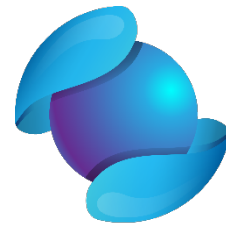


# Rapid Solutions for Critical Problems in Clinical Diagnostics



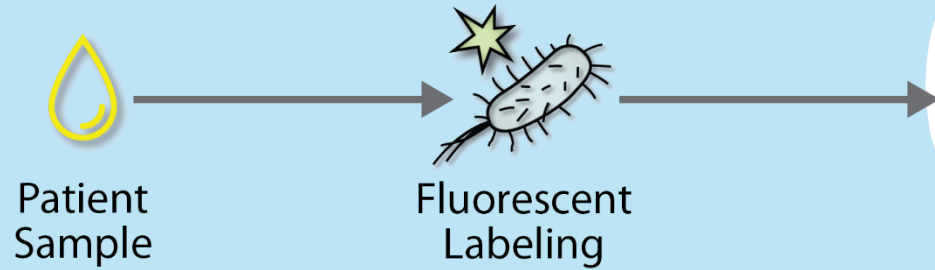
**Velox Biosystems**

defining the future of rapid and sensitive tests

Contact: Weian Zhao, Ph.D. Email: [weianzhao.uci@gmail.com](mailto:weianzhao.uci@gmail.com)

# Velox Ultra Sensitive Rapid Detection System

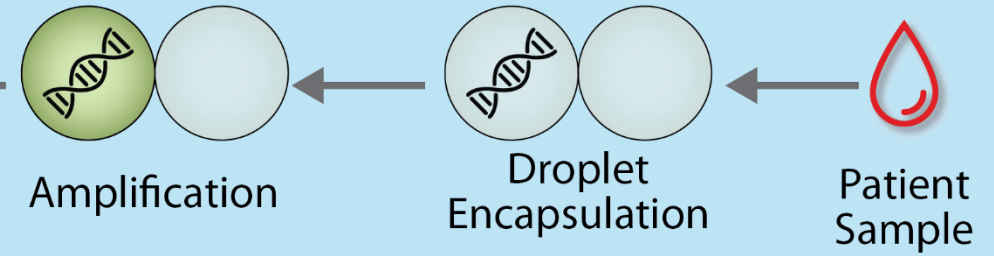
## Culture-free Pathogen Detection



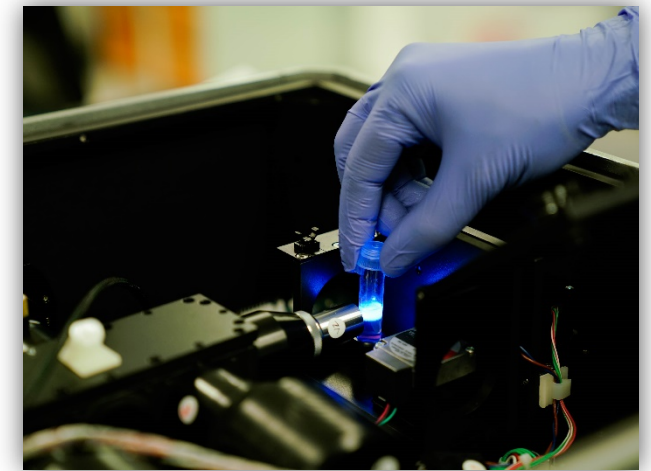
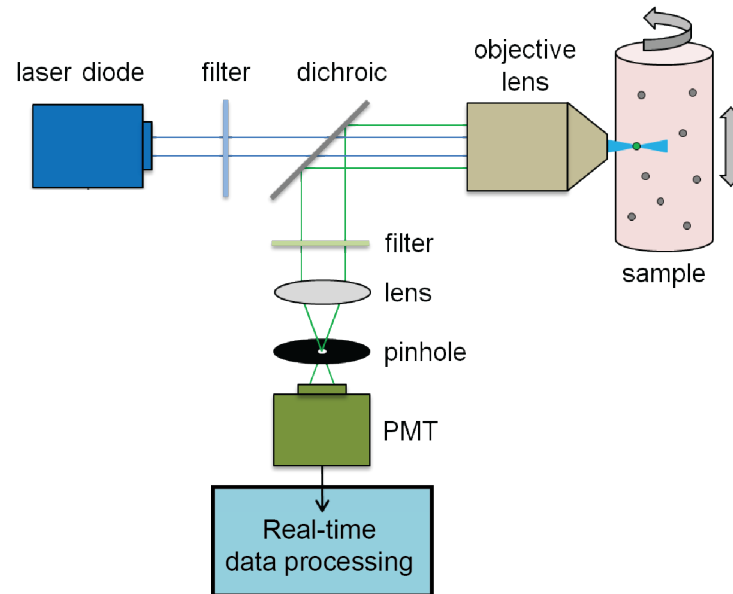
## Rapid 3D scanning



