GUIDATCE

For the right UTI therapy right from the start

References

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PATH: NOSTICS®

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The only molecular test that provides personalized therapy options.

GUIDANCE®

UTI

FOR SYMPTOMATIC UTI PATIENTS

BYPASS CHALLENGES TO GET TO THE RIGHT UTI TREATMENT QUICKLY

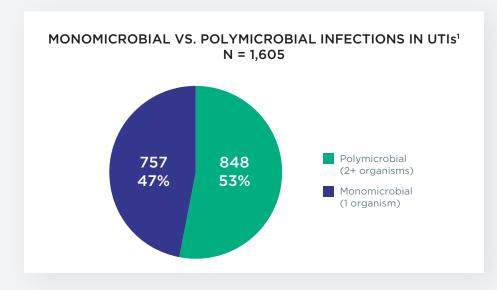




Guidance® UTI is 43% more sensitive and 51% more specific than standard urine culture¹



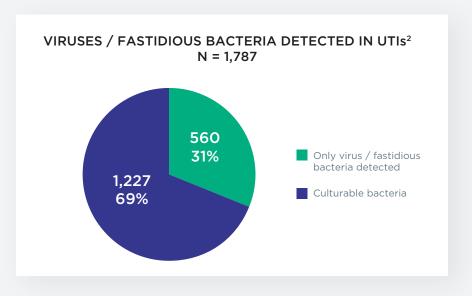
53% of detected cases involve polymicrobial infections with two or more organisms. Urine culture does not detect or provide antibiotic susceptibility for fastidious bacteria or polymicrobial infections, which are called "mixed flora."



Guidance UTI identifies the specific organisms in polymicrobial samples and determines antibiotic susceptibility using multiplex PCR and P-AST™.

FASTIDIOUS BACTERIA AND VIRUSES

31% of detected cases involve viruses only or fastidious bacteria that cannot be detected by urine culture.² Urine culture fails to detect fastidious bacteria because it is difficult to accurately simulate their natural milieu in a culture medium.



With molecular technology, **Guidance UTI** can quickly detect even fastidious bacteria in less than 48 hours.

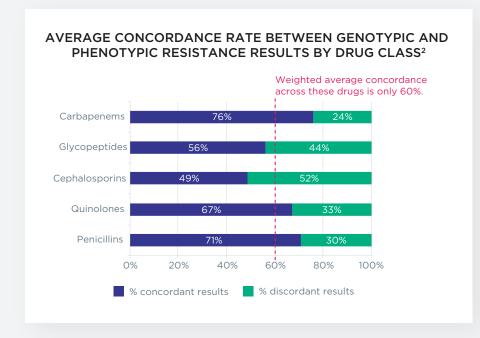


Resistance genes reflect actual susceptibility only 60% of the time²





Microorganisms with antibiotic resistance genes are sometimes still susceptible to antibiotics. In other cases, microorganisms actually display resistance to antibiotics even when no antibiotic resistance genes were detected by molecular testing. In polymicrobial infections, antibiotic resistance may even be less correlated with resistance genes due to the effects of polymicrobial interactions.



Genotypic results can disagree with phenotypic or observed resistance up to 52% of the time.²

Genotypic and phenotypic resistance results were compared across 14 of the 18 antibiotics: one carbapenem (meropenem), one glycopeptide (vancomycin), six cephalosporins (cefaclor, cefazolin, cefepime, cefoxitin, ceftazidime, and ceftriaxone), two quinolones (ciprofloxacin and levofloxacin), and four penicillins (ampicillin, amoxicillin/clavulanate, ampicillin/sulbactam, and piperacillin/tazobactam).

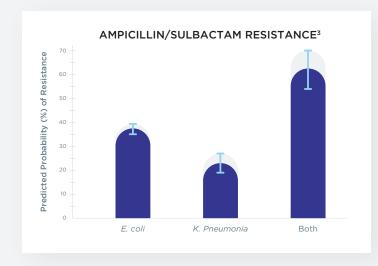
GUIDANCE® UTI ACCURATELY IDENTIFIES TREATMENTS THAT WILL WORK QUICKLY BY GIVING PRECISE AND PERSONALIZED THERAPY OPTIONS

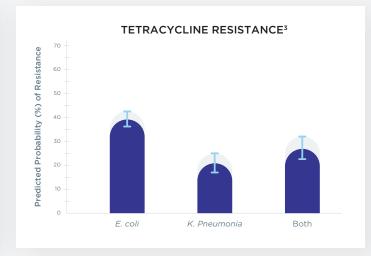
Phenotypic antibiotic susceptibility testing is the only way to accurately capture antibiotic resistance. Guidance UTI uses P-AST™ to measure the pathogen's actual sensitivity and resistance to antibiotics.



CULTURE'S ANTIBIOTIC SUSCEPTIBILITY TESTING RESULTS ARE NOT ALWAYS ACCURATE IN POLYMICROBIAL INFECTIONS

Bacteria are social organisms that interact within and between species. Because of this, polymicrobial interactions can **increase** or **decrease** pathogen susceptibility to antibiotics.³ Standard antibiotic susceptibility tests are performed on isolates, which means the impact of polymicrobial interactions on the pathogen group's susceptibility is not accounted for in the results.





