*Michael A. Smith, M.Phil., Ph.D., PMP, Director, Critical Reagents
Program, Medical Countermeasure Systems, JPEO, U.S.
Department of Defense*

The Critical Reagents Program's (CRP) TARMAC initiative bridges the gap between the identification of disease events of interest and the evaluation and development of material solutions that mitigate the threats posed by associated etiological agents. TARMAC facilitates the establishment of relationships and processes required for the real-time transfer of biological materials from relevant outbreaks and established repositories.

9:30 Multi-Wavelength Spectroscopic Detection of Bacteria

*Jacob Grun, Ph.D, Chief, Special Projects, Plasma Physics Division, Naval
Research Laboratory*

*Co-developed with: Pratima Kunapareddy, Ph.D, Chief, Special Projects, Plasma
Physics Division, Naval Research Laboratory*

Multi-wavelength resonance-Raman signatures are used to identify the effects of growth phase and growth medium on bacteria. We find that spectra of the same bacterial species exhibit differences due to both growth condition and growth phase, but the larger differences reflect changes due to growth phase. Using a Pearson correlation based algorithm, we achieve successful identification of these bacteria in 83% of the cases.

10:00 Coffee Break

ADVANCES IN NUCLEIC ACID-BASED TECHNOLOGIES FOR PATHOGEN DETECTION

10:30 Real-Time Genomic Characterization of Viral Threat Agents Using Nanopore Sequencing

*Andy Kilianski, Ph.D., National Research Council Fellow, BioDefense Branch,
BioSciences Division, Edgewood Chemical Biological Center*

The MinION™ from Oxford Nanopore is a hand-held, USB-powered sequencing platform that has recently been released for alpha-testing. The MinION™ rapidly and correctly identified virus in addition to genetically characterizing these agents, demonstrating the enormous potential of nanopore sequencing as a fieldable technology for pathogen identification and characterization.

11:00 Standardized Methods for Evaluating Biodetection Technologies with Mock Clinical Specimens

*Robert Duncan, Ph.D., Principle Investigator, Center for Biologics Evaluation
and Research, Office of Blood Research and Review, Division of Emerging and
Transfusion Transmitted Diseases, U.S. Food and Drug Administration*

In developing biodetection technologies, a device's ability to detect limiting amounts of pathogen in an infected or contaminated specimen must be evaluated. The types of pathogens, especially biothreat agents, are rare or impossible to find in clinical specimens. Standardized methods will be described for culturing the pathogens, spiking in blood or plasma and molecular methods for quantifying the pathogen content.

11:30 Pall ForteBio BLI Systems: Label-Free Pathogen Detection and Characterization

*Michele Halvorson, North America Field Applications
Manager, Sales Pall ForteBio LLC*

Label free protein interaction analysis is a versatile platform for biomolecular interaction characterization. Enabling complex characterization with minimal sample consumption, real-time binding patterns are observed to obtain sample concentrations, kinetic binding constants, or specificity information. Bio-layer interferometry (BLI) allows for high-throughput biomolecular interaction analysis without the use of microfluidics which can be a significant advantage over other platforms. Here we demonstrate the versatility of BLI and how it is being implemented in the biodefense community. Using BLI, hybridoma clone selection and characterization is streamlined, and more informed decisions can be made compared to traditional techniques.

12:00 pm Luncheon Presentation (*Sponsorship Opportunity
Available*) or **Enjoy Lunch on Your Own**

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ADVANCES IN NUCLEIC ACID-BASED TECHNOLOGIES FOR PATHOGEN DETECTION (CONT.)

1:55 Chairperson's Remarks

Andy Kilianski, Ph.D., National Research Council Fellow, BioDefense Branch, BioSciences Division, Edgewood Chemical Biological Center

2:00 Development of Diagnostics Assays for Ebola Detection: Real-Time PCR to Next-Generation Sequencing

Timothy D. Minogue, Ph.D., Chief, Molecular Diagnostics Department, Division of Diagnostic Systems, U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)

Understanding of endemic pathogens in a geographic location aids in effectively utilizing diagnostic assays. This is especially true in regions prevalent for highly pathogenic viruses co-circulating with organisms that present with similar pathology. In this context, our group strives to develop improved diagnostics to allow for timely, accurate and robust diagnosis of Ebola detection and other diseases.

