


# Point of Care Diagnostics: Design, Development, & Adoption

August 10, 2016 • 10:00am - 5:00pm EDT • Virtual Symposium

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Thank You to everyone who has made today's program possible. Our Committee, Speakers, Sponsors, and of course You!

This program, like many of our most interesting sessions, came from the ideas and energies of our Committee. Thank you particularly to Winston Kuo, Tom White, and Claudia Campbell-Matland.

The BioPharma Research Council is a nonprofit association for scientists, engineers, and IT professionals from across all the many silos of biomedical research. Currently we reach more than 10,000 scientists through conferences, symposia, webinars, committees, boards, and roundtables.

We are always open to discussions of partnerships that can stimulate medical progress and create fresh relationships for our community!

Best,

Joanne Gere  
Executive Director  
BioPharma Research Council

## Planning Committee:



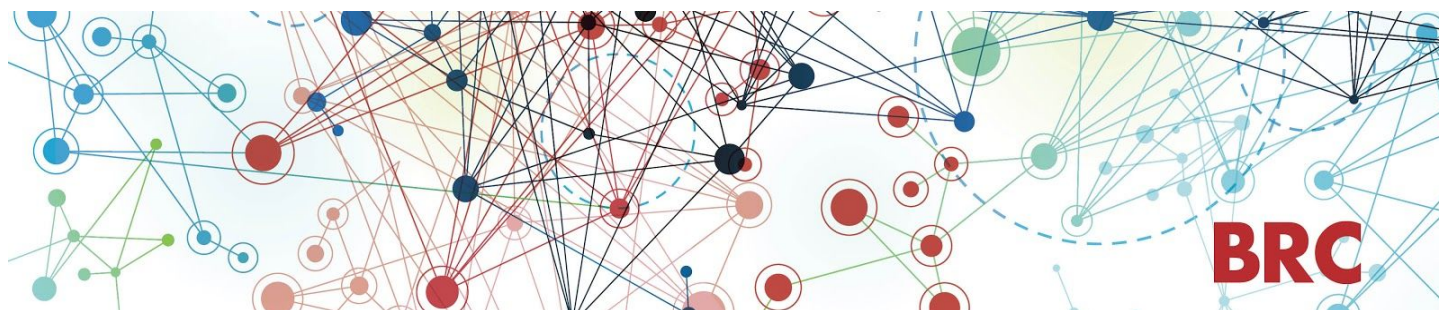
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President  
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Scientific Advisor  
Foundation for Innovative New  
Diagnostics (FIND)



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	<b>Thank you to our Committee, Speakers, and Attendees!</b>	All Times Are EDT
<b>10:00</b>	<b>Keynote: Label-free Magnetic Levitation Technologies for Monitoring Health and Disease</b>	<b>Utkan Demirci Ph.D.</b> Associate Professor of Radiology, Stanford Medicine
<b>10:45</b>	<b>Sample Prep Approaches</b>  <b>Moderator: Tom White Ph.D.</b> Former Chief Scientific Officer and Sr. VP of R&D Celera Corporation	<b>Arjun Ganesan</b> CEO, Ancera  <b>Michael Gavin</b> President, PortaScience
<b>11:40</b>	<b>Detection Systems, Instruments &amp; Reagents</b>  <b>Moderator: Winston Kuo DMSc</b> President, Predicine Holdings Ltd	<b>Ying Pan Ph.D.</b> Research Associate Stanford University School of Medicine  <b>Salvatore Russello Ph.D.</b> Associate Director, Global Business Development New England Biolabs
<b>12:55</b>	<b>Therapeutic Applications &amp; Testing: Connecting the Biology with Engineering</b>  <b>Moderator: Winston Kuo DMSc</b> President, Predicine Holdings Ltd	<b>Barbara Smith Ph.D.</b> Assistant Professor School of Biological and Health Systems Engineering Arizona State University  <b>Umut Atakan Gurkan Ph.D.</b> Case Western Reserve University Assistant Professor Case Biomanufacturing and Microfabrication Laboratory Mechanical and Aerospace Engineering Department Department of Biomedical Engineering Department of Orthopaedics Advanced Platform Technology Center Louis Stokes Cleveland Veterans Affairs Medical Center  <b>Matthew Lei Ph.D., CEO, QuanDx</b>
<b>2:00</b>	<b>Implementation &amp; Adoption</b>  <b>Moderator:</b> <b>Claudia Campbell-Matland</b> Consultant and Managing Member CNCM Consulting	<b>Peggy Mann</b> Clinics Quality, Safety, Environment Program Manager & POCC University of Texas Medical Branch  <b>Paul S. Savuto</b> President & CFO, Blinded Diagnostics
<b>2:55</b>	<b>Final Comments and Adjourn</b>	<b>Joanne Gere</b> Executive Director BioPharma Research Council
		Updated August 4, 2016 Change

