

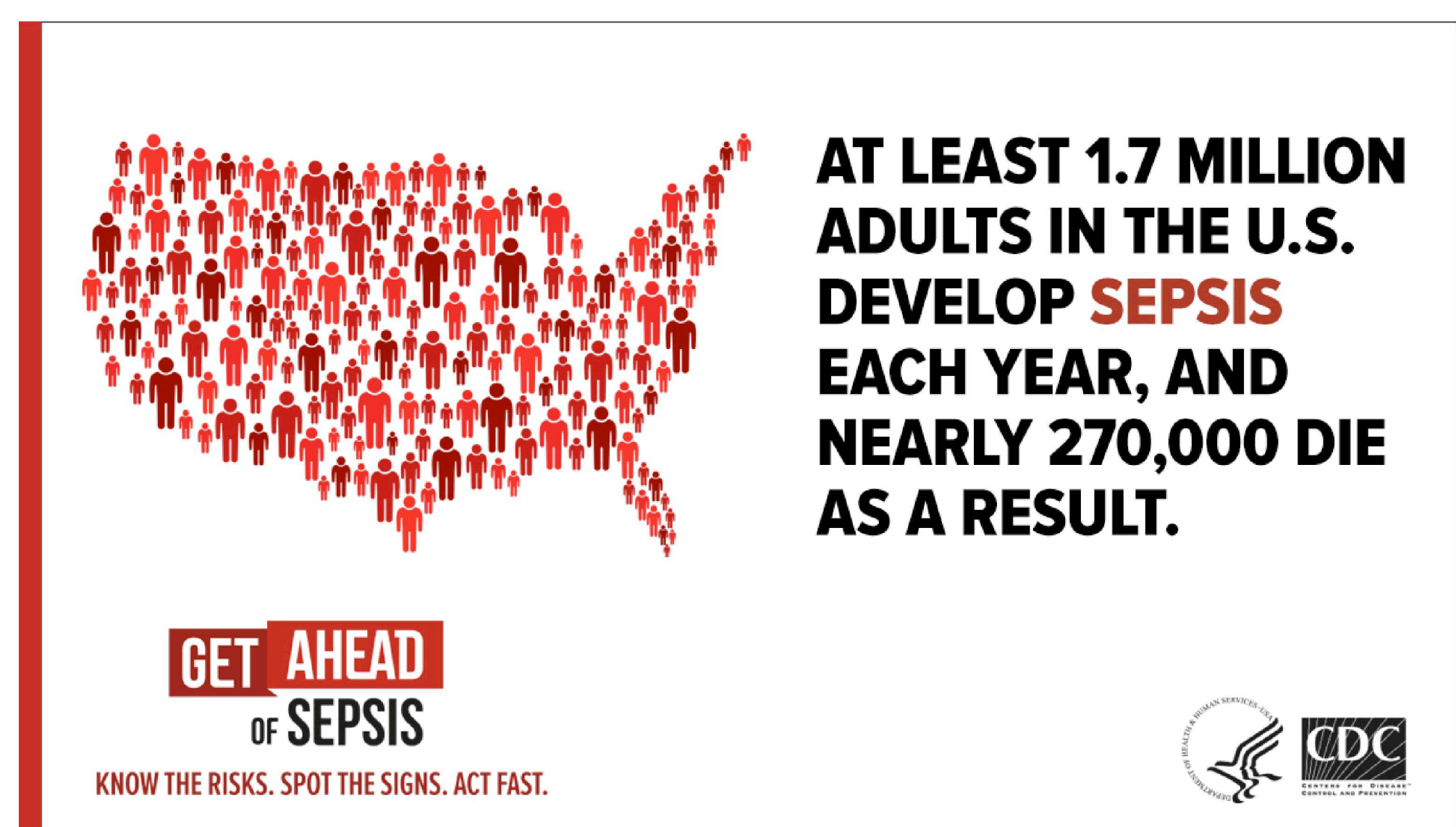
SpinDx - Platform for Point-of-Care Medical Diagnostics

Presenter: Tori VanderNoot
Sandia National Laboratories, Livermore, CA

Robert Meagher, Chung-Yan Koh, Christopher Phaneuf, Betty Mangadu, Tyler Eckles, Anup Singh Sandia National Laboratories

