Exponent®
Engineering & Scientific Consulting

Alexis Sauer-Budge, Ph.D.

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Professional Profile

Dr. Sauer- Budge specializes in the intersection between biology and materials. Trained in chemistry and biophysics, she applies her interdisciplinary experience to the development and design analysis of products for the medical device, biotechnology, and pharmaceutical industries. She has particular expertise in clinical diagnostics (the testing and identification of biological materials), including nucleic acids (DNA and RNA), proteins, microbes (bacteria, fungi, antimicrobial resistance), and human specimens (blood, urine, saliva, etc.). Throughout her career, Dr. Sauer-Budge has been involved in the research and development of biosensors, sample preparation techniques, microfluidic devices, anti-fouling coatings, devices for the continuous monitoring of biomarkers, implants, 3D bioprinting, bench-top instrumentation, and multi-functional surgical tools.

Dr. Sauer-Budge assists clients in device and diagnostics design, identification of microbial and chemical contaminants, assay development (immunoassays, nucleic acid tests, cell-based assays), testing of the impact microbial growth on materials, biocompatible/non-fouling coatings, and scale-up for manufacturing. Dr. Sauer-Budge works with companies at all stages as well as in the government and legal sectors. She is an active participant in peer review, including serving as a standing member of an NIH review committee and has published more than 35 articles. An accomplished inventor, she often participates in the assessment and protection of intellectual property.

Prior to joining Exponent, Dr. Sauer-Budge led the biomedical/biotechnology group at the Fraunhofer Center for Manufacturing Innovation at Boston University for 10 years. She worked in the space between academia and industry, conducting applied research in the areas of medical diagnostics, devices, and instrumentation. She managed translational programs, helping to transition technologies from the bench through scale-up and FDA readiness. Prior to Fraunhofer, Dr. Sauer-Budge worked at BioScale, a start-up focused on commercializing a bioMEMs resonating membrane platform technology for the clinical diagnostic and food safety markets. Her graduate work was in the laboratory of Prof. Daniel Branton developing single molecule sequencing technologies that is now commercialized by Oxford Nanopore.

Academic Credentials & Professional Honors

Ph.D., Biophysics, Harvard University, 2002

M.S., Chemistry, Stanford University, 1997

B.S., Chemistry, Stanford University, 1996

Academic Appointments

Adjunct Associate Professor, Biomedical Engineering, Boston University, 2017-present

Adjunct Research Assistant Professor, Biomedical Engineering, Boston University, 2009-2017

Prior Experience

Senior Research Scientist, Fraunhofer Center for Manufacturing Innovation, 2007-2017

Director of Microbial Assay Development, BioScale, Inc., 2005-2007

Senior Scientist, BioScale, Inc, 2003-2005

Consultant, Eagle Research and Development, 2000-2003

Research Assistant, Hauser Chemical Research, 1993-1995

Professional Affiliations

American Association for Clinical Chemistry (AACC)

Medical Device Group (MDG)

Northeast Branch - American Society for Microbiology (ASM)

Patents

US Patent # 9199250 B2 "Disposable Separator/Concentrator Device and Method of Use." December 2015. A. Sauer-Budge, A. Size, H. Wirz, A. Sharon.

US Patent #9046483 B2 "Characterization of hybridized polymer molecules based on monomer-interface interactions." July 2015. T. Denison, A. Sauer-Budge, J. Golovchenko, A. Meller, E. Brandin, D. Branton.

US Patent #8986528 B2 "Characterization of hybridized polymer molecules based on monomer-interface interactions." March 2015. T. Denison, A. Sauer-Budge, J. Golovchenko, A. Meller, E. Brandin, D. Branton.

US Patent # 8,785,148 "Method and Device for Rapid Detection of Bacterial Antibiotic Resistance/Susceptibility" July 2014. A. Sauer-Budge, A. Sharon, M. Kalashnikov, H. Wirz.