## 10:00 Keynote: Label-free Magnetic Levitation Technologies for Monitoring Health and Disease

Utkan Demirci Ph.D., Associate Professor of Radiology, Stanford Medicine

Dr. Utkan Demirci leads a productive group of ~30 researchers focusing on micro- and nano-scale technologies. Dr. Demirci creates technologies to manipulate cells to enable solutions for real world problems in medicine, including applications in infectious disease and cancer diagnostics, cell encapsulation in nanoliter droplets for cryobiology, and bottom-up tissue engineering.

His research interests involve applications of microfluidics, nanoscale technologies and acoustics in medicine, especially: portable, inexpensive, disposable viral load technology platforms for HIV in resource-constrained settings for global health problems; 3-D bioprinting and tissue models including 3-D cancer and neural cultures. He was selected as one of the world's top 35 young innovators under the age of 35 (TR-35) by the MIT Technology Review. In 2004, he led a team that won the Stanford University Entrepreneur's Challenge and Global Start-up Competition in Singapore. His patents have been translated into multiple start-up companies including DxNOW, Koek Biotech and some of the technologies developed in his lab are clinically available across the globe.

### Abstract:

Micro- and nano-scale technologies can have a significant impact on medicine and biology in the areas of cell manipulation, diagnostics and monitoring. At the convergence of these new technologies and biology, we research for enabling solutions to the real world problems at the clinic. Emerging nano-scale and microfluidic technologies integrated with biology offer innovative possibilities for creating intelligent, mobile medical lab-chip devices that could transform diagnostics and monitoring, tissue engineering and regenerative medicine. In this talk, we will present an overview of our laboratory's work in these areas focused on applications in magnetic levitation methods for assembling cells and label-free sorting of rare cells from whole blood. Cells consist of micro- and nano-scale components and materials that contribute to their fundamental magnetic and density signatures.

Previous studies have claimed that magnetic levitation can only be used to measure density signatures of nonliving materials. Here, we demonstrate that both eukaryotic and prokaryotic cells can be levitated and that each cell has a unique levitation profile. Furthermore, our levitation platform uniquely enables ultrasensitive density measurements, imaging, and profiling of cells in real time at single-cell resolution. This method has broad applications, such as the label-free identification and sorting of CTCs and CTM with broad applications in drug screening in personalized medicine.

### Thank you to our Speakers and Supporters:





# Bios and Abstracts-Point of Care Diagnostic: Design, Development, & Adoption

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## 10:45 Sample Prep Approaches

**Moderator: Tom White Ph.D., Former Chief Scientific Officer and Sr. VP of R&D, Celera Corporation**

Dr. White received his B.A. in Chemistry from Johns Hopkins University and his Ph.D. in Biochemistry from the University of California at Berkeley. His postdoctoral research was carried out at the UCSF Medical Center and the University of Wisconsin in Madison. As VP of Research at Cetus Corporation, he directed R&D for multiple applications of PCR in basic research, forensics and diagnostics.

He subsequently worked for Roche Molecular Systems as Senior VP of R&D. Prior to retiring in 2011, White was Senior VP of R&D and Chief Scientific Officer at Celera Corporation, where his work involved the FDA registration of molecular diagnostic products as well as laboratory developed (CLIA) tests for complex common diseases.

### Arjun Ganesan, CEO, Ancera

Arjun Ganesan is the CEO and co-founder of Ancera, Inc., a Biotechnology Diagnostics Company. Ancera is working on technology focused on faster and more accurate diagnostic data from a point-of-care setting in the food production and healthcare ecosystems. The company has raised \$12.5MM in venture and angel funding. Ancera has also been funded by the Office of Naval Research (ONR), the U.S. Army and the National Institutes of Health (NIH).