## Digital Droplet Molecular Detection



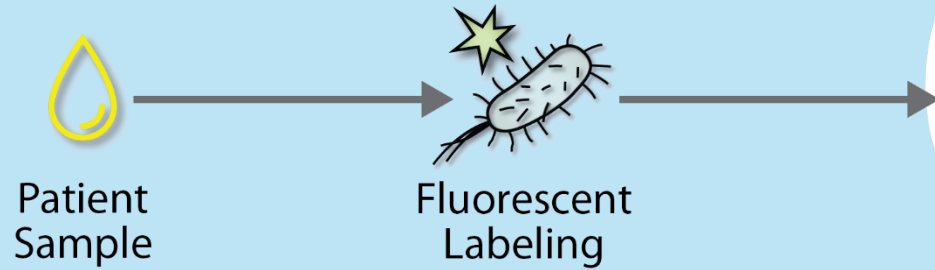
- Patented **platform technology**
- Elegant solution for **high throughput** scanning of **large sample volumes**
- **Single target sensitivity with unprecedented speeds**
- No or minimal sample processing



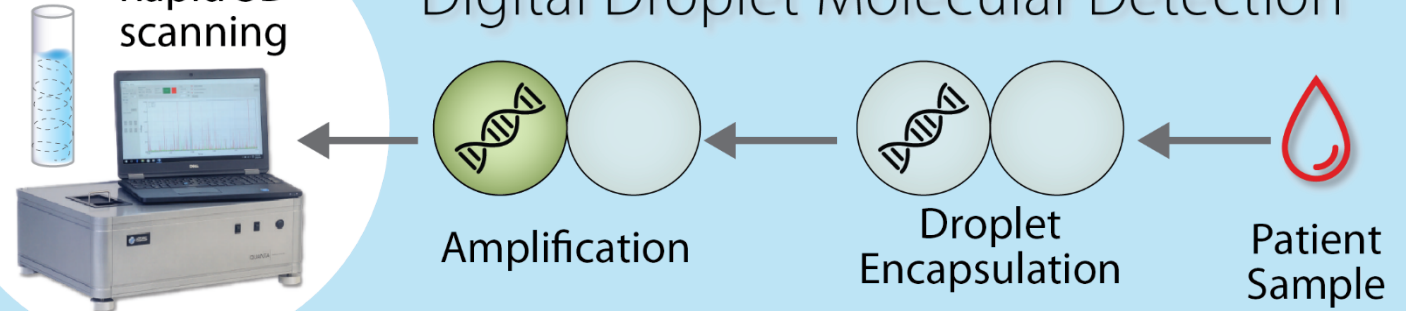
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# Platform Technology, Multiple Applications

## Culture-free Pathogen Detection



## Digital Droplet Molecular Detection



### 1. UTI

- Game-changing rapid and accurate UTI diagnosis and antibiotic resistance tests right at the point-of-care
- UTI Dx launch in early 2021 & UTI AST launch 2022

### 2. Liquid Biopsy

- >> 10x detection sensitivity for cancer early detection
- Ability to interrogate all (vs only partial) cancer DNAs
- Research tool intro 2021 w/ clinical product(s) later

