

BioAmp Diagnostics

Evolving Clinical Microbiology Beyond Growth-Based Diagnostics

Presenter: Tara deBoer, Ph.D.

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Contact: Tara deBoer, PhD (CEO)

tdeboer@bioampdx.com

www.bioampdx.com

BioAmp is a mission driven company working to address a significant global healthcare challenge: Antibiotic Resistance (AMR)

1 BioAmp: We are a tiny and mighty team working to combat AMR

The Team:



Tara de Boer, PhD



Angel Resendez, PhD



Nicole Jackson, PhD



Isha Kane, B.S.



Clarissa Araújo, Ph.D.



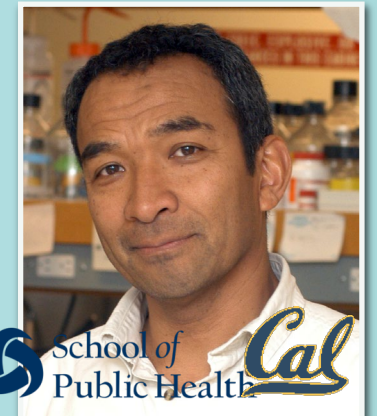
Kevin Krause, MBA.



Dr. Bradley Frazee



Danka-Florence



Prof. Lee Riley

Collaborators:



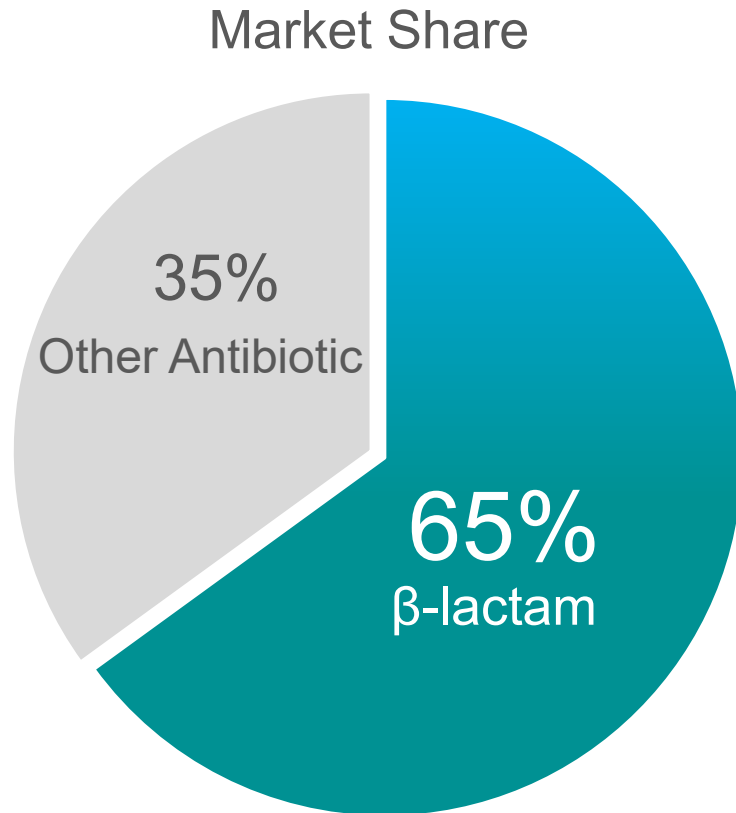
BioAmp's Aim: Build a pipeline of low-tech tests that fit into diverse workflows, are simple, affordable, and designed to provide immediately actionable information



Supporting antibiotic selection on day-1 whenever possible

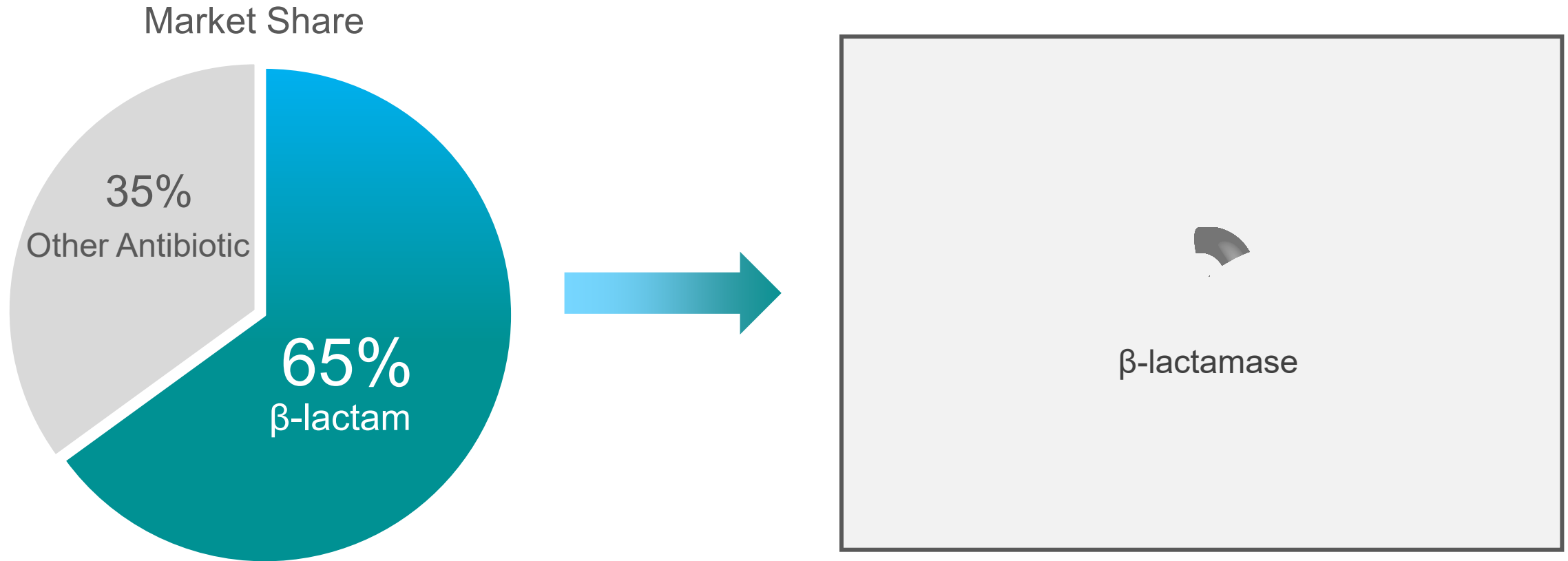
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Our Approach: Targeting biomarkers as a strategy to offer results on a timescale that can impact treatment selection