Before Ancera, Arjun was involved in successfully starting and selling 14labs, a branding for financial services company. He was then involved in starting Southside, an entertainment content company, as well as Southside Aviation, a private aviation company. Arjun also worked with the Religions for Peace at the United Nations on the International Youth Committee.

Arjun has an MBA from Yale University and a Bachelors in Engineering from Anna University, India.

### Michael Gavin President, PortaScience

Michael Gavin's expertise includes Medical Device Design, Development and Commercialization; Medical Device Regulatory Requirements, Project Management, Program Management, and CEO and P&L responsibilities. Positions include: 2010-Current - President, PortaScience Inc., Moorestown, NJ; 2001-2010 - President, Somerset Consulting, Warren, NJ; 1992-2001 - VP R&D ITC, Edison, NJ; 1990-1992 - Director Engineering, Bayer Diagnostics, Tarrytown, NY. He has had six patents issued. Past and Present Affiliations include AACC, IEEE, AAMI and PMI. He received his BSEE in Electrical Engineering from Fairleigh Dickinson University.

### Abstract: A Novel Blood Filtering Membrane for Blood Separation

Many diagnostic tests require separation of the red blood cells (RBC) from a whole blood sample to allow the plasma to react with the reagents. PortaScience will present a novel blood filtering membrane coated with a proprietary RBC-agglutinating agent that demonstrates high separation efficiency with no appreciable hemolysis. This membrane provides rapid separation and can easily be integrated into a variety of Point-of-Care Tests (POCT) and formats, including lateral flow tests, microfluidics, and the newest lab on a chip tests. This blood filtering membrane will create significant opportunities to increase the number and quality of POCT diagnostic tests.

Panel Discussion: Sample Prep Approaches; A Novel Blood Filtering Membrane for Blood Separation

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## 11:40 Detection Systems, Instruments & Reagents

**Moderator: Winston Kuo DMSc, President, Predicine Holdings Ltd**

Dr. Kuo has spent over 20 years in academia and three years in industry. He was formerly Chief Operating Officer of the IES Diagnostics, developing molecular immune diagnostics tests for use in personalized medicine focused on measuring interferons for auto-immune diseases and cancer. Dr. Kuo has also been an active member of NIH/SBIR grant review study section since 2009 and a peer reviewer for the Qatar National Research Fund since 2013. He sat and advised on the Public-Private-Partnership and Translational CTSA Key Function Committees at the NIH and sits on numerous Scientific Advisory Boards. Dr. Kuo is on the editorial board of several international journals and is Editor-in-Chief of the Journal of Circulating Biomarkers and NanoBioMedicine. He is also founder of the Otto Heinrich Warburg Cancer Research Foundation, focused to foster, fund, and realize biomedical scientific research aimed at advancing knowledge in science and discovering effective and affordable cancer treatments with a focus on cancer metabolism.

### **Abstract:**

Point of care diagnostics (POC Dx) has gained much attention in the biomedical community as a methodology for early screening to diagnosing and monitoring the effectiveness of therapeutics (companion diagnostics) that is cost-effective and, yet easy to use. The ability to utilize POC Dx to screen and quantify biomarkers associated with disease prognosis and predictive therapeutic response would assist health care providers in their treatment selection and the ability for real-time monitoring. Implementation and developing a POC Dx device requires innovative ideas crossing disciplines with multiple levels of expertise that integrate processes and technical components for POC Dx devices to be impactful and beneficial to society.

**Ying Pan Ph.D., Research Associate, Stanford University School of Medicine**

### **Abstract:**

Time delay between diagnosis and treatment of urinary tract infection (UTI) resulted from the time-consuming conventional diagnostics has given rise to the existence of multi-drug resistant pathogens. Electrochemical biosensors are well suited for urinary diagnostics to promote rapid diagnosis of UTI and timely initiation of appropriate treatment due to their excellent sensitivity, low cost, and ability to detect a wide variety of target molecules including nucleic acids and protein biomarkers. Recent advances in electrochemical biosensor technologies have great potential to deliver point-of-care diagnosis by providing a versatile platform for rapid determination of pathogen identification, antibiotics susceptibility, and severity of disease.