2:30 Microbial Detection Array Applied to Biodefense and Public Health

Crystal Jaing, Ph.D., Group Leader, Applied Genomics, Physical & Life Sciences, Lawrence Livermore National Laboratory

The Lawrence Livermore Microbial Detection Array is a comprehensive DNA detection technology that contains probes to detect more than 8000 species of microbes including viruses, bacteria and fungi. The technology has been applied to vaccine safety, infectious disease, biodefense, and microbiome to rapidly identify known and emerging pathogens. The technology is a cost-effective and faster alternative than next generation sequencing.

3:00 GenArrayion MultiFLEX™ Molecular Assays- Your Platform, Your Targets, Your Fluors, No Ceiling™

R. Paul Schaudies, Ph.D., CEO, GenArrayion, Inc.

GenArrayion identifies candidate genomic regions based on uniqueness and functionality. Target genomic regions are amplified using PCR chemistry. GenArrayion has developed multiple panels for the identification of biothreat agents, tick borne diseases, and hospital acquired infections. Panels consist of four to twenty individual targets and can be configured as complete or partial panels.

3:30 Refreshment Break in the Exhibit Hall with Poster Viewing

RAPID AND FUTURE TECHNOLOGIES FOR BIODETECTION

4:15 Label-Free Detection of High-Consequence Pathogens in Complex Mixtures

Bennett Goldberg, Ph.D., Professor of Physics and Biomedical Engineering, Dept of Physics and Biomedical Engineering, Boston University

We have developed an LED based virus detection technology that offers capture and direct multiplexed detection of virus particles. Our technology allows the identification of viruses such as Ebola, Marburg and Lassa that cause hemorrhagic fever directly from blood or serum with the need for nucleotide isolation and amplification. The technology has the capacity to do real-time detection of virus capture in a closed-system sample-to-answer format, enabling the delivery of point-of-need of sensitive detection technology in limited resource settings.

4:45 RNA-Based Diagnosis of Antibiotic Resistance

Deborah Hung, M.D., Ph.D., Co-Director, Infectious Disease Program, Broad Institute & Associate Professor, Department of Molecular Biology, Harvard Medical School

Rapid diagnostics to rapidly identify a pathogen and provide drug susceptibility is critical for preparedness against bioterrorism. In particular, the need to generate real-time drug susceptibility patterns is mounting in the face of increasing natural antibiotic resistance and the possibility of engineered multi-drug resistant bioterrorist pathogens. The detection of RNA expression signatures can serve as such a diagnostic platform.

5:15 Welcome Reception in the Exhibit Hall with Poster Viewing

6:15 End of Day

TUESDAY, JUNE 23

RAPID AND FUTURE TECHNOLOGIES FOR BIODETECTION (CONT.)

8:00 am Morning Coffee

8:25 Chairperson's Remarks

Harshini Mukundan, Ph.D., Principal Investigator and Team Leader, Chemistry, Los Alamos National Laboratory

8:30 Universal Bacteriophage: A New Paradigm for Biological Agent Detection/Diagnostics

Shanmuga Sozhamannan, Ph.D., Technical Coordinator, Critical Reagents Program, Medical Countermeasure Systems, JPEO, U.S. Department of Defense

Currently, there are two general paradigms in biodetection: protein based immunodiagnostics and PCR diagnostics. In this talk, a third paradigm based on phage that addresses many if not all of the limitations of the currently fielded assays and instruments will be discussed. The general concept is to harness the specificity of attachment of phages or phage proteins to bioagents using a rapid high sensitive multiplex platform.

9:00 Reporter Phage Diagnostics for Clinical and Environmental Pathogen Detection

David Schofield, Ph.D., Chief Scientist, Guild BioSciences, Inc.

We are developing 'bioluminescent' reporter phages for pathogen detection. The method is based on integrating the genes encoding bacterial luciferase into the phage genome to create species-specific 'light-tagged' phages. In the absence of a host, the reporter by itself, is unable to bioluminesce. If viable cells are present, the reporter binds to specific receptors, infects, and produces luciferase. Following substrate addition, 'light' is emitted which can be detected.