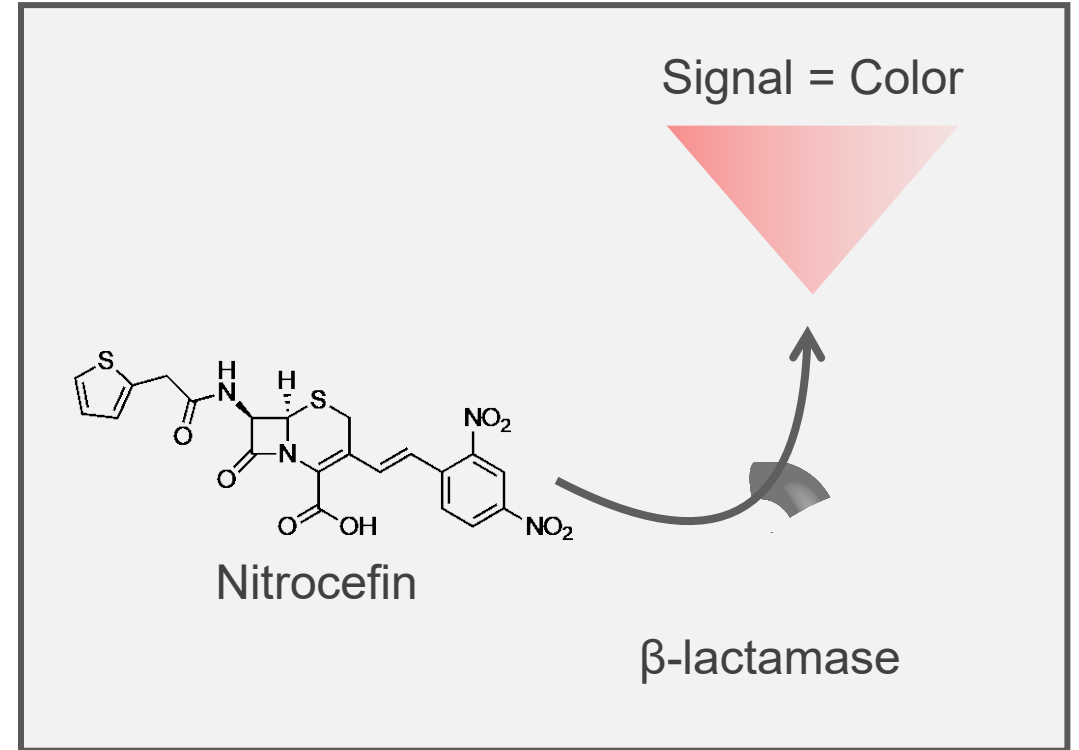
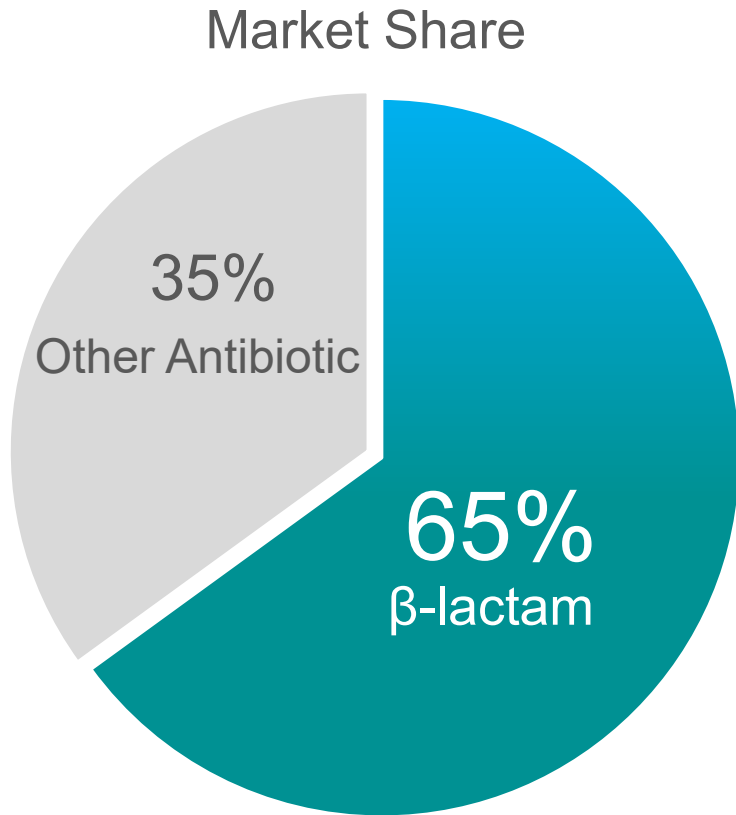
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First Biomarker Family: Targeting one of the most common resistance mechanisms – β -lactamases



4

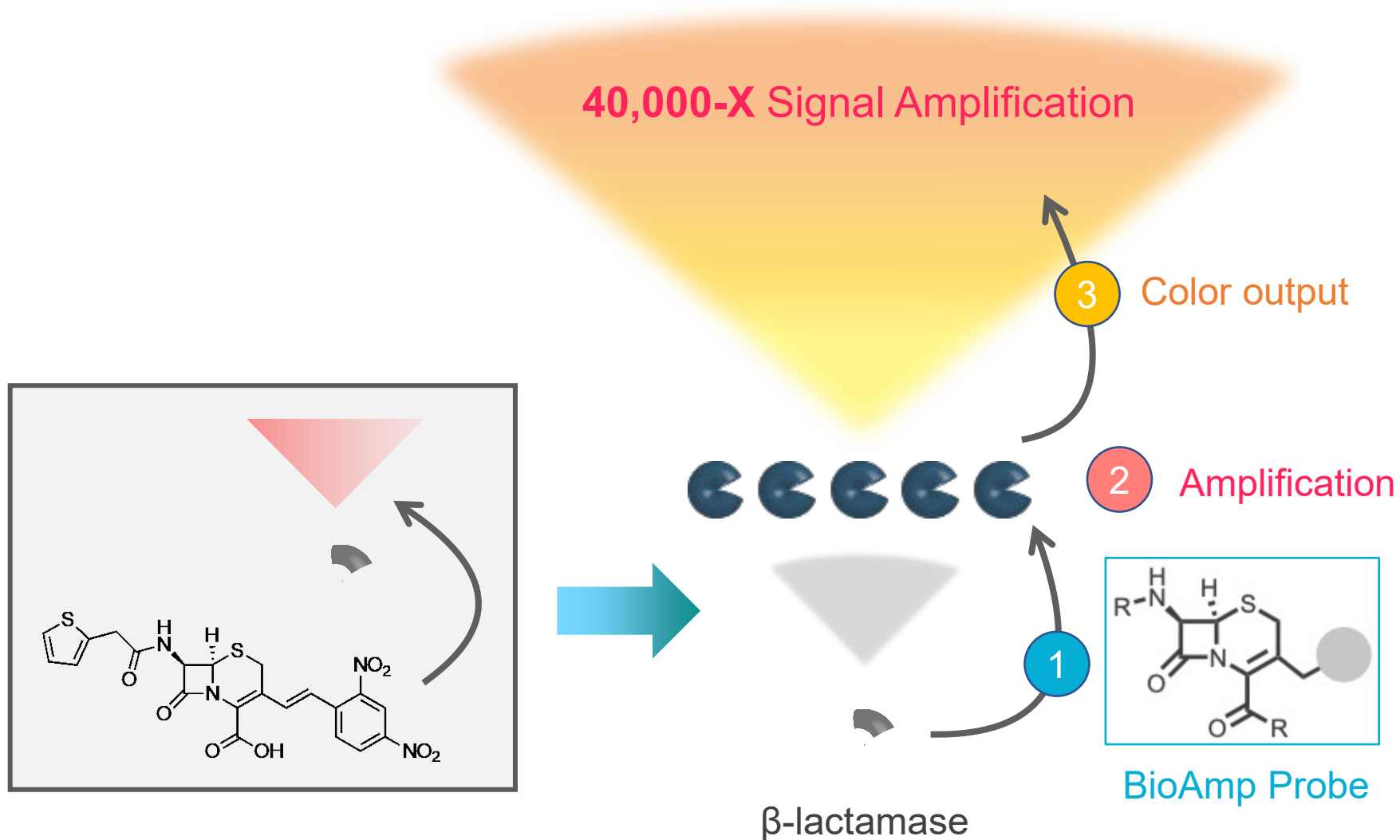
First Biomarker Family: Targeting one of the most common resistance mechanisms – β -lactamases (established target)