**Salvatore Russello Ph.D., Associate Director, Global Business Development, New England Biolabs**

Dr. Russello has a passion for technology and the role it plays in transforming our health, our understanding of biology and ultimately the world we live in. For 15 years, he has held a variety of commercial roles at premier life science companies. In the Global Business Development group at New England Biolabs, he drives strategy, innovation and partnering. In that capacity, he has worked with technology developers to leverage novel molecular biology reagents in a wide array of diagnostic devices. He holds a Ph.D. in Molecular Biology and Genetics, with a focus on the molecular mechanisms of cancer.

### **Abstract: How today's "smart reagents" are changing the game in point of care molecular diagnostics**

The tools of molecular biology have been employed in diagnostic technologies for more than twenty years. To improve the state-of-the-art of point of care (POC) molecular diagnostics, today's innovators integrate sample collection, reagents and engineering solutions into robust, easy to use, cost effective detection platforms. Enzymes are often at the core of these platforms. The optimal design and integration of enzymes into POC devices has the potential to reduce the cost and complexity of POC testing without compromising quality. Several case studies will be presented that outline how reagents are leading to better, more powerful POC diagnostics.

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## 12:55 Therapeutic Applications & Testing: Connecting the Biology with Engineering

**Moderator: Winston Kuo DMSc, President, Predicine Holdings Ltd**

**Barbara Smith Ph.D., Assistant Professor, School of Biological and Health Systems Engineering, Arizona State University**

Dr. Smith joined Arizona State University's School of Biological and Health Systems Engineering as an assistant professor in January 2015. Barbara's career began in industry, with the initiation of a company and the design of commercial products. After completing her Ph.D. in tissue engineering and nanotechnology, Barbara joined the Whitesides' Lab at Harvard University where she developed paper-based diagnostics.

She formed connections across India to translate diagnostic devices, designed on the bench top, into the hands of users in India. At ASU, Barbara's laboratory is actively working to develop non-invasive, point-of-care diagnostics for improving women's health. These methods include paper-based molecular diagnostics, olfactory sensing, and tissue imaging. Barbara's innovative approach is aimed towards driving international exposure and product translation; connecting ASU students to relevant problems that exist both in our back yards and/or throughout the far-reaching areas of the world.

**Umut Atakan Gurkan, Ph.D., Case Western Reserve University**

Assistant Professor, Case Biomanufacturing and Microfabrication Laboratory

Mechanical and Aerospace Engineering Department; Department of Biomedical Engineering

Department of Orthopaedics; Advanced Platform Technology Center; Louis Stokes Cleveland Veterans Affairs Medical Center

Dr. Gurkan is leading the CASE Biomanufacturing and Microfabrication Laboratory (CASE-BML) in Mechanical and Aerospace Engineering at Case Western Reserve University (CWRU). Inspired by modern advanced manufacturing methods, the primary focus of CASE-BML is developing micro/nano-scale technologies for biomanufacturing complex multiscale biological systems and musculoskeletal tissues. Micro/nano-engineered strategies and engineered biological systems developed at CASE BML enable broad applications in musculoskeletal research, regenerative medicine, clinical diagnostics, pharmaceutical research, in vitro models of human diseases, and national security.

Dr. Gurkan's collaborative clinical research and teaching have been recognized with international and institutional awards, such as the IEEE-Engineering in Medicine and Biology Society Wyss Award for Translational Research, and Partners in Excellence Award for Outstanding Community Contributions. Dr. Gurkan is currently serving in the editorial board of International Journal of Nanomedicine, has published original research articles, reviews and editorials in engineering as well as clinical international journals, including, Advanced Materials, Advanced Healthcare Materials, Biomaterials, Tissue Engineering, Lab on a Chip, Annals of Biomedical Engineering, Biotechnology Journal, International Journal of Nanomedicine, ACS Nano, Nanomedicine, Biomicrofluidics, Biofabrication, Journal of Biomedical Materials Research, PLoS One, Calcified Tissue International, and Clinical Orthopedics and Related Research.

