OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

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NAME: Berry, Scott M.

eRA COMMONS USER NAME (credential, e.g., agency login): smberr03

POSITION TITLE: Associate Professor, University of Kentucky; Co-Founder and CSO, Salus Discovery, LLC

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Louisville	B.S.	05/2003	Mechanical Eng.
University of Louisville	M. Eng.	08/2004	Mechanical Eng.
University of Louisville	M.B.A.	12/2007	Business
University of Louisville	Ph.D.	12/2008	Mechanical Eng.
University of Wisconsin-Madison	Post-doctoral	06/2011	Biomedical Eng.

A. Personal Statement

My research is focused on the application of engineering principles to molecular diagnostics. Over the past 13 years, I have investigated how novel fluid mechanics phenomena can be applied to “improve” molecular assays. Many of these improvements have served to increase throughput, reduce operational complexity, and/or minimize costs. However, they can also unlock fundamentally new functionalities, enabling clinicians and basic scientists to measure molecular and cellular analytical processes that were previously unobservable. This concept has led to the development of many new assay technologies and platforms focused on a broad menu of diseases, including HIV, TB, HBV, HCV, influenza, several types of cancer, and most recently SARS-CoV-2. I have led many collaborative studies involving engineers, basic scientists, biologists, clinicians, and public health experts spanning multiple countries as well as the interfaces between academia, industry, and government. Most recently, I have successfully led multiple projects involving the development and deployment of new technologies for measuring biomarkers in environmental samples including wastewater and surface water.

Ongoing Research Support

NSF PIPP Phase 1 **August 2022 – February 2025**

Advancing Environmental Surveillance for Pandemic Prediction in Remote and Resource Poor Settings

- Identify key challenges associated with global implementation of environmental surveillance of pathogens
- Perform pilot pathogen detection activities in Sub-Saharan Africa and Southeast Asia

Role: PI ***Total Costs: $1M***

NIH/NIDA U01 **January 2021-May 2025**

Wastewater Assessment for Coronavirus in Kentucky: Implementing Enhanced Surveillance Technology

- Develop new technology for point-of-care wastewater analysis
- Screen for SARS-CoV-2 virus in wastewater in Appalachia

Role: PI ***Total Costs: $3.38M***

SUPRA Pilot Proposal **January 2022–June 2024**

Wasted WATER (Wastewater Analysis to Track Emerging Risks)

- Apply wastewater monitoring technology to the detection of licit and illicit drugs
- Integrate mass spectroscopy endpoints into existing wastewater analyses

Role: PD/PI **Total Direct Costs: $50,000**

NIEHS UK-CARES High Impact Pilot Award **August 2023–March 2023**

Surveillance of Water and Vector-borne Pathogens Following Climate-Disasters in Eastern Kentucky

- Develop technologies for testing of pathogens in flood waters following a natural disaster
- Work with citizen scientists to demonstrate deployment of technology

Leadership: Berry (PD/PI) **Total Costs: $77,721**

B. Positions and Honors

Positions and Employment

2001-2002 Mechanical Engineer (co-op), Louisville Gas & Electric
2003-2003 Graduate Assistant (Biomechanics), Dept. of Mechanical Eng., Univ. of Louisville 2003-2009 Graduate Assistant (Microfludics), Dept. of Mechanical Eng., Univ. of Louisville 2009-2011 Postdoctoral Fellow, Dept. of Biomedical Eng., Univ. of Wisconsin-Madison
2011-2019 Research Scientist, Dept. of Biomedical Eng., Univ. of Wisconsin-Madison 2013-Present Chief Scientific Officer, Salus Discovery, LLC
2019-Present Associate Professor, Dept. of Mechanical Eng., Univ. of Kentucky

Other Experience and Professional Memberships

2008-present Member, Biomedical Engineering Society
2011-present Member, American Association for Cancer Research

C. Contributions to Science (among 45 publications)

Google Scholar Link: https://scholar.google.com/citations?hl=en&user=iX4Z680AAAAJ

1. My early work focused on using microscale-based phenomenon to pattern precise micro- and nano-structures. Our goal was to use “passive” principles, including surface tension and evaporation in this case, to enable the production of finely scaled structures without the need for precision fabrication equipment. After developing and optimizing this process, these structures were used in a variety of application areas including nano-electronics, microfluidics, and tissue engineering. The publications below describe this unique fabrication process and showcase the variety of ways that it can be applied. As a graduate student, my specific role in this project was to perform the research and design future experiments.
    a. **Berry, S. M.**, Cambron, S. D., Warren, S. P., Pabba, S., Cohn, R. W., and Keynton, R. S. Characterization and Modeling of Direct Write Fabrication of Microscale and Sub-Microscale Polymer Fibers. Polymer, 2011, 52(7) 1654-1661.
    b. **Berry, S. M.**, Warren, S. P., Hilgart, D. A, Pabba, S., Gobin, A. S., Cohn, R. W., and Keynton R. S. Endothelial Cell Scaffolds Generated by 3D Direct Writing of Biodegradable Polymer