Not sensitive enough for clinical use...

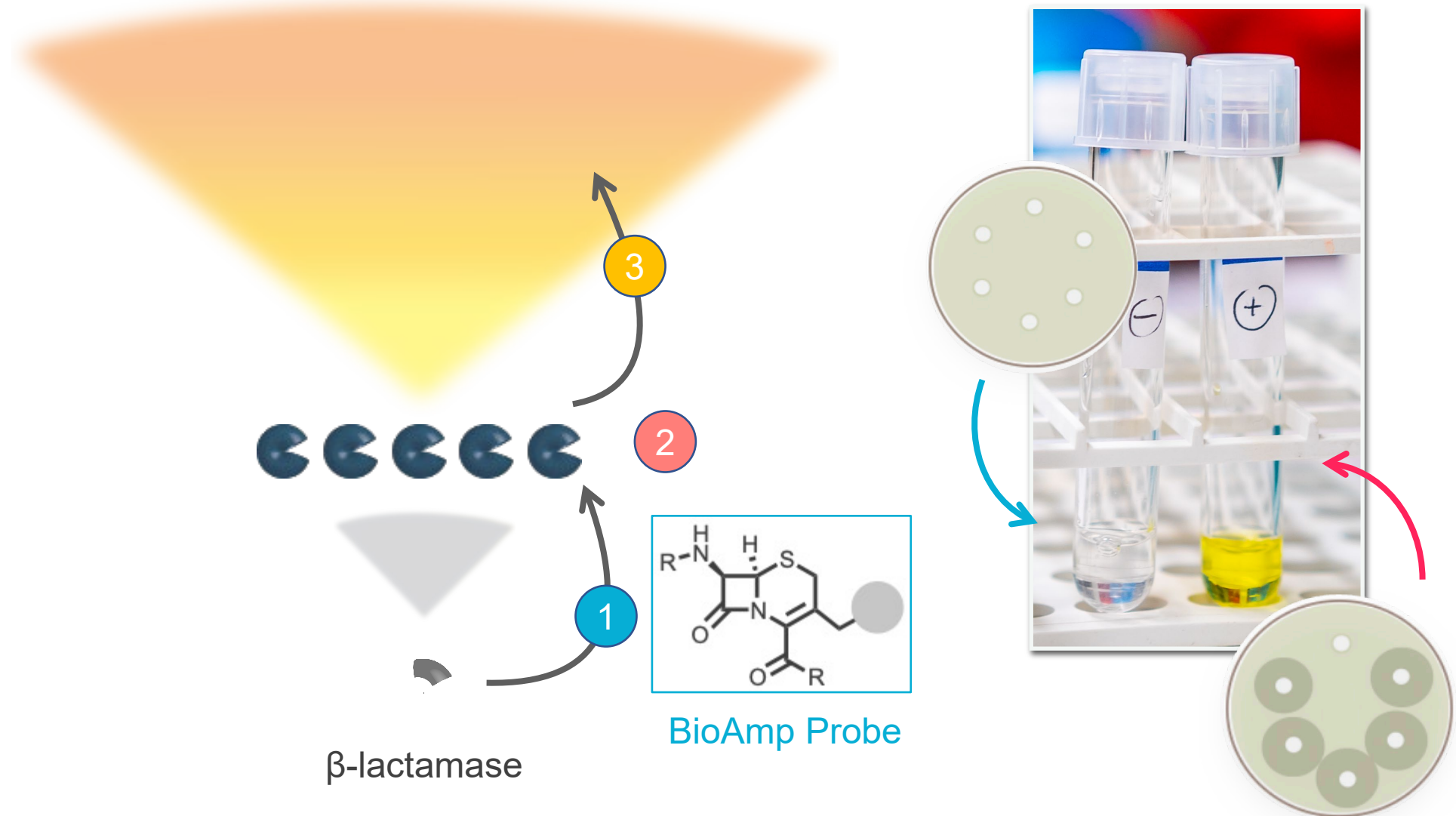
5

Overcoming sensitivity limitations: Instrument-free amplification mediated by unique BioAmp probe



5

Overcoming sensitivity limitations: Instrument-free amplification mediated by unique BioAmp probe



Tuning the BioAmp Probe: Targeting the β -lactamases that influence clinical outcomes for patients and complicate care delivery



Penicillinase	Cephalosporinases [ESBL]	Cephalosporinases [pAmpC]	Carbapenemase (Serine or [metallo])
TEM-1A, TEM-1B, TEM-1C, TEM-35, TEM-76	CTX-M-14, CTX-M-15, CTX-M-27, CTX-M-55	CMY-2, CMY-4, CMY-42, CMY-130	<u>Serine</u> : KPC-2, KPC-9, OXA-10, OXA-48
SHV-1, SHV-33, SHV-89, SHV-172,	TEM-10, TEM-15, TEM-26	DHA-1, DHA-6	<u>Metallo</u> : NDM-1, IMP-27
OXA-1, OXA-9, OXA-320	SHV-2, SHV-11, SHV-12, SHV-27, SHV-106		