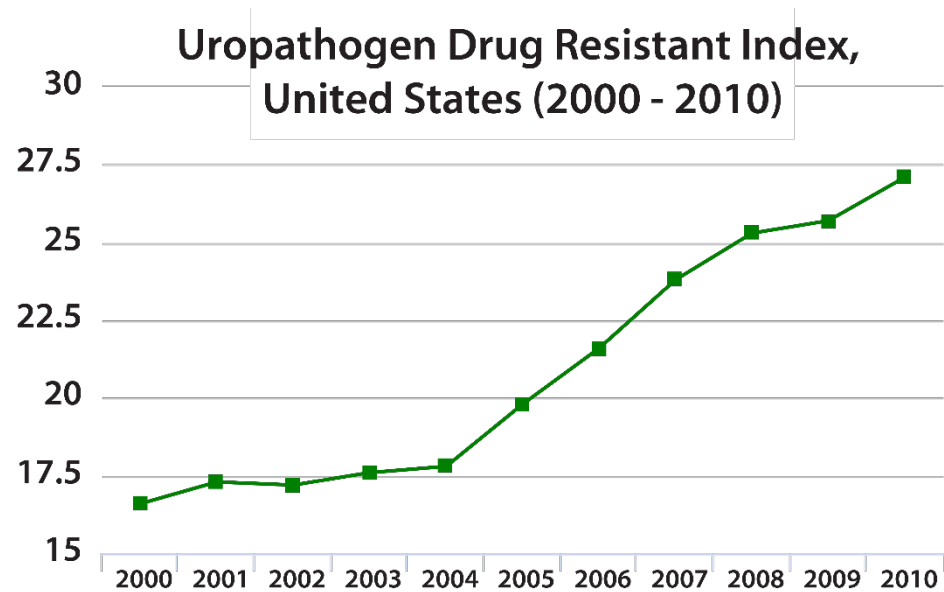
### 3. Sepsis

- Rapid and ultrasensitive detection of bloodstream infection & sepsis
- Bacterial ID & antibiotic resistance info
- Target launch 2023

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# Critical & Unmet Clinical Need in Urinary Tract Infection (UTI)

- High prevalence/recurrence rate
- High false positives (> 30%) in current PoC Dx
- Empirical antibiotic Rx as antibiotic resistance test takes > 2-3 days currently



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## UTI Quick Facts

- 2<sup>nd</sup> most common type of infection in the body (NIH)
- 150 million UTI cases/year global (2001)
- 40-60% women will get UTI at least once; 25% women has recurrent UTIs (NIH)
- All pregnant women need to be screened for UTIs
- 52% increase in hospitalization due to UTIs
- 15+% annual growth in US
- \$6 billion in healthcare expense w.w. (AUA)

- **Antibiotic resistance** is one of the most urgent threats to public health (CDC)
- **Rapid increase of resistance in UTI** (even in the U.S.) due to high prevalence/recurrence, high misdiagnosis, and empirical use of antibiotics

# Velox Point-of-Care UTI Diagnostic Products

## UTI Rapid Dx Test (UTI Screening)

UTI bacteria CFU/ml result in 3 minutes

No culture or sample processing required

> 5x improvement in UTI Dx accuracy

## Point-of-care Antibiotic Susceptibility Test

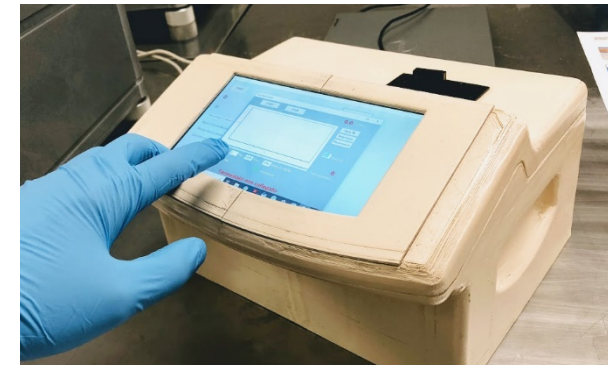
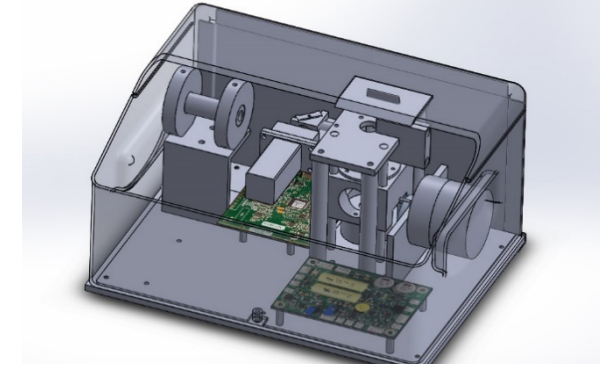
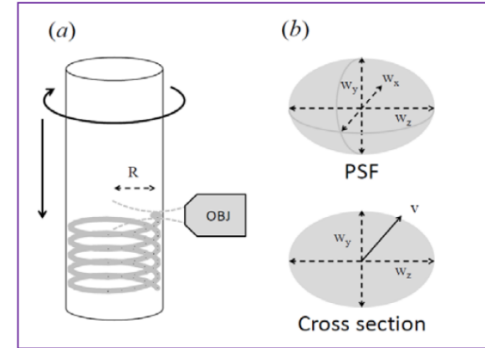
Results in 2 hours or less