US Patent # 8,227,261, "Methods and apparatus for assay measurements." July 2012. B. Masters, M. Miller, A. Sauer-Budge.

US Patent # 7,632,638 B2 "Methods and apparatus for detecting viruses using an acoustic device." December 2009. A. Sauer-Budge, B. Masters, M. Miller, M. Lundstrom.

US Patent # 7,629,137 B2 "Methods and apparatus for detecting bacteria using an acoustic device." December 2009. A. Sauer-Budge, E. Fitch, B. Masters, M. Miller, M. Lundstrom.

US Patent # 6,673,615 "Characterization of hybridized polymer molecules based on monomer-interface interactions." January 2004. T. Denison, A. Sauer, J. Golovchenko, A. Meller, E. Brandin, D. Branton.

US Patent # 6,362,002 B1 "Characterization of hybridized polymer molecules based on monomer-

interface interactions." March 2002. T. Denison, A. Sauer, J. Golovchenko, A. Meller, E. Brandin, D. Branton.

Publications

Sauer-Budge, A. F. 2019. New technologies for the rapid identification of drug-resistant bacteria. TechConnect Briefs:310-313.

Gladman, A. S., M. Garcia-Leiner, and A. F. Sauer-Budge. 2019. Emerging polymeric materials in additive manufacturing for use in biomedical applications. 6(1):1-20.

Gutermuth, A., J. Maassen, E. Harnisch, D. Kuhlen, A. Sauer-Budge, C. Skazik-Voogt, and K. Engelmann. 2019. Descemet's Membrane Biomimetic Microtopography Differentiates Human Mesenchymal Stem Cells Into Corneal Endothelial-Like Cells. Cornea 38(1):110-119.

Fernandez-Carballo, B. L., C. McBeth, I. McGuiness, M. Kalashnikov, C. Baum, S. Borros, A. Sharon, and A. F. Sauer-Budge. 2018. Continuous-flow, microfluidic, qRT-PCR system for RNA virus detection. Anal Bioanal Chem 410(1):33-43.

Ganser, P., C. Baum, D. Chargin, A. F. Sauer-Budge, and A. Sharon. 2018. A practical approach for the optimization of channel integrity in the sealing of shallow microfluidic devices made from cyclic olefin polymer. Biomed Microdevices 20(2):24.

Kalashnikov, M., J. C. Lee, and A. F. Sauer-Budge. 2018. Optimization of Stress-Based Microfluidic Testing for Methicillin Resistance in Staphylococcus aureus Strains. Diagnostics (Basel) 8(2).

Sauer-Budge, A. F., S. J. Brookfield, R. Janzen, S. McGray, A. Boardman, H. Wirz, and N. R. Pollock. 2017. A novel device for collecting and dispensing fingerstick blood for point of care testing. PLoS One 12(8):e0183625..

Kalashnikov, M., M. Mueller, C. McBeth, J. C. Lee, J. Campbell, A. Sharon, and A. F. Sauer-Budge. 2017. Rapid phenotypic stress-based microfluidic antibiotic susceptibility testing of Gram-negative clinical isolates. Sci Rep 7(1):8031..

McBeth, C., A. Gutermuth, J. Ochs, A. Sharon, and A. F. Sauer-Budge. 2017. Automated Tissue Dissociation for Rapid Extraction of Viable Cells. Procedia CIRP 65:88-92..

Kulik, M., J. Ochs, N. König, C. McBeth, A. Sauer-Budge, A. Sharon, and R. Schmitt. 2017. Parallelization in Automated Stem Cell Culture. Procedia CIRP 65:242-247.

McBeth, C., J. Lauer, M. Ottersbach, J. Campbell, A. Sharon, and A. F. Sauer-Budge. 2017. 3D bioprinting of GelMA scaffolds triggers mineral deposition by primary human osteoblasts. Biofabrication 9(1):015009.