**Matthew Lei Ph.D., CEO, QuanDx**

Dr. Lei founded QuanDx in 2010 and brings broad experience in finance, research, and clinical development and manufacturing to his role as Chief Executive Officer. Prior to founding QuanDx, Dr. Lei served as Eastern Regional Account Manager of CVC Microtech, where he was responsible for marketing and sales in the eastern region of the US. Dr. Lei received his Bachelors in Medicine from Tongji Medical College of Huazhong University of Science and Technology. He received his Ph.D. in Pharmacology from Cornell University, where he worked as a research associate at Memorial Sloan-Kettering Cancer Center on cancer diagnostics and anti-cancer drug development.



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## 2:00 Implementation & Adoption

**Moderator: Claudia Campbell-Matland, Consultant and Managing Member, CNCM Consulting**

Ms. Campbell-Matland's over 30-year career in the diagnostics industry has included leadership positions in R&D, Business Development and Marketing. A certified Project Management Professional and Quality System auditor, her experience has included management of a variety of business-critical programs such as new product development programs from conception to commercialization, product acquisitions, functional department integrations and remediation of Quality System and Regulatory audit deficiencies.

As an independent consultant, she is leveraging her expertise to assist start-up and small medical device companies with project management and compliance services for new product development and other programs, and assisting universities with their research commercialization efforts. She received her M.S. in Microbiology at the Rutgers University Graduate School of Biomedical Sciences/UMDNJ.

**Peggy Mann, Clinics Quality, Safety, Environment Program Manager & POCC, University of Texas Medical Branch**

At the University of Texas Medical Branch, Ms. Mann is the Ambulatory POCC, a Program Manager, and the laboratory liaison. Her clinic oversight extends 400 miles from the medical school campus to include clinics related to three campuses and covers more than 100 clinics.

She is the current AACC CPOCT Board Secretary. She is the CLSI Vice-Chair of the POC Expert Panel and serves on a five year CLSI-CDC Project studying 'Improving the Impact of Laboratory Practice Guidelines'. She is active in two POCC Groups and the AACC Texas Section.

### **Abstract: Challenges to Implementation and Use of Point of Care Testing in a Clinical Environment**

Diagnostic tests which use a patient sample are subject to the CLIA regulations (42CFR493). Upon receiving market clearance, whether 510(k) or PMA, all tests are assigned a CLIA complexity (high, moderate or waived), and the hoops through which an end user must jump to comply with these requirements vary by test complexity.

This talk will focus on the requirements for implementation and routine use of moderately complex diagnostics. The specific needs of the end user that should be addressed by the device manufacture will be explained.

**Paul S. Savuto, President & CFO, Blinded Diagnostics**

Mr. Savuto has been a sales and marketing executive in the medical device and diagnostic field for 28 years. His industry experience includes development and product launch of over 40 medical devices for Baxter, Vickers Medical, WR Grace, Medtronic, PDI and International Technidyne Corporation.

He holds a Bachelor's degree in Microbiology from the University of Maine at Orono, a Master's degree in Clinical Microbiology from Columbia University's College of Physicians and Surgeons and a Masters of Business Administration in Marketing from Pace University's Lubin School of Business. Also an author of several medical industry publications, he is co-founder of Blinded Diagnostics, a contract service organization that provides point of care diagnostic solutions for use in pharmaceutical and biopharmaceutical clinical trials.

### **Abstract: Use of Point of Care Diagnostics in Biopharmaceutical Clinical Trials**

Point of Care Testing (POCT) has been used routinely in hospitals, clinics and physician offices for decades. The use of electrochemistry in small portable devices, starting in the 1960s with glucose meters, has dramatically advanced the use of POCT. Throughout the 1990s to present day, there has been a steady adoption of POCT technology to fulfill the demand for reliable and actionable diagnostic test results within minutes with a small patient sample.

What once was the domain of the central laboratory has shifted to a hybrid model that incorporates both lab testing and POCT to optimize patient care. The deployment of POCT in pharmaceutical clinical trials is a relatively new and innovative development. Application of POCT in interventional pharmaceutical clinical trials started around 1995. Since then, POCT has continued to be used in clinical trials due to advancements in platform technologies and enhanced test menus driven by the in-vitro diagnostics market. A substantial number of randomized controlled trials have shown that POCT correlates closely with Central Lab.

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