Phenotypic AST wrt a panel of common UTI antibiotics

Same day effective antibiotic treatment (vs empirical)

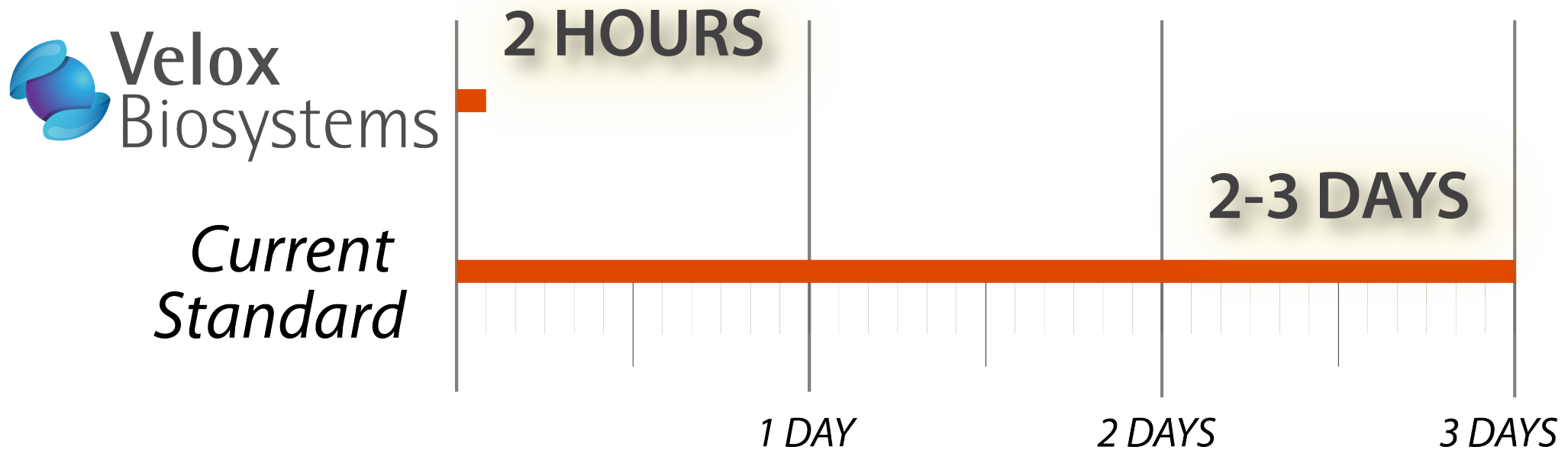
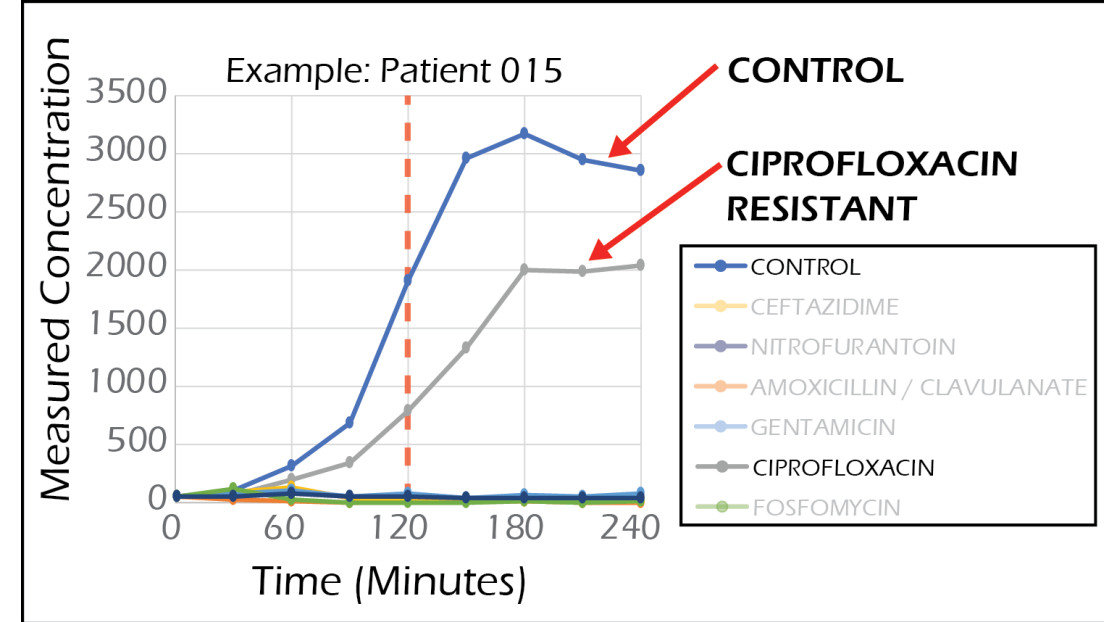
## Cloud-based Local Resistance Rate Surveillance