Teng, F., T. Cormier, A. Sauer-Budge, R. Chaudhury, V. Pera, R. Istfan, D. Chargin, S. Brookfield, N. Y. Ko, and D. M. Roblyer. 2017. Wearable near-infrared optical probe for continuous monitoring during breast cancer neoadjuvant chemotherapy infusions. J Biomed Opt 22(1):14001..

Campbell, J., C. McBeth, M. Kalashnikov, A. K. Boardman, A. Sharon, and A. F. Sauer-Budge. 2016. Microfluidic advances in phenotypic antibiotic susceptibility testing. Biomed Microdevices 18(6):103.

Boardman, A. K., W. S. Wong, W. R. Premasiri, L. D. Ziegler, J. C. Lee, M. Miljkovic, C. M. Klapperich, A. Sharon, and A. F. Sauer-Budge. 2016. Rapid Detection of Bacteria from Blood with Surface-Enhanced Raman Spectroscopy. Anal Chem 88(16):8026-8035..

Premasiri, W. R., J. C. Lee, A. Sauer-Budge, R. Theberge, C. E. Costello, and L. D. Ziegler. 2016. The biochemical origins of the surface-enhanced Raman spectra of bacteria: a metabolomics profiling by SERS. Anal Bioanal Chem 408(17):4631-4647.

Fernandez-Carballo, B. L., I. McGuiness, C. McBeth, M. Kalashnikov, S. Borros, A. Sharon, and A. F. Sauer-Budge. 2016. Low-cost, real-time, continuous flow PCR system for pathogen detection. Biomed Microdevices 18(2):34.

Keenan, M., C. Howard, T. Tate, I. McGuiness, A. Sauer-Budge, J. Black, U. Utzinger, and J. K. Barton. 2016. Design of an everting balloon to deploy a microendoscope to the fallopian tubes. SPIE BiOS: Photonic Therapeutics and Diagnostics XII. SPIE.

Teng, F., T. Cormier, A. Sauer-Budge, and D. M. Roblyer. 2016. A wearable optical device for continuous monitoring during neoadjuvant chemotherapy infusions. SPIE BiOS:Optical Diagnostics and Sensing XVI: Toward Point-of-Care Diagnostics. SPIE.

Campbell, J., N. Pollock, A. Sharon, and A. F. Sauer-Budge. 2015. Development of an automated on-chip bead-based ELISA platform. Anal Methods 7(19):8472-8477.

Campbell, J., I. McGuinness, H. Wirz, A. Sharon, and A. F. Sauer-Budge. 2015. Multimaterial and Multiscale Three-Dimensional Bioprinter. Journal of Nanotechnology in Engineering and Medicine 6(2):021005-021007.

Boardman, A. K., J. Campbell, H. Wirz, A. Sharon, and A. F. Sauer-Budge. 2015. Rapid microbial sample preparation from blood using a novel concentration device. PLoS One 10(2):e0116837.

Rosen, J. E., A. Size, Y. Yang, A. Sharon, and A. Sauer-Budge. 2015. Artificial hand for minimally invasive surgery: design and testing of initial prototype. Surg Endosc 29(1):61-67.

Briggs, J. C., O. A'amar, I. Bigio, J. E. Rosen, S. L. Lee, A. Sharon, and A. F. Sauer-Budge. 2014. Integrated Device for in Vivo Fine Needle Aspiration Biopsy and Elastic Scattering Spectroscopy in Preoperative Thyroid Nodules. Journal of Medical Devices 8(2):021003-021006.

Kalashnikov, M., J. Campbell, J. C. Lee, A. Sharon, and A. F. Sauer-Budge. 2014. Stress-induced antibiotic susceptibility testing on a chip. J Vis Exp (83):e50828.

Byrnes, S., A. Fan, J. Trueb, F. Jareczek, M. Mazzochette, A. Sharon, A. F. Sauer-Budge, and C. M. Klapperich. 2013. A Portable, Pressure Driven, Room Temperature Nucleic Acid Extraction and Storage System for Point of Care Molecular Diagnostics. Anal Methods 5(13):3177-3184.