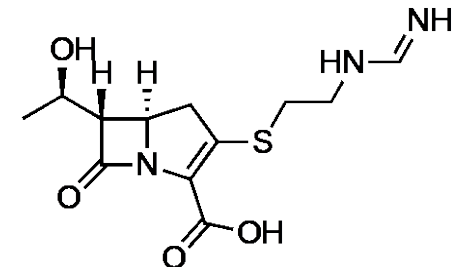
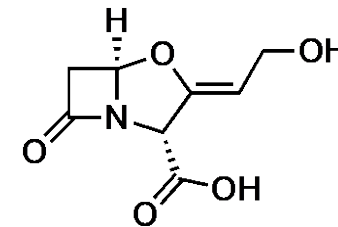
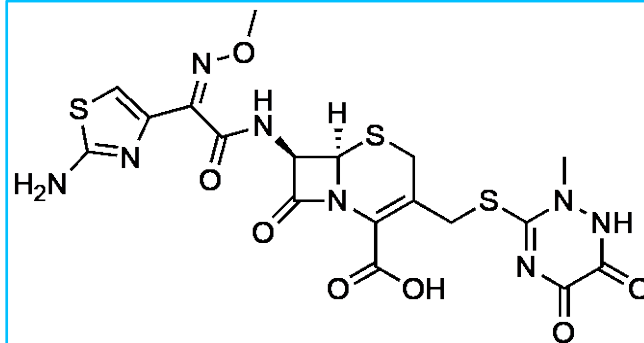
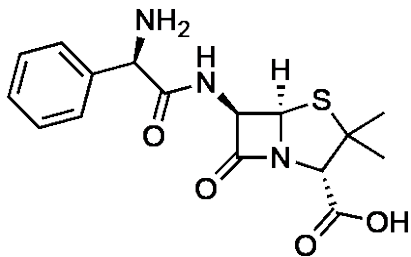
R/S =

Ampicillin (AMP) R

Ceftriaxone R, AMP R

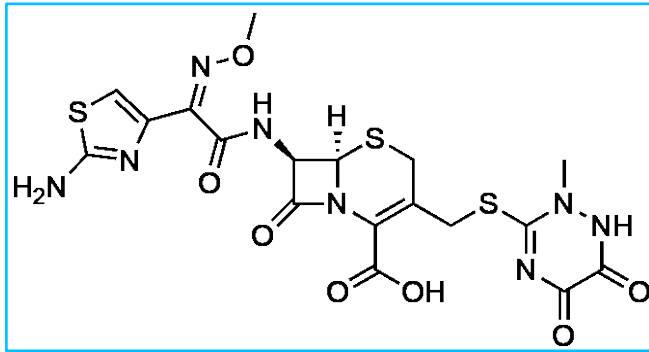
BL/BLI R, Ceftriaxone R, AMP R

Imipenem R, BL/BLI R, Ceftriaxone R, AMP R

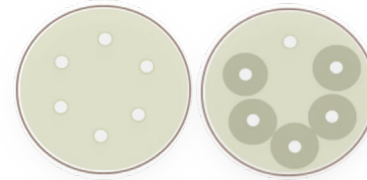


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Diagnostic Landscape: Comprehensive time intensive versus rapid and targeted results



Ceftriaxone



Culture & Sensitivity



Strength: Yields high-value clinical information

Limitations: Long TAT, family-level resolution requires multiple test

Cephalosporinases
[ESBLs]

CTX-M-14, CTX-M-15, CTX-M-27, CTX-M-55

TEM-10, TEM-15, TEM-26

SHV-2, SHV-11, SHV-12, SHV-27, SHV-106



Molecular Diagnostic
(Genetic)

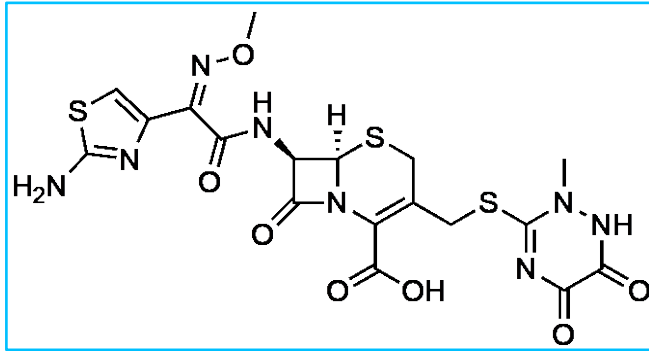


Strength: Rapid, simple, capable of detecting discrete gene targets (AMR genes)

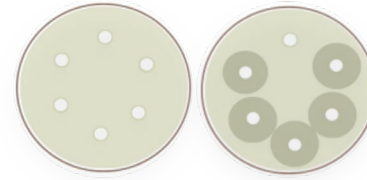
Limitations: Only able to target handful of variants, *Continuous evolution of variants (risk of FN)*

7

Diagnostic Landscape: Comprehensive time intensive versus rapid and targeted results



Ceftriaxone



Culture & Sensitivity

Cephalosporinases
[ESBLs]

CTX-M-14, CTX-M-15, CTX-M-27, CTX-M-55

TEM-10, TEM-15, TEM-26

SHV-2, SHV-11, SHV-12, SHV-27, SHV-106

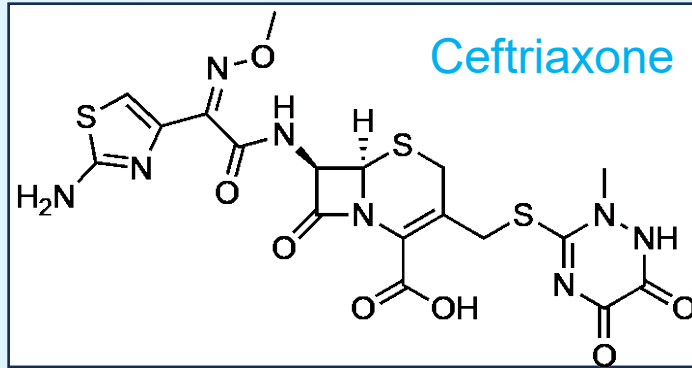


Molecular Diagnostic
(Genetic)