Antibiotic resistance monitoring/tracking



Velox  
Prototype  
Device

# Rapid Phenotypic AST at the Point-of-Care



# Exciting Clinical Feasibility Data

## UTI Rapid Dx Test

- Clinical feasibility study (n = 500)
- > 5x better in accuracy - False positives 6.7%; False negatives 1.2%
- Current UTI Test Strips: False positives 34–49%; False negatives 6-26%

See Data  
Table 1

## UTI Antibiotic Susceptibility Test

- Clinical feasibility study (n = 60)
- Accuracy (categorical agreement) close to or exceeds 90%
- Enables physicians to provide same day effective antibiotic treatment (vs empirical treatment today)

See Data  
Table 2

**Primary care, Urgent care, Urology, OB-GYN, ER physicians:**

*“this product certainly has the opportunity to be a game changer in this space.”*

# The State of Competition:

Point-of-care requirements are very challenging for other technologies

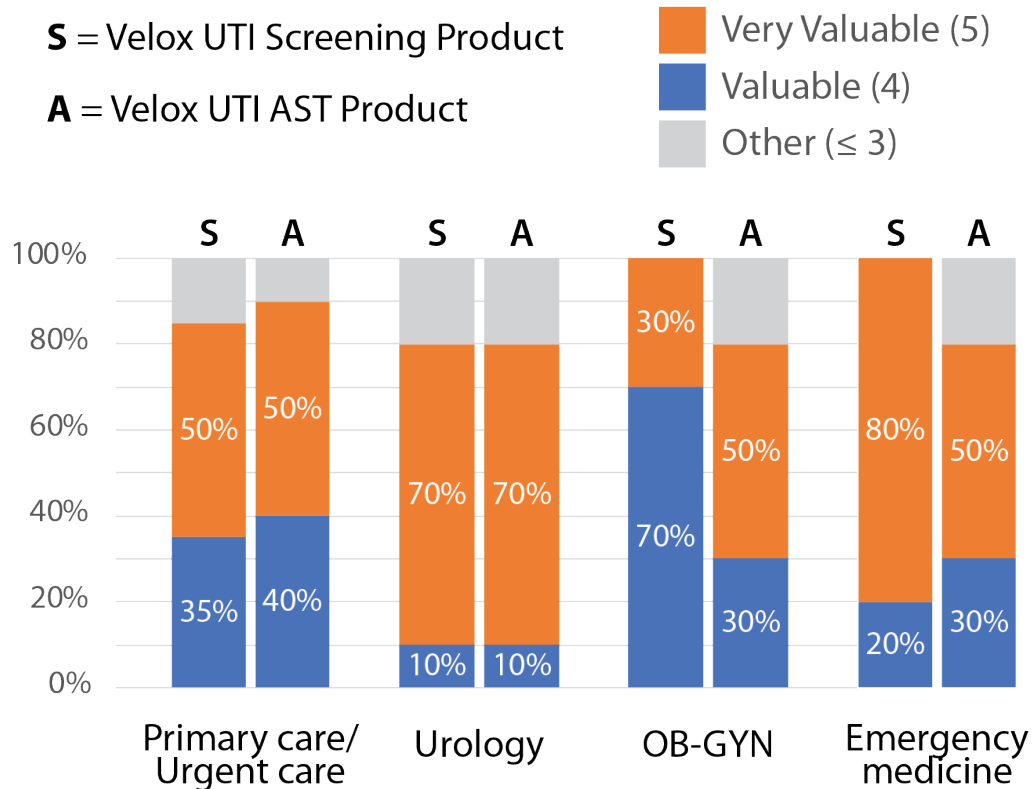
[Click here for detailed comparison](#)