Boardman, A. K., S. Allison, A. Sharon, and A. F. Sauer-Budge. 2013. Comparison of anti-fouling surface coatings for applications in bacteremia diagnostics. Anal Methods 5(1):273-280.

Sauer-Budge, A. F., A. K. Boardman, S. Allison, H. Wirz, D. Foss, and A. Sharon. 2013. Materials and Surface Properties Optimization to Prevent Biofouling of a Novel Bacterial Concentrator. Procedia CIRP 5:185-188.

Mirsky, P., A. Chatterjee, A. F. Sauer-Budge, and A. Sharon. 2012. An automated, parallel processing approach to biomolecular sample preparation. J Lab Autom 17(2):116-124.

Kalashnikov, M., J. C. Lee, J. Campbell, A. Sharon, and A. F. Sauer-Budge. 2012. A microfluidic platform for rapid, stress-induced antibiotic susceptibility testing of Staphylococcus aureus. Lab Chip 12(21):4523-4532.

Wirz, H., A. F. Sauer-Budge, J. Briggs, A. Sharpe, S. Shu, and A. Sharon. 2012. Automated production

of plant-based vaccines and pharmaceuticals. J Lab Autom 17(6):449-457.

Premasiri, W. R., A. F. Sauer-Budge, J. C. Lee, C. M. Klapperich, and L. D. Ziegler. 2012. Rapid bacterial diagnostics via surface enhanced Raman microscopy. Spectroscopy (Springf) 27(6):s8-31.

Campbell, J., P. Mirsky, A. Chatterjee, A. Sharon, and A. F. Sauer-Budge. 2012. A semi-automated liquid handler for parallel sample preparation. Biotech International (May / June):23-25.

Gruentzig, A. W., C. M. Klapperich, A. Sharon, J. Braman, A. Chatterjee, and A. F. Sauer-Budge. 2011. A new DNA extraction method for automated food analysis. Analytical Methods 3:1507-1513.

Sauer-Budge, A. F., and A. Sharon. 2011. Editorial for the special issue of RCIM on translational research — Where engineering meets medicine. Robotics and Computer-Integrated Manufacturing 27(2):235-236.

Size, A., A. Sharon, and A. Sauer-Budge. 2011. An automated low cost instrument for simultaneous multi-sample tissue homogenization. Robotics and Computer-Integrated Manufacturing 27(2):276-281.

Sauer-Budge, A.F., P. Mirer, A. Chatterjee, N. Pollock, C. Klapperich, and A. Sharon. Integrated lab-on-a-chip Influenza diagnostic designed for low cost manufacturing. Techworld 2010, 2010. Anaheim, CA.

Chatterjee, A., P. L. Mirer, E. Zaldivar Santamaria, C. Klapperich, A. Sharon, and A. F. Sauer-Budge. 2010. RNA isolation from mammalian cells using porous polymer monoliths: an approach for high-throughput automation. Anal Chem 82(11):4344-4356.

Sauer-Budge, A. F., P. Mirer, A. Chatterjee, C. M. Klapperich, D. Chargin, and A. Sharon. 2009. Low cost and manufacturable complete microTAS for detecting bacteria. Lab Chip 9(19):2803-2810.

Sauer-Budge, A. F., J. A. Nyamwanda, D. K. Lubensky, and D. Branton. 2003. Unzipping kinetics of double-stranded DNA in a nanopore. Phys Rev Lett 90(23):238101.

Sauer-Budge, A. and Branton, D. (2002). "Unzipping Double-Stranded DNA Molecule by Molecule through a Nanopore." Thesis presented to Harvard University in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Biophysics. October.