INTRODUCTION

- **Sepsis** is one of the leading causes of death globally due to difficulties in rapid diagnosis of the disease
- **No single biomarker** allows for rapid and reliable diagnosis
- Laboratory tests such as blood culture are **too slow** to give actionable information



TECHNOLOGY OVERVIEW

SpinDx is a **portable platform technology** capable of performing multiplexed immunoassays for panels of up to 20 targets at a time

Disposable assay disks (cartridges)

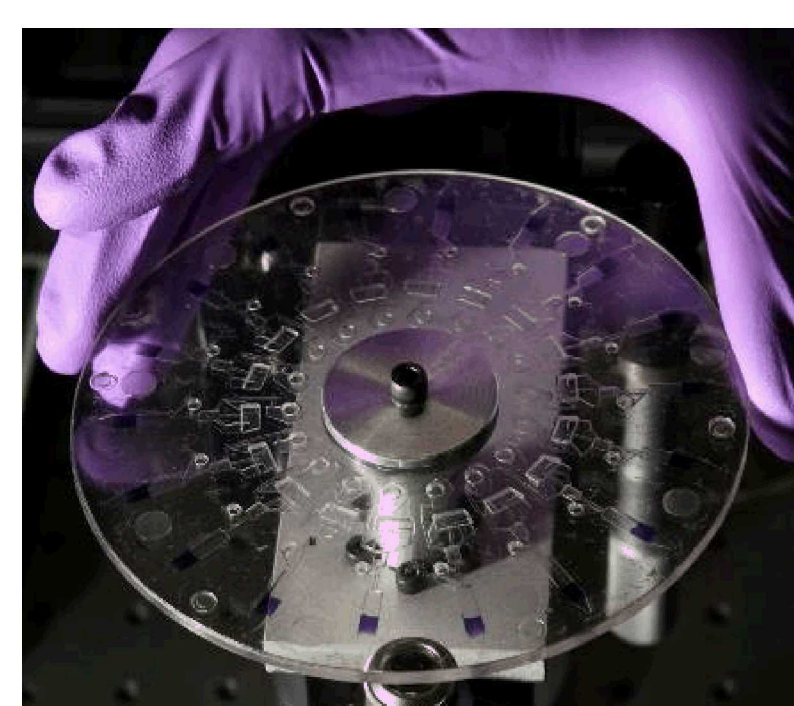
- preloaded and pre-packaged with reagents within microfluidic channels