9:30 Next Generation Sequencing Based Approaches for Targeting Nucleic Acids

Kevin Shianna, Ph.D., Sequencing Specialist, Illumina

Pathogen detection requires a quick, sensitive and inexpensive method for screening of samples. Combining nucleic acid based targeted methods with next generation sequencing allows for the rapid identification of pathogens. Approaches to target DNA and RNA (cDNA) will be described.

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10:00 Coffee Break in the Exhibit Hall with Poster viewing

DIRECT PATHOGEN DETECTION: APPLICATION OF BIOMARKERS AND IMMUNOTECHNOLOGIES

10:45 MAGPIX: The Future of Viral Immunodiagnosics

Randal J. Schoepp, Ph.D., Applied Diagnostics Branch Chief, Diagnostic Systems Division, U.S. Army Medical Research Institute of Infectious Diseases

The enzyme-linked immunosorbent assay (ELISA) is often utilized because of its relative simplicity and ease of use. The components, antibodies and antigens, can be a limitation when required in large amounts, as in the current Ebola outbreak. Today, we are developing assays that use monoclonal antibodies and recombinant proteins on the MAGPIX (Luminex Corporation) platform and take advantage of addressable magnetic bead sets to multiplex assays to detect and identify multiple targets in single wells.

11:15 Integrating Non-Infectious AccuPlex Recombinant Virus Reference Materials into Biodetection Assay Development

Catherine Huang, Ph.D., Principal Scientist, Research and Development, SeraCare Life Sciences

Stable, noninfectious process controls enable laboratories to confidently develop and validate assays. AccuPlex recombinant viruses offer several distinct advantages because they are mammalian, noninfectious viral vectors with extended stability, and offer the ability to multiplex large nucleic acid target regions into one virus.

11:30 Site-Specific Conjugation to Fab Fragments via the Conserved Nucleotide Binding Site (NBS) for Enhanced Ebola Detection Capabilities

Nathan J. Alves, Ph.D., National Research Council Research Associate, Naval Research Laboratory; Department of Chemical and Biomolecular Engineering, University of Notre Dame

Site-specific Fab modification techniques are extremely limited and often require complex molecular biology based modifications. Described here is a site-specific UV-NBS photocrosslinking technique in which Fab fragments are immobilized to surfaces. This study demonstrates the oriented immobilization of biotinylated Ebola detecting Fab fragments (KZ52) yielding improved antigen detection sensitivity and lower limits of detection compared to commonly used immobilization techniques.

11:45 Targeting Amphiphiles: An Ignored Category of Biomarkers in Biodetection

Harshini Mukundan, Ph.D., Principal Investigator and Team Leader, Chemistry, Los Alamos National Laboratory

Many bacterial biomarkers are atypical amphiphiles (e.g. lipidated sugars). Detection of this disparate group of moieties requires methods that not only exploit their biochemical diversity, but also account for their interaction with host molecules *in vivo*. We will present methods developed by our team to characterize and detect amphiphilic bacterial virulence factors in clinical samples with exquisite sensitivity.

12:15 pm Lunch on Your Own

1:40 Chairperson's Remarks

Amy L. Altman, Ph.D., Vice President, Biodefense and Protein Diagnostics, Luminex Corporation

PLENARY KEYNOTE SESSION: THE FUTURE OF BIODETECTION

1:45 The Future of Biological Incident Characterization – A High Level View



Gerald Epstein, Deputy Assistant Secretary for Chemical, Biological, Radiological, and Nuclear Policy at U.S. Department of Homeland Security

In the event of a bioterrorist attack, officials will require information as quickly as possible about the organism that was involved, the environment that was affected, and the population that was exposed. Gathering and making sense of this information places great stress on environmental biodetection and clinical diagnostic capabilities. This talk will explore issues involved in providing the necessary information, including the role of biodetection and diagnostics.