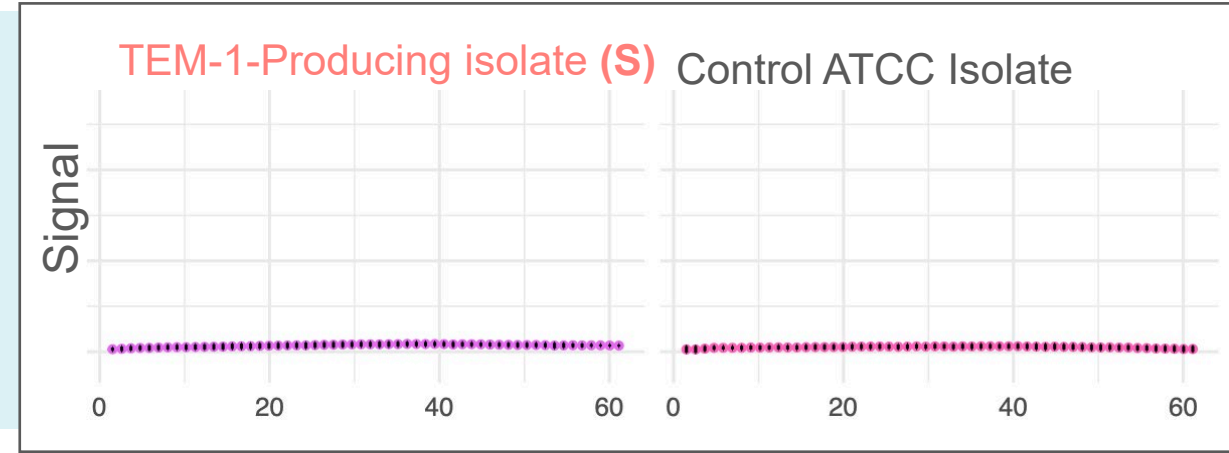


Biochemical test:
Detect biomarkers as a
surrogate for susceptibility

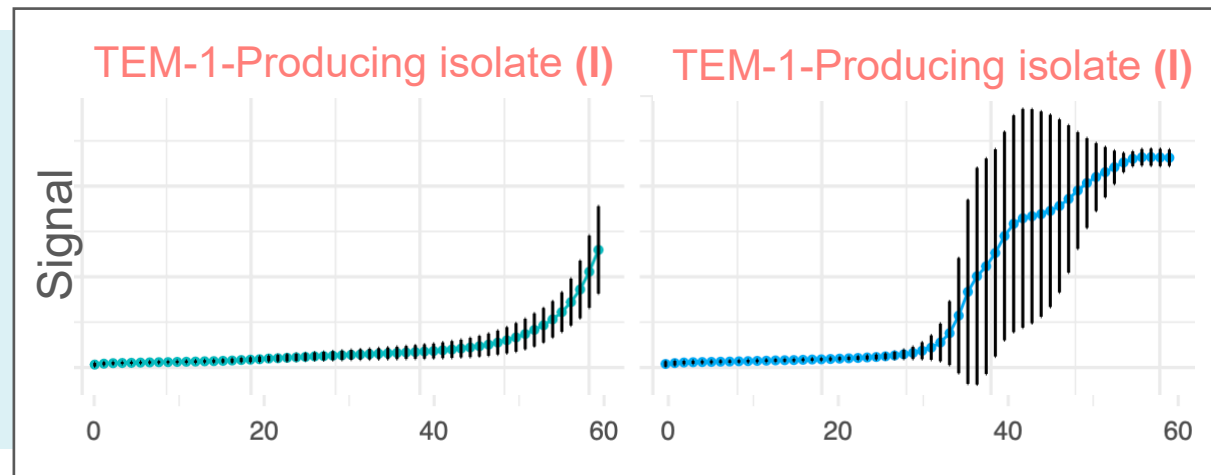
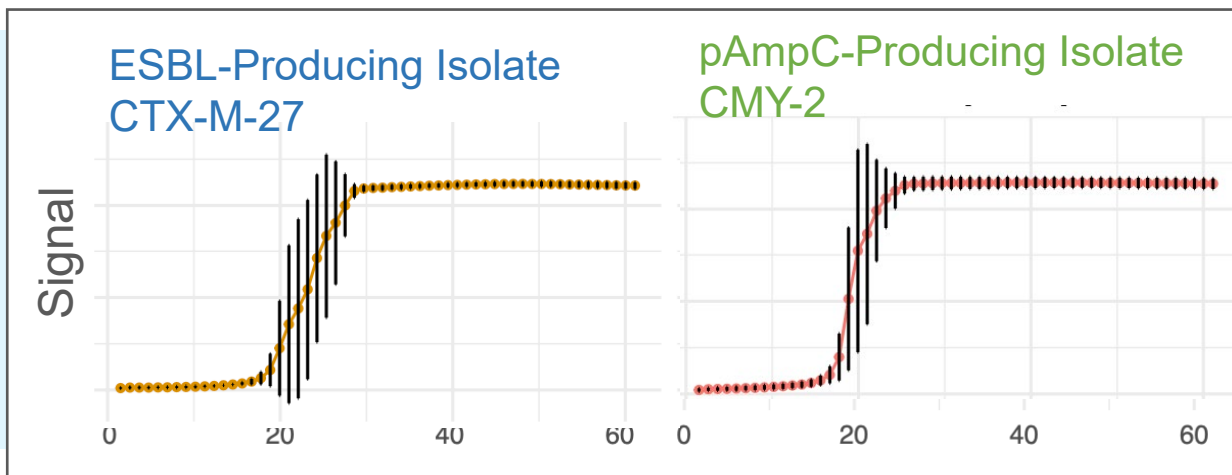
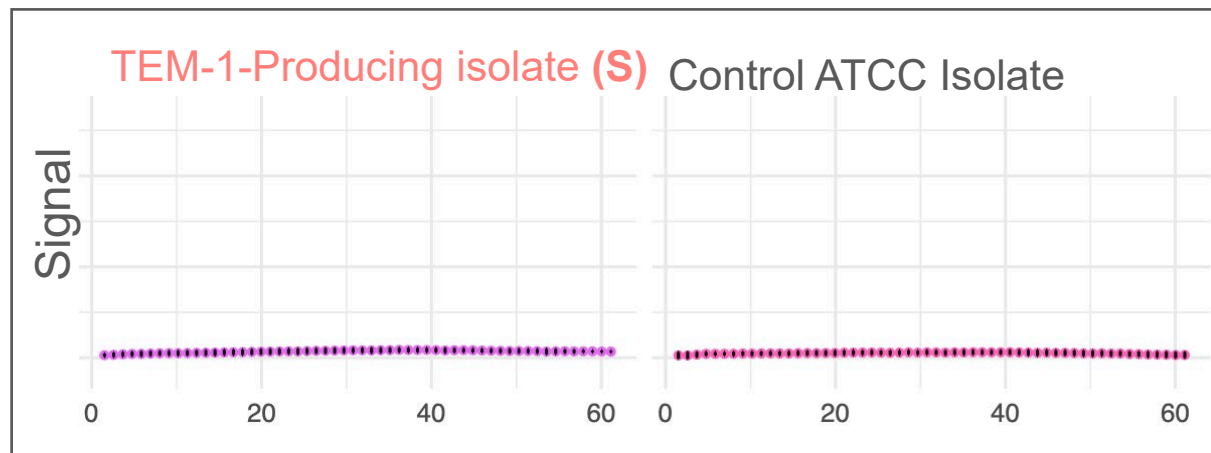
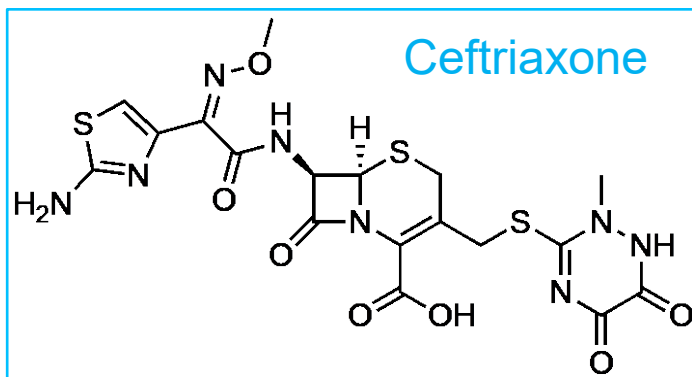
BioAmp Probes: Resolve clinical isolates that display ceftriaxone susceptible, resistant, and intermediate