Miniaturized fluorescence optics

- detection of proteins, carbohydrates, and nucleotides

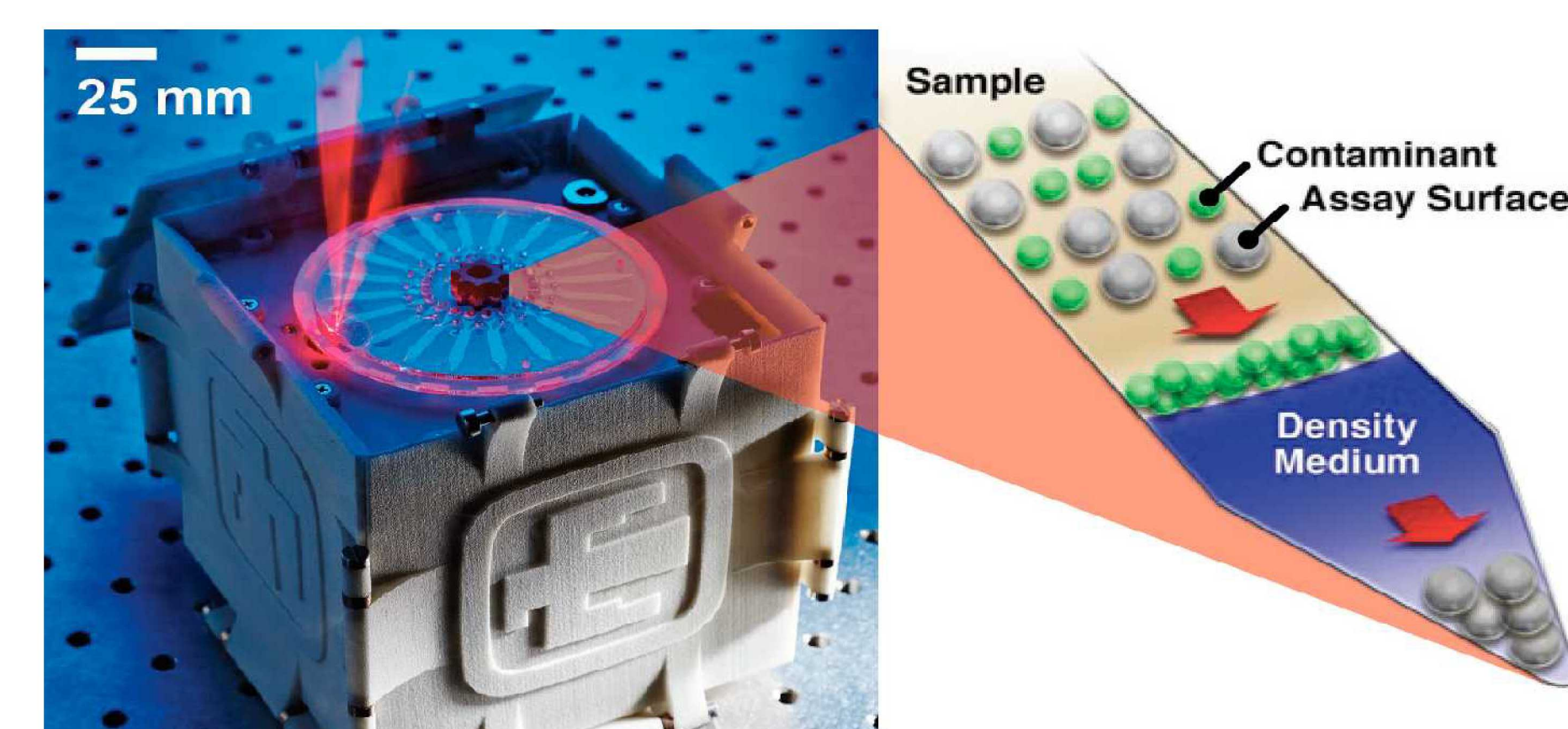
Microfluidic platform

- allows for small sample sizes and POC uses



PRODUCT/TECHNOLOGY DESCRIPTION

Much smaller sample size needed compared to ELISA



High Sensitivity

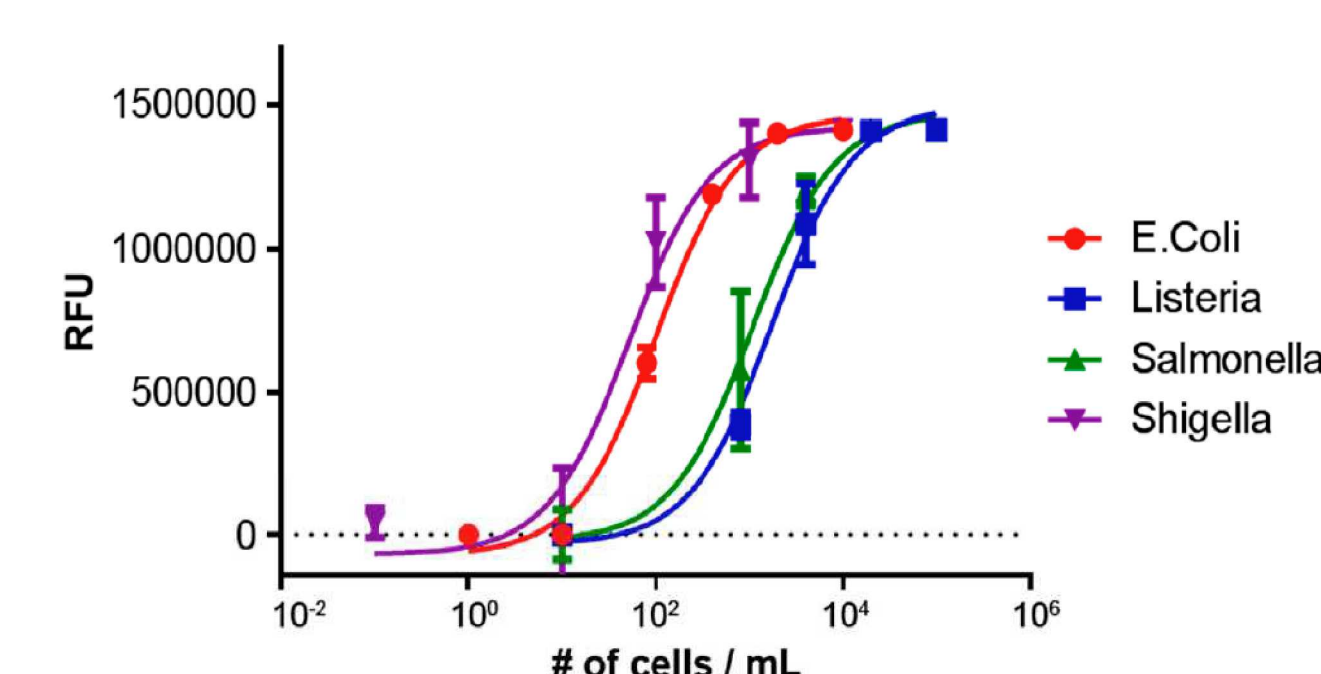


Figure 2. Multiplexed detection of *E. coli*, *Listeria*, *Salmonella*, and *Shigella* from a stool sample. Each target pathogen was detected in the presence of a background pool of the other non-targeted pathogen to demonstrate specificity and selectivity.

Low Detection Limit

	LOD (# of Cells)						
	Microfluidic Singleplex				Microfluidic Multiplex		Conventional Singleplex
	Buffer	Urine	Blood	Stool	Buffer	Stool	Buffer
<i>E. coli</i>	11	34	33	9	51	31	38
<i>Listeria</i>	999	796	1668	320	2849	238	1745
<i>Salmonella</i>	2416	703	1200	974	1154	328	2648
<i>Shigella</i>	53	33	61	20	94	12	1236

Table 1. The limit of detection was determined for the full panel of bacteria in a variety of sample matrices, including assay buffer, urine, blood, and stool. Singleplex detections were performed for all matrices and multiplex detections were confined to assay buffer and stool. Conventional ELISA detections in assay buffer are also shown for comparison.