2:30 Biodetection Systems—Solving for the Complex Challenges of Effective Surveillance, Timely Detection, and Accurate Attribution in a Fiscally-Constrained Environment



Matthew J. Shaw, Vice President, CBRNE Defense, Battelle

Amid an era of evolving natural and man-made biological threats, the need for highly accurate and fast biodetection systems and effective point of care is critical. Matt Shaw will discuss the future of biodetection technologies in a fiscally-constrained environment, how they have evolved and how they must adapt to meet needs of the changing threat, how they are essential for effective point-of-care, and the potential impacts of regulatory hurdles on their fielding.

3:15 Sponsored Presentation (Opportunity Available)

3:45 End of Biodetection Technologies: Pathogen & Biothreat Detection

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TUESDAY, JUNE 23

12:15 pm Conference Registration

1:40 Chairperson's Remarks

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**3:15 Diagnostics for the Public Health Emergency Medical
Countermeasures Enterprise: The BARDA CBRN Diagnostics Portfolio**

Paul Eder, Ph.D., Senior Advisor, Tunnel Consulting Services (Contractor), BARDA

BARDA's mission, within HHS' Office of the Assistant Secretary for Preparedness and Response, is to develop and procure medical countermeasures that would mitigate the adverse health effects of CBRN incidents, antimicrobial resistance, pandemic influenza, or other emerging infectious disease outbreaks. BARDA's diagnostics portfolio supports the development of rapid diagnostics to detect resistance, infection or onset of illness caused by these threats for the purpose of patient management and clinical decision-making.

3:45 Refreshment Break in the Exhibit Hall with Poster Viewing

OPTIMIZING PERFORMANCE OF TRADITIONAL POC BIODETECTION TECHNOLOGIES

**4:15 EbolaCheck - The First True POC qRT-PCR Device for 3rd World
Humanitarian Crisis Responses**

Sterghios Moschos, Ph.D., Reader (Associate Professor), Biomedical Sciences, University of Westminster

EbolaCheck is a whole biofluid qRT-PCR POC system for simple, economical and <40 min molecular diagnosis of Ebola in the field. The battery-powered platform delivers sensitivity and specificity equal to clinical diagnostics with no specialist training requirements, suitable for humanitarian crisis responses. The work is funded by DfID / Wellcome Trust / Save the Children UK and ELRHA and represents the UK response for rapid point-of-need diagnostics.

**4:45 Use of Advance Optical Imaging for Field Diagnostics of
Biothreat Agents**

Vinod Jyothikumar, Ph.D., Director, Office of Laboratory Safety, George Washington University

The use of optical imaging for medical diagnostics at the point-of-care (POC) has great potential, but is limited by cost and the need for highly trained personnel. To this end, the cost, complexity, and size of optical microscopy devices can be reduced. These techniques can perform particularly well at specific tasks such as cytometry, Field diagnostic, and infectious disease management.

5:15 End of Day

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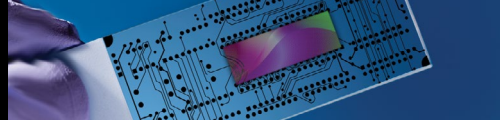
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WEDNESDAY, JUNE 24

FIELD-READY PATHOGEN DETECTION

8:00 am Morning Coffee

8:25 Chairperson's Remarks

8:30 Development and Validation of Rapid Detection and Diagnostics Assays: The Simplified Approach to Production of Successful Assays

David R. Hodge, Ph.D., Program Manager, Chemical Biological Defense Division, U.S. Department of Homeland Security (DHS)

The creation and validation of rapid point-of-care detection and diagnostic assays are often thought of as separate parts of a project. Instead they must be combined together in order to be successful in the final commercialization and end user acceptance of the assays. Here we describe a comprehensive yet inexpensive program inside DHS known as Public Health Actionable Assays, which involves a series of simple techniques and steps required to properly validate assays, and gain acceptance of such tools by the government and private end users.