	Point-of-care	UTI Dx Test		UTI AST	
		< 10 minutes	Accuracy > 90%	< 2 hours	Accuracy > 90%
VELOX Biosystems	✓	✓	✓	✓	✓
Dipstick	✓	✓			
Urine Culture			✓		✓
Microscopic Analysis		✓			
Clinical laboratory systems (Beckman Coulter, BioMérieux, BD, etc.)			✓		✓

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# Market Opportunity & Go-to-Market Strategy



In-depth market research with 50 clinicians

## Total Available Market > \$1 billion

- U.S. market:
  - >11 million UTI outpatient cases/year (suspected cases even higher)
  - 5 million intended pregnancies/year; average 2-3 screenings per pregnancy
  - U.S. point-of-care TAM > \$400M
- Global market: > \$1 billion

## Go-to-market Strategy

- Selling directly or partnering with top global diagnostic companies
- “Razor/razorblade business” model: PoC analyzer device + high volume/high profit consumable test kit sales

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# Publications

- [A modular microarray imaging system for highly specific COVID-19 antibody testing.](#) Hedde PN, Abram TJ, Jain A, Nakajima R, Ramiro de Assis R, Pearce T, Jasinskas A, Toosky MN, Khan S, Felgner PL, Gratton E, Zhao W. Lab Chip. 2020 Sep 21;20(18):3302-3309.
- [Rapid bacterial detection and antibiotic susceptibility testing in whole blood using one-step, high throughput blood digital PCR.](#) Abram TJ, Cherukury H, Ou CY, Vu T, Toledano M, Li Y, Grunwald JT, Toosky MN, Tifrea DF, Slepentin A, Chong J, Kong L, Del Pozo DV, La KT, Labanieh L, Zimak J, Shen B, Huang SS, Gratton E, Peterson EM, Zhao W. Lab Chip. 2020 Feb 7;20(3):477-489.
- [A rapid, point-of-care antibiotic susceptibility test for urinary tract infections.](#) Toosky MN, Grunwald JT, Pala D, Shen B, Zhao W, D'Agostini C, Coghe F, Angioni G, Motolese G, Abram TJ, Nicolai E. J Med Microbiol. 2020 Jan;69(1):52-62.
- [An ultrasensitive test for profiling circulating tumor DNA using integrated comprehensive droplet digital detection.](#) Ou CY, Vu T, Grunwald JT, Toledano M, Zimak J, Toosky M, Shen B, Zell JA, Gratton E, Abram TJ, Zhao W. Lab Chip. 2019 Mar 13;19(6):993-1005.
- [Rapid detection of single bacteria in unprocessed blood using Integrated Comprehensive Droplet Digital Detection.](#) Kang DK, Ali MM, Zhang K, Huang SS, Peterson E, Dighman MA, Gratton E, Zhao W. Nat Commun. 2014 Nov 13;5:5427.