Minimal Sample Prep Needed

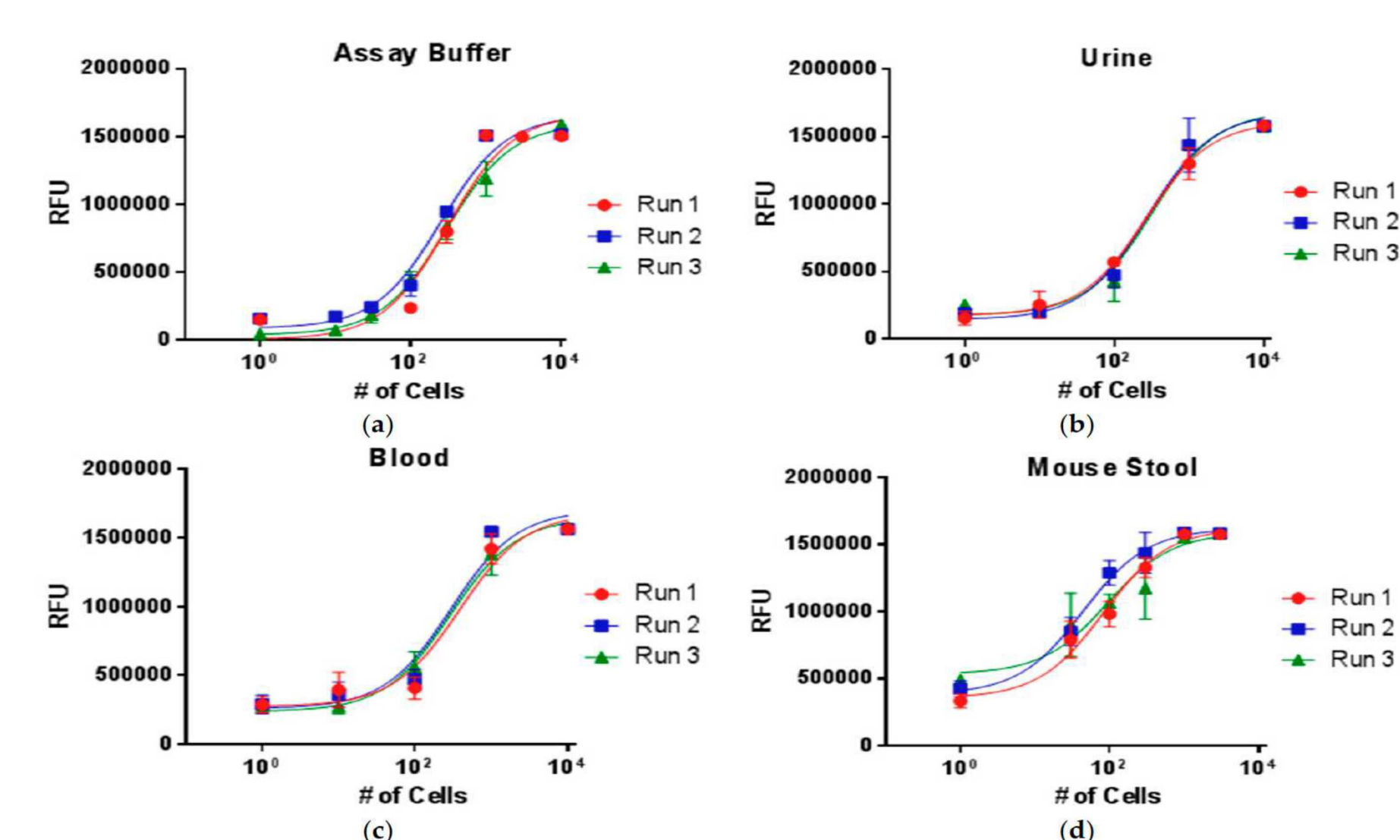


Figure 4. The ability to work with clinical samples without extensive sample preparation was demonstrated with the detection of *E. coli* in a variety of complex sample matrices: (a) buffer; (b) urine; (c) blood; and (d) mouse stool.

PRODUCT PROFILE

- Allows **direct analysis of clinical samples** with minimal sample prep or pre-treatment.
- **Compact and portable** for easy point-of-need use
- Dramatically **reduces time** between sample acquisition and diagnostic results
- Enables **rapid administration of treatment** to maximize positive patient outcomes

BUSINESS MODEL

- Multiple revenue streams possible
 - Capital equipment sales – device enclosure
 - Consumables sales – cartridges
 - Customized assays and cartridges

ADVANTAGES

Cost effective, rapid solution for wide range of in vitro and POC diagnostic testing needs

- infectious disease, cardiac markers, neonatal/ pediatric monitoring, others

Expandable to multiple markets

- food testing, veterinary, agriculture

Multiple Simultaneous Assays

- detect multiple sepsis microorganisms
- allows for redundancy with same assay in multiple microfluidic channels

STAGE

- **SpinDx** is currently an advanced laboratory prototype (TRL 5-6), approximately 10 units produced in-house.
- Developed with **Sandia internal funding**, and transitioning to government sponsorship (NIH, DHS, DTRA)
- Available through **non-exclusive license** with field of use carve outs and periods of restraint
- Ready for **transfer to a commercialization partner** for optimization, productization, and scale-up.

CONCLUSIONS

- **SpinDx** is ideally suited for rapid diagnostics at the point of need for medical emergencies such as sepsis.
- **SpinDx** is a platform technology that is readily adapted to many different assays and panels of biomarkers.

ACKNOWLEDGEMENTS



Funding has been provided by NIH, DHS, and DTRA. Sandia National Laboratories is a multimission laboratory managed and operated by National Technology and Engineering Solutions of Sandia, LLC, a wholly owned subsidiary of Honeywell International Inc., for the U.S. Department of Energy's National Nuclear Security Administration under contract DE-NA0003525.

**Tri-Valley Life Sciences
IP Roundtable**