9:00 ScanDrop – Portable Lab-on-a-Chip Diagnostic Platform for Ultra Fast Pathogen Detection and Susceptibility Testing

Tania Konry, Ph.D., Assistant Professor, Department of Pharmaceutical Sciences, Northeastern University

The ability to shrink the window of empiric therapy by rapidly identifying and determining antimicrobial susceptibility for pathogens will improve patient outcomes by ensuring early, active therapy. Therefore, our novel portable Lab on a Chip technology, ScanDrop, provides ultrafast and highly sensitive detection without the need for culture pre-amplification as well as phenotypic susceptibility results within 3 hours of specimen acquisition. Importantly, the ScanDrop microfluidics-based technology can be deployed with simple, inexpensive, portable instrumentation and disposables, which make the technology ideally suited to permit significantly accelerated institution of appropriate, tailored antibiotic therapy, thereby significantly improving patient outcomes and fostering antimicrobial stewardship goals. Lastly, the portability and low cost of consumables should allow for wide utility across the healthcare continuum.

9:30 Moving Biological Sensors Forward: Challenges and Opportunities

Charles Young, Ph.D., Principal Professional Staff, Chief Scientist, Applied Biology Group, Asymmetric Operations Sector, The Johns Hopkins University Applied Physics Laboratory

This presentation will touch on specific drawbacks of existing sensor technologies as well compare the current move toward point-of care-instrumentation in hospitals and how it overlaps with Department of Defense's needs. Unfulfilled DOD needs will also be addressed in the context of existing and new point-of-care technologies.

10:00 Coffee Break in the Exhibit Hall

10:45 PANEL: Portability, Compatibility, Reliability, and Scalability of Diagnostic and Detection Devices

- Getting regulatory approval – What must be considered?
- Enabling response – Should testing originate clinically or environmentally?
- Understanding the business case

Moderator: David R. Hodge, Ph.D., Program Manager, Chemical Biological Defense Division, U.S. Department of Homeland Security (DHS)

Tania Konry, Ph.D., Assistant Professor, Department of Pharmaceutical Sciences, Northeastern University

Panelists: Charles Young, Ph.D., Principal Professional Staff, Chief Scientist, Applied Biology Group, Asymmetric Operations Sector, The Johns Hopkins University Applied Physics Laboratory

11:45 Current Requirements in the World of Point-of-Care Applications: A Short Overview

Roberto Spricigo, Ph.D., OEM Manager, QIAGEN Lake Constance

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Healthcare professionals are looking for faster patient evaluation and efficient diagnosis. Rapid point-of-care tests are therefore becoming increasingly important as they provide precise quantitative results. The presentation will cover the requirements for POC devices for lateral flow and isothermal amplification applications.

12:00 pm HIV RNA Detection and Quantification by Nucleic Acid Testing-PNA Enzyme Linked Assay (NAT-PELA) for Viral Load Assays

Daniel Appella, Ph.D., Senior Investigator, LBC, NIDDK, NIH

This presentation will demonstrate how to engineer peptide nucleic acids (PNAs) to detect HIV RNA at levels competitive with standard PCR assays. Since PNA is resistant to degradation by enzymes, diagnostic devices using PNA probes are very stable. With the proper PNA probes, standard ELISA platforms can be used to directly detect HIV RNA and may be used to quantify viral load in plasma at clinically useful levels.

12:15 pm Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

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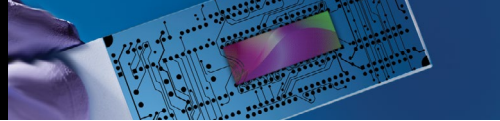
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BRINGING NGS INTO THE FIELD

1:40 Chairperson's Remarks

1:45 Moving HTS from Research Lab to Diagnostic Core

Yuriy Fofanov, Ph.D., Professor, Department of Pharmacology & Toxicology; Director of Genomics and Bioinformatics Lab at The Sealy Center for Structural Biology & Molecular Biophysics (SCSMB), University of Texas Medical Branch (Galveston) The price of High Throughput Sequencing (HTS) has dropped dramatically, while the speed of the instruments has also improved. As such, three major challenges remain to be resolved before this technology will be able to move from being nearly exclusively a research tool to routine diagnostic use. This talk will focus on strengths and weaknesses of available approaches to resolve these challenges.