Sauer, A. and Zare, R. (1997). "The Interaction Of Peptide Nucleic Acid With Complementary Single-Stranded DNA And Double-Stranded DNA In The Development Of A Genetic Screening Protocol" Thesis presented to Stanford University in partial fulfillment of the requirements for the degree of Master of Science in Chemistry. June.

Presentations

Sauer-Budge, A. (2017) Invited talk. "Rapid Sample to Answer Antibiotic Susceptibility Testing for Bacteremia" Lab-on-a-Chip & Microfluidics World Congress 2017, San Diego, CA.

Sauer-Budge, A. (2017) Invited talk. "Automated tissue dissociation for rapid extraction of viable cells" CIRP Biomanufacturing, Chicago, IL.

Kalashnikov M, Mueller M, McBeth C, Lee JC, Sharon A, Sauer-Budge, A. (2017) Poster "Phenotypic stress-based antibiotic susceptibility testing of Gram-negative clinical isolates" Gordon Research Conference, Microfluidics, Italy.

Sauer-Budge, A. (2017) Invited talk. "Assay development while designing for manufacturing" Microfluidics 8.4, Boston, MA

Sauer-Budge, A. (2017) Invited talk. "Plasma surface modifications for microfluidic and diagnostic devices" PlasmaTreat Open House.

Sauer-Budge, A. (2017) Invited talk. "Empowering Rapid Diagnostics with Sample Preparation Methodologies" Sample Prep, Washington DC.

Sauer-Budge, A. (2016) Invited Talk. "Rapid phenotypic methods for diagnosing infections and antibiotic susceptibility testing" BioDefense Global Summit, Baltimore, MD.

Sauer-Budge, A. (2015) Invited Talk. "Isolation of Dilute Pathogens from Blood" Select Bio Circulating Biomarkers World Congress 2015, Boston, MA..

Sauer-Budge, A. (2015) Invited Talk. "Rapid sample preparation of viable bacteria directly from blood specimens" Sample Prep 2015. Bethesda, MD.

Sauer-Budge, A. (2015) Invited Talk. "Rapid phenotypic methods for diagnosing infections and antibiotic susceptibility testing." AACC Emerging Clinical & Laboratory Diagnostics: Pushing the Envelope, Los Angeles, CA.

Kalashnikov M, Campbell J, Hanelt I, Lee J, Sharon A, Sauer- Budge AF. (2014) Invited Poster. "Enhanced microfluidic platform for stress- induced rapid antibiotic susceptibility testing." AACC Emerging Clinical & Laboratory Diagnostics Conference, San Jose, CA.

Sauer-Budge, A (2014) Invited talk. "Design for low cost manufacturing of point of care microfluidic devices", SLAS 2014, San Diego, CA.

Sauer-Budge, A (2013) Invited talk. "Rapid Bacterial Sample Preparation from Blood", Sample Prep 2013, San Diego, CA.

Sauer-Budge, A (2013) Invited talk. "Automated on-chip bead-based ELISA", Sample Prep East, Boston, MA.

Sauer-Budge, A (2012) Invited talk. "Innovations at the Intersection of Mechanical Engineering and Life Sciences", Boston University Mechanical Engineering Department Seminar Series, Boston, MA.

Sauer-Budge, A. (2012) Invited talk. "Development of a point-of-care rapid and sensitive bacteremia diagnostic," AACC Oakridge 2012, San Jose, CA.

Sauer-Budge, A (2012) Invited talk. "Isolation of dilute bacteria from blood for rapid diagnostics", Sample Prep 2012, San Diego, CA.

Kalashnikov, M., Campbell, J., Lee, J.C., Sharon, A., Sauer-Budge, A.F. (2012) Poster presentation. "Rapid, Stress-Induced Antibiotic Susceptibility on a Chip". IEEE Micro- and Nano-engineering conference, Maui, HI.

Campbell J, Sauer-Budge AF, and Sharon A. (2012) Poster presentation. "Research at the Intersection of Life Sciences and Engineering: Developing Microfluidic Platforms for Diagnostic Applications". Gordon Research Conference: Bioanalytical sensors, Newport, RI.