A)



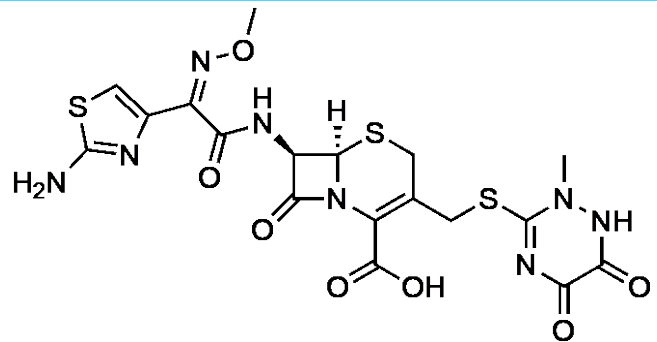
BioAmp Probes: Resolve clinical isolates that are characterized as susceptible, resistant, and intermediate towards CAX



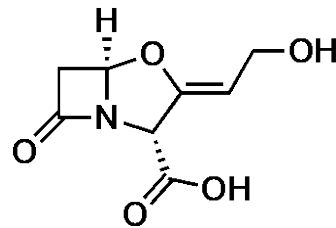
Figures. Kinetic plots collected over 1 hour at 35 C with 1000 nM papain, 37.5 μ M BioAmp Probe, and 350 μ M Signaling Molecule

BioAmp Probes: Resolve families of β -lactamase when combined with inhibitors

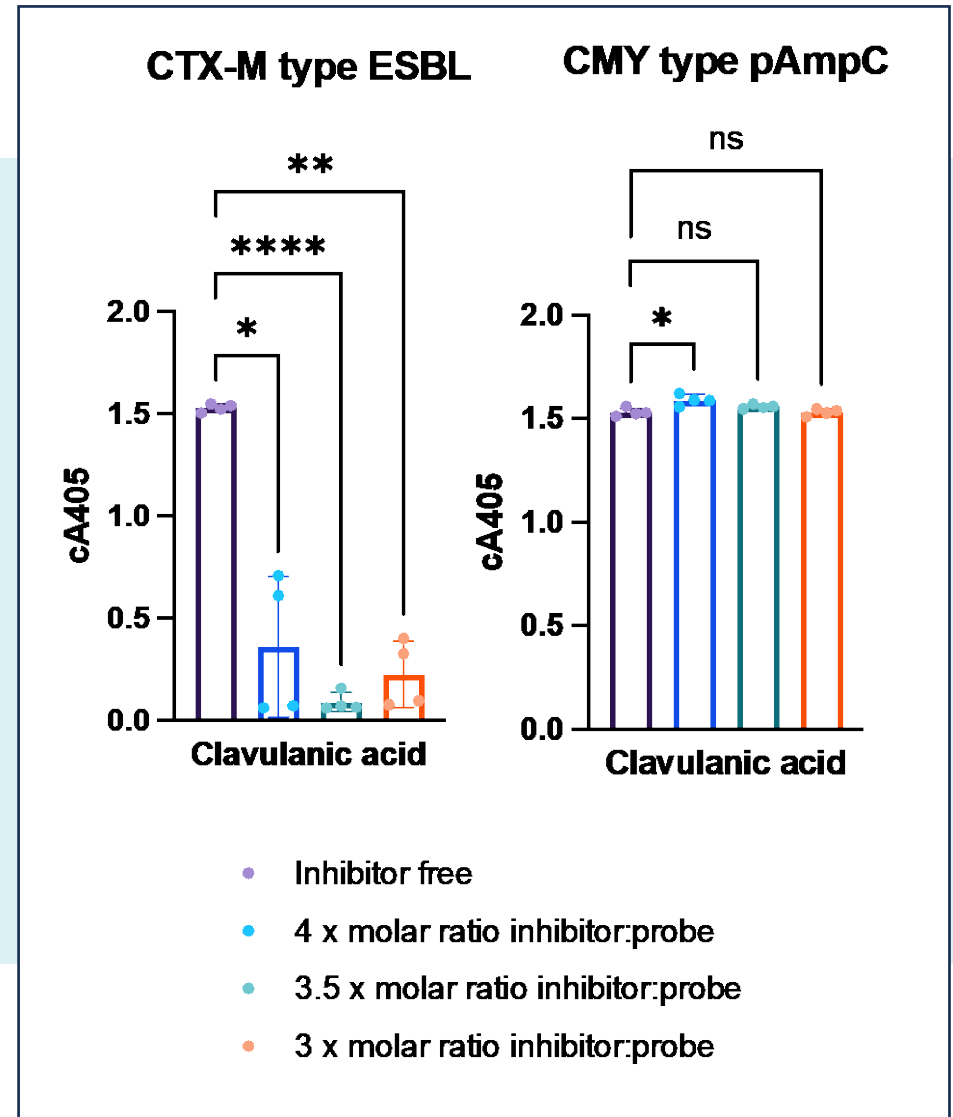
Cephalosporinases [ESBL]	Cephalosporinases [pAmpC]
CTX-M-14, CTX-M-15, CTX-M-27, CTX-M-55	CMY-2, CMY-4, CMY-42, CMY-130
TEM-10, TEM-15, TEM-26	
SHV-2, SHV-11, SHV-12, SHV-27, SHV-106	DHA-1, DHA-6