2:15 Opportunities and Challenges for Diagnostic Applications of NGS

Richard Winegar, Ph.D., Chief Scientist, Biosurveillance and Diagnostics, Global Health Security, MRIGlobal

NGS has potential to provide the ultimate characterization of infectious agents. This could be especially useful in diagnosis of sepsis and fevers of unknown origin. However, significant challenges must be addressed before NGS-based diagnostics become widely adopted. These include sample and library preparation, automation, trusted reference libraries, bioinformatics, and regulatory pathways. This presentation will focus on MRIGlobal's research projects to accelerate the use of NGS as a powerful diagnostic tool.

2:45 Strengths and Weakness of NGS in Biosurveillance

Brian Young, Ph.D., Technology Initiatives Leader, Applied Genomics, Battelle Here I describe how NGS extends the range of species and strain identification possible within single assays and why NGS provides broader support for attribution. NGS also provides ancillary information such as virulence and resistance not possible from other genetic tests. However, metagenomic data presents significant data analysis challenges; where improper use of analytical tools can result in false positives or over-interpretations. The proper roles of NGS in both detection and identification are discussed.

3:15 Dessert Break in the Exhibit Hall with Poster Viewing

TECHNOLOGY TO ENABLE DECISION MAKING

4:00 Tools to Enhance Situational Awareness in Infectious Disease Surveillance

Alina Deshpande, Ph.D., Scientist, Defense Systems and Analysis Division, Los Alamos National Laboratory

Los Alamos National Laboratory has developed a suite of publicly available web-based tools that provide actionable information and knowledge for enhanced situational awareness during an unfolding event—the Surveillance Window Application (SWAP), the Biosurveillance Resource Directory (BRD), and the Biosurveillance Analytics Resource Directory (BARD). This presentation will review each tool and its application to various disease surveillance situations.

4:30 The BioWatch Program: Mission and Future

Michael Walter, Ph.D., Detection Branch Chief, BioWatch Program Manager, Office of Health Affairs, U.S. Department of Homeland Security (DHS)

Dr. Walter will provide an overview of the various BioWatch mission components, opportunities for integration and collaboration within the larger biodetection community, and the importance of engagement with regional coalitions. As the Program is looking at ways to improve bio-aerosol threat monitoring capability and capacity while increasing overall cost effectiveness, the future of the program's technology and analysis of specific capability areas for advancement will be discussed, the overall goal being to reduce the time required to accurately detect the presence of biological threats.

5:00 Close of Conference

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Biosurveillance Integration:

INTEGRATED MANAGEMENT OF THREATS

THURSDAY, JUNE 25

7:25 am Registration & Morning Coffee

RISK ANTICIPATION

8:25 Chairperson's Opening Remarks

Major General (ret) John Doesburg, International Security and Analysis Programs, Oak Ridge National Laboratory

» **8:30 KEYNOTE PRESENTATION:**

Department of Defense Advanced Technology Demonstrations in Biosurveillance

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Peter Emanuel, Ph.D., ECBC BioSciences Division Chief & JPEO-CBD JUPITR ATD Lead, Aberdeen Proving Grounds

» **9:15 KEYNOTE PRESENTATION:**

Advances in National Biosurveillance – Integrating New Analytic Capabilities for Improved Early Warning and Situational Awareness



Steve Bennett, Ph.D., Executive Director, National Biosurveillance Integration Center, U.S. Department of Homeland Security

Infectious disease outbreaks, such as the current Ebola outbreak in West Africa, or the emergence of new diseases such as SARS, MERS-Coronavirus, or new strains of avian influenza, all present difficult challenges in using traditional epidemiological approaches to the early warning problem. This talk will present a motivation for why the early warning problem is both important and difficult, and will present recent advances in the integration of different analytic capabilities as an important way forward.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

THREAT IDENTIFICATION & CHARACTERIZATION

10:45 The Biosurveillance Vision for JPEO

Nicole Rosenzweig, Director, Joint Program Executive Office for Chemical & Biological Defense, U.S. Department of Defense

The Joint Program Executive Office (JPEO) is working globally to improve the biosurveillance capacity for the Department of Defense. By systematically deploying the GBTI suite of hardware to improve detection capacity while connecting these labs to a networked analytics and communication hub, JPEO provides worldwide users with timely, actionable, and operationally valuable information enabling a more effective response to a health crisis anywhere in the world.