Microfibers. Biomaterials, 2011, 32(7) 1872-1879.

c. **Berry, S. M.**; Roussel, T. J.; Cambron, S. D.; Cohn, R. W.; Keynton, R. S. Fabrication of suspended electrokinetic microchannels from directly written sacrificial polymer fibers. Microfludics and Nanofluidics, 2012, April Issue.

d. **Berry, S. M**., Harfenist, S. A., Cohn, R. W., Keynton, R. S. Characterization of Micromanipulator-Controlled Dry Spinning of Micro- and Sub-Microscale Polymer Fibers. J. Micromech. Microeng. 16 (2006) 1825-1832.

2. As a postdoctoral researcher, I applied my knowledge of microscale physics, gained during my PhD studies, to develop new methods for isolating biomolecules (e.g., protein, DNA, RNA) and cells. These methods, termed Immiscible Filtration Assisted by Surface Tension (IFAST) and Exclusion-based Sample Preparation (ESP), accelerated the rate at which biomedical separations could be performed while also significantly reducing costs. While the breath of applications for this technology is very large (used by >50 collaborating labs for many different applications), our main area of application focused on improving access to infectious disease assays. We have recently completed a field study in Uganda and demonstrated that ESP-based assays can reduce the cost of this lifesaving test by over 50% without a decrease in performance.

   a. **Berry SM**, Alarid ET, Beebe DJ. One-Step Purification of Nucleic Acid for Gene Expression Analysis *via* Immiscible Filtration Assisted by Surface Tension (IFAST). *Lab on a Chip*, 2011, 11, 1747-53.

   b. **Berry, SM**; LaVanway, AJ; Pezzi, HM; Guckenberger, DJ; Anderson, MA; Loeb, JM; Beebe, DJ. HIV Viral RNA Extraction in Wax Immiscible Filtration Assisted by Surface Tension (IFAST) Devices. Journal of Molecular Diagnostics, 2014, 16(3) 297-304.

   c. **Berry, SM**, Strotman, L. N., Kueck, J. D., Alarid, E. T., Beebe, D. J. Purification of Cell Subpopulations via Immiscible Filtration Assisted by Surface Tension (IFAST). Biomedical Microdevices, 2011, 13(6) 1033-42. PMCID: PMC3314424.

   d. **Berry SM**, Pezzi HM, Williams ED, Loeb JM, Guckenberger DJ, Lavanway AJ, Puchalski AA, Kityo CM, Mugyenyi PN, Graziano FM, Beebe DJ. Using Exclusion-Based Sample Preparation (ESP) to Reduce Viral Load Assay Cost. PLoS ONE 2015 Dec;10(12):e0143631.

3. In parallel with the development of analyte isolation techniques, I also developed several microfluidic cell culture platforms, which have been applied to both basic research and diagnostic contexts. The main motivation for this work is the favorable cell signaling kinetics that can be obtained via miniaturization. Specifically, at small scale, dilutive convection currents are minimized and dissemination of cellular secretions is governed exclusively by diffusion. Practically, this phenomenon ensures that cellular secretions remain highly concentrated within the vicinity of the secreting cell, given that the cells are confined within a microfluidic device. Consequently, signaling within co-culture assays is improved, resulting in enhanced sensitivity, reduced timescales, and/or the emergence of new phenotypes generated by paracrine signaling.

   a. **Berry SM**, Singh C, Lang JD, Strotman LN, Alarid ET, Beebe DJ. Streamlining Gene Expression Analysis: Integration of Co-Culture and mRNA Purification. Integrative Biology 2014, 6(2): 224-31.

   b. Lang JD, **Berry SM**, Powers GL, Beebe DJ, Alarid ET. Hormonally responsive breast cancer cells in a microfluidic co-culture model as a sensor of microenvironmental activity. Integr Biol (Camb). 2013 May;5(5):807-16.

   c. Regier MC, Maccoux LJ, Weinberger EM, Regehr KJ, **Berry SM**, Beebe DJ, Alarid ET. Transitions from mono- to co- to tri-culture uniquely affect gene expression in breast cancer, stromal, and immune compartments. *Biomed Microdevices* **18**(4), 70, 2016. PMCID: PMC5076020

   d. Li C, Yu J, Schehr J, **Berry SM**, Leal TA, Lang JM, Beebe DJ. Exclusive Liquid Repellency: An Open Multi-liquid-phase Technology for Rare Cell Culture and Single Cell Processing. *ACS Appl. Mater. Interfaces* 10 (20), 17065–17070, 2018.