Ceftriaxone



Ceftazidime/Clavulanate

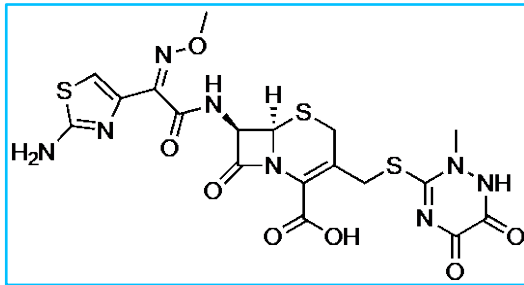


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Clinical Utility: Case Study – Linking phenotype with biomarkers via genotypic analysis to offer true clinical impact



570 (98.79%)
E. coli



Ceftriaxone (CAX)

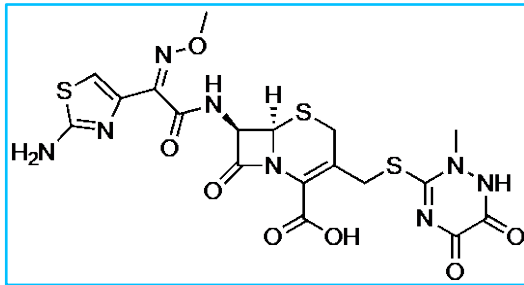
Clinical Utility: Case Study – Linking phenotype with biomarkers via genotypic analysis to offer true clinical impact



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E. coli



ESBL (+)
523 (92.1%)



Ceftriaxone (CAX)

Clinical Utility: Case Study – Linking phenotype with biomarkers via genotypic analysis to offer true clinical impact



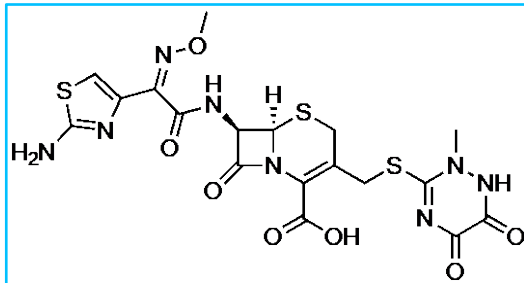
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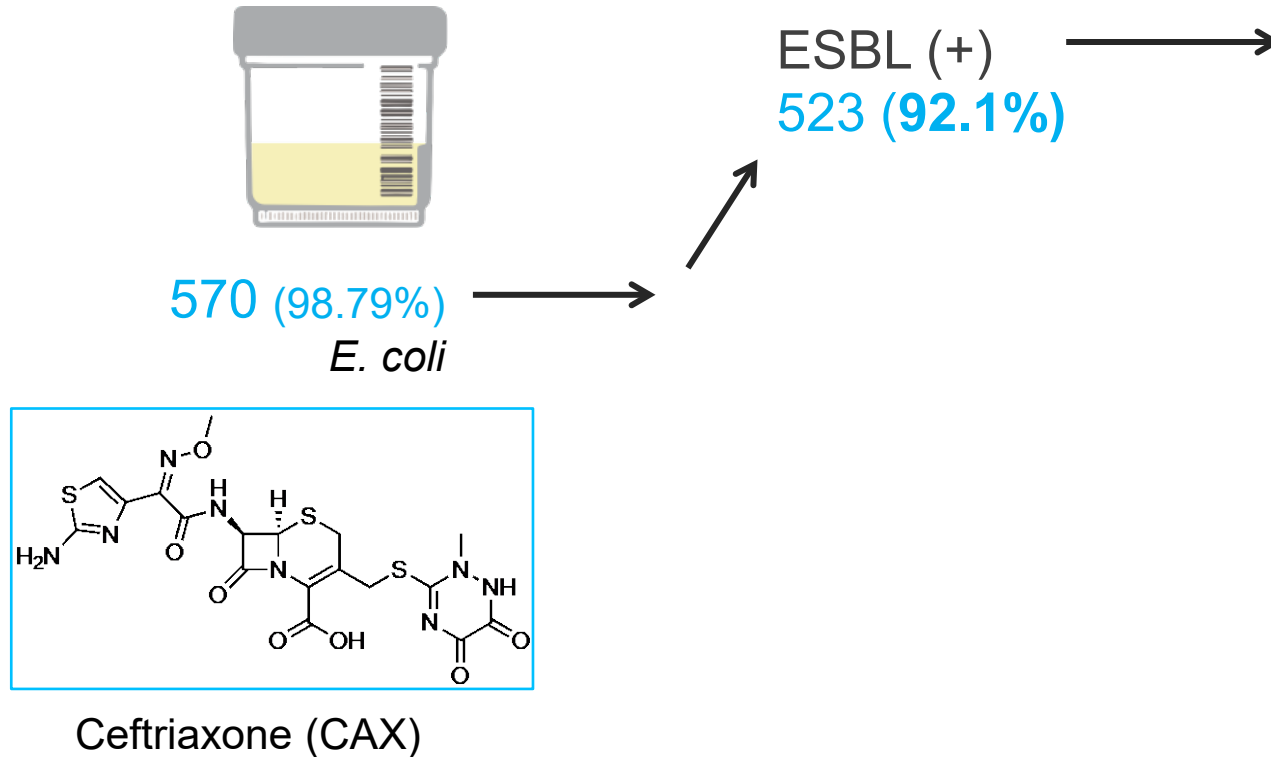