11:15 Third Generation Sequencing for Rapid Biosurveillance

Dave Ussery, Ph.D., Director, Comparative Genomics, Biosciences Division, Oak Ridge National Laboratory

The best unique identifier for an organism is its DNA sequence. Small USB sticks that can sequence using microfluidics and nanopore technology allow for portable monitoring, with only a small computer necessary to provide the power and to interpret the DNA sequence reads. This emerging technology will enable rapid detection of viruses, bacteria and other organisms from an environmental sample.

11:45 Integrative Biosurveillance in High Burden of Disease Populations

Harshini Mukundan, Ph.D, Principal Investigator, Chemistry Division, Los Alamos National Laboratory

Our team is working on the development of a predictive epidemiological model for surveillance of multiple pathogens while accounting for co-morbidities. Our ambitious efforts to integrate clinical, geographical and meta-data with novel diagnostics and pathogen characterization data to derive specific information that guides situational awareness will be presented.

12:15 pm Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

1:00 Dessert Break in the Exhibit Hall with Poster Viewing

THREAT IDENTIFICATION & CHARACTERIZATION (CONT.)

1:40 Chairperson's Remarks

Major General (ret) John Doesburg, International Security and Analysis Programs, Oak Ridge National Laboratory

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1:45 Biosurveillance Comparative Analysis - Lessons Learned

Robert Hooks, Division Director of CBRNE Technologies, TASC, Inc.

Utilizing the experiences of the 2009 H1N1 event, MERS-COV event, and the ongoing Ebola experience, this talk will provide a comparative review of the similar challenges and unique differences seen in managing the federal response to these events and effectively coordinating with international and local officials. Challenges in biosurveillance integration, rapid information sharing to support decision-making, governance challenges, and incorporating meaningful technology solutions during a crisis will be described.

2:15 The Economic and Social Impact of Emerging and Re-Emerging Infectious Disease: Mitigation through Education, Detection, Research, and Response

David L Hirschberg, Ph.D., Lecturer and Scientist, Department of Interdisciplinary Arts and Sciences and the Institute of Global Engagement, University of Washington, Tacoma

Emerging infectious diseases include new or unrecognized diseases, those that are spreading to new geographic areas and hosts, as well as those that are re-emerging. In this talk, I will separate data from hysteria and discuss ideas that could lead to better policy decisions for world agencies, international businesses, local governments, and individuals when faced with an emerging infection.

2:45 Refreshment Break in the Exhibit Hall with Poster Viewing

THREAT IDENTIFICATION & CHARACTERIZATION (CONT.)

3:15 Becoming ADEPT: Accelerating the Description of Emerging Pathogen Threats

Gustavo Palacios, Director, Genomic Center, United States Army Research Institute of Infectious Diseases (USAMRIID)

High-throughput sequencing technologies have become a common component in nearly all aspects of viral research, including molecular epidemiology, drug and vaccine development, surveillance and diagnostics. The presentation will address becoming ADEPT by accelerating the description of emerging pathogen threats.

3:45 PANEL DISCUSSION: Biosurveillance Integration - Challenges and Opportunities for Integrated Management of Threats to Public Health & Safety

Moderator: David L Hirschberg, Ph.D., Lecturer and Scientist, Department of Interdisciplinary Arts and Sciences and the Institute of Global Engagement, University of Washington, Tacoma

A well-integrated national biosurveillance enterprise can save lives by providing essential information for better decision making at all levels. This panel will explore how technological advances can be implemented to further address the biosurveillance core functions of aberration detection, risk anticipation, threat identification and characterization and information integration, analysis and sharing.