Kalashnikov MK, Lee JC, Sharon A, and Sauer-Budge AF. (2012) Poster presentation. "Microfluidic platform for stress-induced rapid antibiotic susceptibility testing". AACC Oakridge 2012, San Jose, CA.

Sauer-Budge, A (2009) Invited talk. "Microfabricated tools for programming live neural pathways", Neural Restoration Workshop, Washington D.C.

Sauer-Budge, A. (2008) Invited talk. Boston University Biomedical Engineering Department Seminar Series. "Integrating microfluidic sample preparation and molecular diagnostics into a low cost disposable device"

Sauer-Budge, A. (2005) Invited talk to the NIH Viral Load Working Group, NIH, Bethesda, MD, November.

Sauer-Budge, A., Nyamwanda, J., Lubensky, D. K. and Branton, D. (2003). "Progress towards Nanopore-based single molecule sequencing: The Unzipping of Double-Stranded DNA Forced through a Nanopore Measured at the Single Molecule Level." BioMEMS, The Knowledge Foundation, Cambridge, MA.

Sauer, A., Dulay, M.D., and Zare, R. (1996). "Kinetic Studies of Mixed Base PNA-DNA Hybridization with Capillary Electrophoresis and Laser Induced Fluorescence Detection" Johnson Symposium for Organic Chemistry, Stanford University.

Editorships & Editorial Review Boards

Robotics and Computer-Integrated Manufacturing, Editor for Special Issue on "Translational Research - Where Engineering Meets Medicine" (2011).

Peer Reviewer

Journals

Lab On A Chip

Scientific Reports

Bioengineering

PLOS One

Antibiotics

ASME Journal of Nanotechnology in Engineering and Medicine

RSC Advances

NIH Review Panels

NIH Center for Scientific Review Enabling Bioanalytical and Imaging Technologies (EBIT), Standing member, 2017 - 2020

NIH Center for Scientific Review EBIT, Ad hoc reviewer, 2016

NIH Center for Scientific Review Clinical Research and Field Studies (CRFS), Ad Hoc Reviewer, 2016

NIH/NIAID ZAI1 RRS-M (C2), Contracts Sample Preparation, 2015

NIH/NIAID ZAI MM-1 (M1), Development of Sample Sparing Assays for Monitoring Immune Responses, 2015

NIH ZRG1 F130C 20, Center for Scientific Review Special Emphasis panel, Fellowships, 2015

NIH /NIAID ZAI1 ALW0M (J1), NIAID Clinical Trial Planning Grant (R34), 2015

NIH/NIGMS ZGM1 BBCB-A(BI), Biomedical Instrumentation Special Emphasis Panel (SEP), 2014

NIH/NIMH ZMH1 ERB-L (04), BRAIN Initiative Review Special Emphasis Panel (SEP), 2014

NIH Center for Scientific Review CRFS, Ad Hoc Reviewer, 2014

NIH/NIAID ZAI MFH-M (J1), Partnerships for Diagnostics to Address Antimicrobial Resistance of Select Bacterial Pathogens, 2014

NIH/NIGMS ZGM1 BBCB-A (BT), Biomedical Instrumentation Special Emphasis Panel (SEP), 2013

NIH/NIAID ZAI-LG-M-J1, Partnerships for Biodefense (Diagnostics), 2012

NIH/NHLBI SBIR Contract Proposals: Phase 2, Protein Capture Agents for Cardiovascular Research, 2011

NIH/NIAID U.S. India Bilateral Collaborative Research Partnerships (CRP) for Prevention of HIV/AIDS and Co-Morbidities, 2010

NIH/NIAID ZAI1 LG-M (J3) Partnerships for Biodefense (Diagnostics), 2010

NIH/NHLBI SBIR Contract Proposals: Phase 1 Protein Capture Agents for Cardiovascular Research, 2010