Only **37 %** of patients treated with appropriate antibiotic the first time

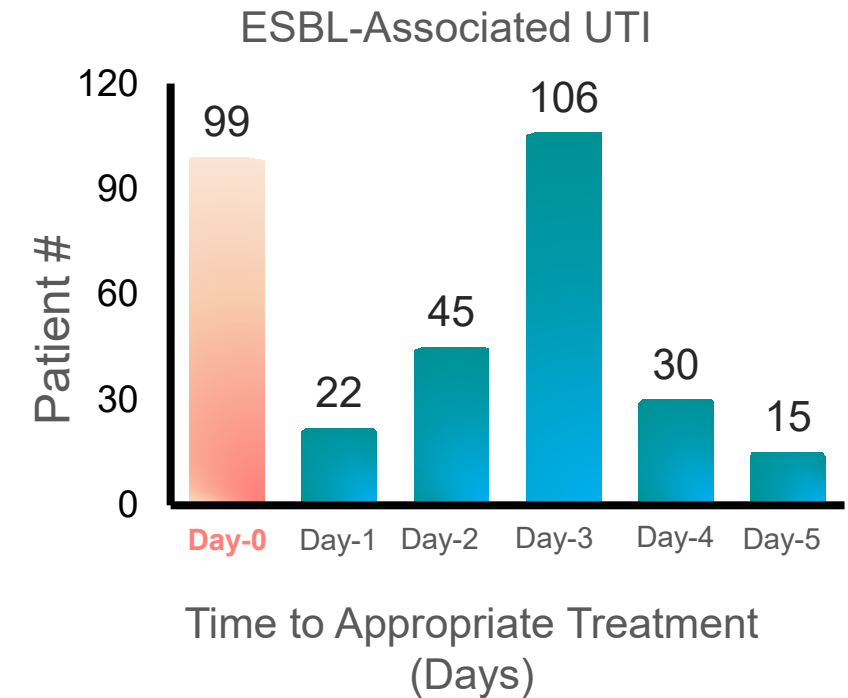


Ceftriaxone (CAX)

Clinical Utility: Case Study – Linking phenotype with biomarkers via genotypic analysis to offer true clinical impact



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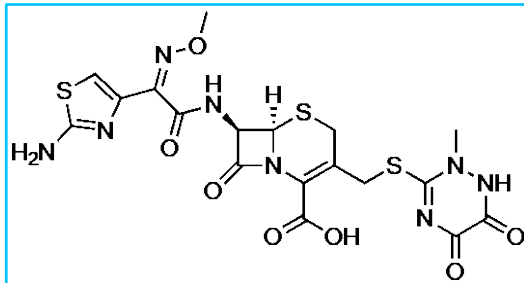
Clinical Utility: Case Study – Linking phenotype with biomarkers via genotypic analysis to offer true clinical impact



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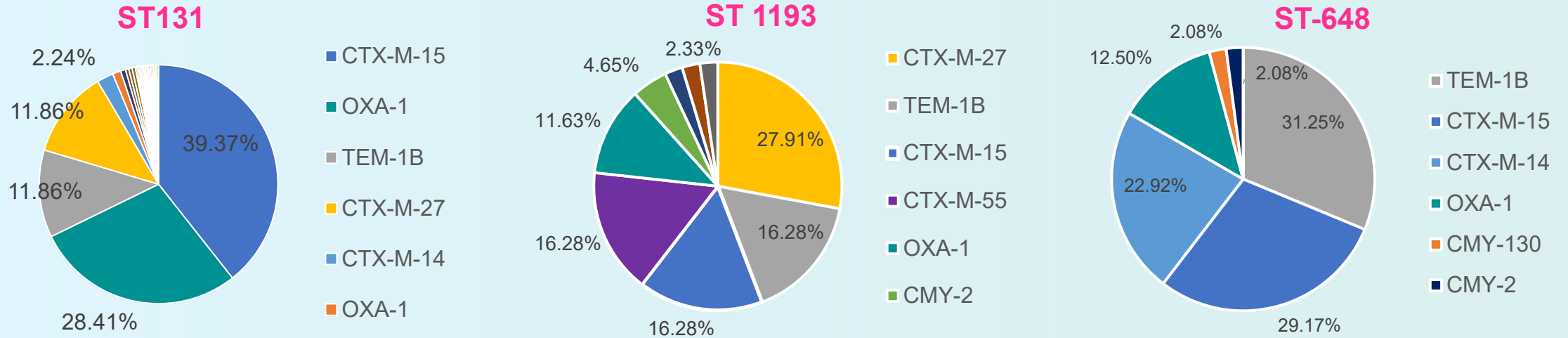
ESBL (+)
523 (92.1%)

Diagnostic intervention that can rapidly reveal ESBL-associated UTI would be clinically valuable



Ceftriaxone (CAX)

Technical Challenges: Addressing the unique fingerprints of drug-resistant bacteria across communities (6 healthcare centers, CA)



Sequence Type	Common Across All Sites		Not Common Across All Sites			
	ST-131	ST-448	ST-410	ST-4981	ST-40	ST-624
ST-1193**	ST-224	ST-88	ST-5148	ST-2325	ST-1670	ST-354
ST-648**	ST-1136	ST-5614	ST-453	ST-141	ST-2509	ST-540
ST-38	ST-6025	ST-359	ST-998	ST-2659	ST-1722	Unknown ST
ST-10	ST-4553	ST-602	ST-457	ST-155	ST-28	ST-2179
ST-69	ST-963	ST-2279	ST-404	ST-701	ST-491	ST-5744
ST-405**	ST-345	ST-361	ST-68	ST-162	ST-295	ST-372
ST-744**	ST-484					
ST-636**	ST-216					
ST-617**	ST-90					
ST-73		ST-6448	ST-6359		ST-746	

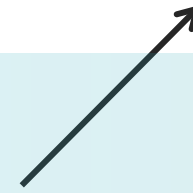
HIGHLIGHT: Our interest and engagement in B2B2B Virtual benchmarking platform (VBP) project – to help streamline our efforts

Developmental Horizon: Building a product pipeline strategically and efficiently, shared core reagent

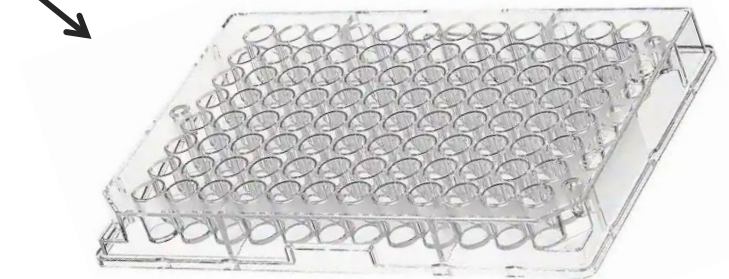
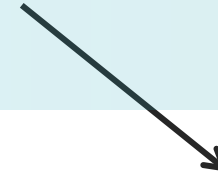
2023: Final optimization of all reagents



2024: Reagent manufacturing readiness by end of year



Dry Reagent Test Strip
Compatible with urine
(complicated UTI)



AST Compatible Tests
Integration of our chemistry onto the surface of AST panel (CPEs)

Open to Partnerships and Collaborations:

- Collaborate with on test validation studies
- Clinical outcomes simulations
- Surveillance projects (condition [cUTI or uUTI] or phenotype-focused studies)

Thank You!



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