4:45 End of Day

FRIDAY, JUNE 26

8:00 am Morning Coffee

INTEGRATION ANALYSIS & SHARING

8:25 Chairperson's Opening Remarks

Major General (ret) John Doesburg, International Security and Analysis Programs, Oak Ridge National Laboratory

» 8:30 FEATURED PRESENTATION: DTRA's Biosurveillance Ecosystem

Richard Schoske, Ph.D., Chief of the Diagnostic Detection and Threat Surveillance Division, Chemical and Biological Technologies Department, DTRA

The Joint Science and Technology Office (JSTO) at DTRA is developing an innovative Biosurveillance Ecosystem (BSVE) that will dramatically accelerate our "detect-identify-respond" capabilities. The BSVE is a rapidly emerging set of integrated/interoperable tools and data analytics being developed to address user-defined capability need areas and to support real-time biosurveillance for early warning and course of action analysis for warfighters and first responders facing biological threats.

» 9:15 FEATURED PRESENTATION: U.S. Government's Perspective on Innovative Strategies for Improving Biosurveillance

Susan Collier Monarez, Ph.D., Director for Medical Preparedness Policy, National Security Council Staff, Executive Office of the President of the United States

The National Strategy for Biosurveillance builds on the capabilities already in place to ensure everything possible is done to identify and understand threats as early as possible. This presentation will address the U.S. Government's perspective on taking that directive and working to further innovation for improving biosurveillance.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

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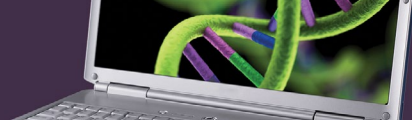
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INTEGRATION ANALYSIS & SHARING (CONT.)

10:15 Point-of-Need Metagenomic Sequence Analysis: Self-Contained NGS Analyses when Cloud Access Is Not an Option

Tom Slezak, Ph.D., Program Leader Informatics, Lawrence Livermore National Laboratory

The LLNL Pathogen Bioinformatics team has previously developed and delivered to a Federal sponsor two versions of a transportable stand-alone NGS analysis system for microbial forensics (MTCP: Microbial Threat Characterization Pipeline). We will discuss our experience in running analyses on these platforms and the benefits and disadvantages of local NGS analyses.

10:45 Community Health Resilience Toolset: An All-Hazards Web-Based Approach to Enhance a Community's Ability to Prepare, Respond and Recover from Manmade or Naturally Occurring Biological Events.

Jeffrey Stiefel, Ph.D., Executive Coordinator, Climate Change and Health Resilience, U.S. Department of Homeland Security

The Department of Homeland Security's Office of Health Affairs has

developed a web-based Community Health Resilience Toolset to strengthen/enhance health resilience across the Nation. It combines a Community Health Resilience Planning Guide and Toolkit to assist communities in initiating, maintaining and improving health resilience during steady-state and disaster operations.

11:15 Investigative Bioforensics via Heterogeneous Data Integration

Bobbie-Jo Webb-Robertson, Ph.D., Senior Research Scientist and Applied Statistics Team Lead, Pacific Northwest National Laboratory

In this work we present a Bayesian statistical network to fuse different types of analytical measurements that predict the production environment of a microorganism of interest under investigation with automated test processing of scientific publications to identify institutions with a history of growing the microbe under similar conditions.

11:45 pm Closing Remarks and End of Conference

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	Monday-Tuesday (am) June 22-23	Tuesday (pm) - Wednesday June 23-24	Thursday - Friday (am) June 25-26
Biodefense World Summit	Biodetection Technologies: Pathogen & Biothreat Detection	Biodetection Technologies: Point-of-Care for Biodefense	Biosurveillance Integration
Co-Located Events	Rapid Detection for Food Safety	Next Gen Drones	Sample Prep Technologies

Workshop Pricing (Includes access to workshops only)	Commercial	Academic, Government, Hospital-Affiliated
One Workshop	\$499	\$299
Two Workshops	\$799	\$399
Three Workshops	\$999	\$499

Tues., June 23 5:45-8:45pm Dinner Workshop	Thurs., June 25 5:30-8:30pm Dinner Workshop	Fri., June 26 1-5:00pm
Rapid Sample Preparation for Pathogen Detection	How to Launch a Laboratory Test: Everything You Wanted to Know But Were Afraid to Ask	Rapid Vaccine Technologies: Therapeutics for Emerging & Re-Emerging Infectious Diseases

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