4. Initial successes with the ESP in the research and global health arena led to an expansion of this technology into the field in rare cell analysis cancer. After taking on more of a supervisory role (as

Associate Scientist), our group continued to make both technological and clinically driven advances, particularly (but not exclusively) with regard to the isolation and molecular analysis of circulating tumor cells. Key advantages of technology enable us to perform "multi-omic" analyses on this very rare cell population. This capability has led to strong clinical collaborations within the UW and analysis of over 500 patient samples with this technology. While the clinical goals are variety, the overarching theme of these studies is the development of biomarkers that can predict and/or monitor responsiveness to specific anti-cancer therapies.

a. Casavant BP, Mosher R, Warrick JW, Maccoux LJ, **Berry SM**, Becker JT, Chen V, Lang JM, McNeel DG, Beebe DJ. A negative selection methodology using a microfluidic platform for the isolation and enumeration of circulating tumor cells. Methods. 2013 Jun 24.

b. Casavant, B. P., D. J. Guckenberger, **S. M. Berry**, J.T. Tokar, J.M. Lang and D. J. Beebe, "The Vertical IFAST: An integrated for cell isolation and extracellular/intracellular staining," Lab Chip, Vol. 13, pp. 391-396, 2013.

c. Sperger JM, Strotman LN, Welsh A, Casavant BP, Chalmers Z, Horn S, Heninger E, Thiede S, Tokar J, Gibbs BK, Guckenberger DJ, Carmichael L, Dehm SM, Stephens PJ, Beebe DJ, **Berry SM**, Lang JM. Integrated analysis of multiple biomarkers from circulating tumor cells enabled by exclusion-based analyte isolation. *Clin Cancer Res Off J Am Assoc Cancer Res* 2016.

d. Schehr JL, Schultz ZD, Warrick JW, Guckenberger DJ, Pezzi HM, Sperger JM, Heninger E, Saeed A, Leal T, Mattox K, Traynor AM, Campbell TC, **Berry SM**, Beebe DJ, Lang JM. High Specificity in Circulating Tumor Cell Identification Is Required for Accurate Evaluation of Programmed Death-Ligand 1. *PLoS ONE* **11**(7), e0159397, 2016.

5. As faculty at the University of Kentucky during the COVID-19 pandemic, I pivoted my work to environmental surveillance. This involved the development, optimization, and deployment of new devices and protocols that quantified the amount of SARS-CoV-2 (and other pathogens) in wastewater and surface water. Using statistical methods, our group demonstrated that environmental concentrations of pathogen biomarkers in the environment is correlated with and predictive of trends in clinical cases. Specifically, we worked to develop "point-of-care"-type technologies that could be decentralized and deployed to locations where they are most needed. Importantly, decentralization (partially via the development of a van-based lab) enabled data collection within three hours of samples acquisition. Rapid results are critical in this case, as viral RNA degrades quickly in matrices like wastewater and the "early warning" provided by environmental surveillance precedes clinical case increases by only a few days. Taken all together, we have developed a suite of technologies and protocols to maximize the public health impact of environmental surveillance.

   a. Torabi S, Amirsoleimani A, Dehghan Banadaki M, Strike WD, Rockward A, Noble A, Liversedge M, Keck JW, **Berry SM**. Stabilization of SARS-CoV-2 RNA in Wastewater via Rapid RNA Extraction. Science of the Total Environment 2023 Mar 21;878:162992.

   b. Dehghan Banadaki M, Torabi S, Strike WD, Noble A, Keck JW, **Berry SM**. Improving wastewater-based epidemiology performance through streamlined automation. Journal of Environmental Chemical Engineering 2023 Apr; 11(2): 109595.

   c. Strike WD, Amirsoleimani A, Olaleye A, Noble A, Lewis K, Faulkner L, Backus S, Lindeman S, Eterovich K, Fraley M, Zeitlow E, Brann T, Hobbs S, Hibbard D, Liversedge M, Keck JW, **Berry SM**. A Simplified Method for Analysis of SARS-CoV-2 RNA in Wastewater. ACS EST Water 2022, 2 (11), 1984–1991.

   d. Keck JW and **Berry SM**. Wastewater Surveillance - "Messy" Science With Public Health Potential. Am. J. Public Health 2023, 113 (1), 6–8.