ONLY GUIDANCE® UTI PROVIDES SUSCEPTIBILITY RESULTS THAT REFLECT THE EFFECT OF BACTERIAL INTERACTIONS

Guidance UTI's P-AST™ methodology tests antibiotics on polymicrobial infections, ensuring that the impact of bacterial interactions is fully captured in the results and the right treatment is identified.

Our patented P-AST technology measures resistance and susceptibility in pooled cultures to deliver phenotypic results that are more reliable than genotypic resistance results and standard antibiotic susceptibility testing.

Using Guidance UTI decreases hospitalization rates

The use of Guidance UTI was associated with a 13.7% decrease in hospital admissions and/or emergency department (ED) utilization when compared to the use of urine culture.⁴

22% cost reduction

A 13.7% reduction in hospital utilization can lead to a **22% reduction in costs of ED and hospital visits** due to UTI. 5,6

\$64K savings per patient

Based on other studies, a reduction of 13.7% in ED utilization and hospitalizations would equate to approximately **\$64,000 savings per patient.**⁷ With a cohort of 30,000 patients, **up to \$10 million dollars could be saved.**

<48 hr turnaround time*

Improved turnaround time by Guidance UTI was a contributing factor to overall performance.

*From when a sample reaches the lab.

Order Guidance UTI for symptomatic patients.

Scan me to learn more:





Simple and easy reporting to guide therapy that works quickly

S = Pooled Phenotypic Sensitivity Detected R = Pooled Phenotypic Resistance Detected RGD = Resistance Gene(s) Detected Formulations PO/IV IM/IV Pooled Phenotypic Sensitivity Resistance Gene(s) RGD RGD RGD Detected 8 16/4 (ug/mL) Organism(s) Tested - Detected: \checkmark = Check marks are supportive data and are NOT patient specific Citrobacter freundii Enterococcus faecalis Escherichia coli Viridans Group Strep Actinotignum schaalii Alloscardovia omnicolens ✓ = Check marks indicate situations for which antibiotic use is either FDA-approved or off label use for antibiotics is illustrated in peer review literature. References available upon request.

Patient: First Last DOB: 01-01-1800				Physi	ician:	Best F	hysic	ian				Case#	: PUX	R19-01	10846	-TS				
Gender: U Facility: Phone: Phone: MRN#: 1234 Fax:								Collection Method: Voided Date Collected: 06-25-2019 Date Received: 06-26-2019 Date Reported: 06-27-2019												
			RESI	JLT:	S: P/	λTΗ	OGE	NIC	DN/	DE	TEC	TED								
ORGANISM(S) TESTED -	DET	ECTE	D: (9	iee las	t page	for O	rganis	m(s) T	ested	- Not	Detect	ed)								
Citrobacter freundii >100, Enterococcus faecalis >10 Escherichia coli >100,000	0,00	0 cel						Act	inotig	num	schaa	ilii 50	00,00 0,000 s 50,0	-99,9	99 ce	lls/m				
LEGEND									Ē											
S = Pooled Phenotypic Sensitivity Detected							ctam		rimethopr		nate					E				
R = Pooled Phenotypic Resistance Detected	_		_	.5			Tazoba		T/ azole		Clavula					Sulbacta				
RGD =Resistance Gene(s) Detected	Levofloxacin	Tetracycline	Ciprofloxacin	Nitrofurantoin	Fosfomycin	Ampicillin	Piperacillin / Tazobactam	Ceftazidime	Sulfamethoxazole / Trimethoprim	Gentamicin	Amoxicillin / Clavulanate	Cefacior	Ceftriaxone	Meropenem	Vancomycin	Ampicillin / Sulbactam	Cefepime	Cefazolin		
Formulations	PQ/IV	РО	PQ/IV	РО	РО	PQ/IV	IV	IV	PQ/IV	IM/IV	РО	РО	IM/IV	IV	IV	IV	IV	IV		
Pooled Phenotypic Sensitivity	s	s	s	s	s	s	s	s	R	R	R	R	R	R	R	R	R	R		
Resistance Gene(s) Detected						RGD	RGD	RGD			RGD	RGD	RGD	RGD	RGD	RGD	RGD	RGD	9	
MIC Results (ug/mL)	1	2	1	32	64	8	16/4	4												
Organism(s) Tested - Detecte	d:	√ =	Check	mark	s are	supp	ortive	data	and a	re NC	T pat	ient s	pecifi	c.						
Citrobacter freundii	✓	~	~	~			~	~	~	~			~	~			~			
Enterococcus faecalis	✓	~	~	~	~	~	~				~			~	~	~				
Escherichia coli	~	✓	~	~		✓	✓	✓	~	~	~	~	~	~		~	~	~		
Viridans Group Strep ****	~	~				~	~	~					~	~	~	~	~	~		
Actinotignum schaalii	~	~	~	~		~				~			~		~					
Alloscardovia omnicolens	- ,	-	,	. /	-	. 1	. /	. /		/	_				/				T	

ANTIBIOTICS ARE ORGANIZED LEFT TO RIGHT IN THE ORDER WE RECOMMEND THEM, BASED ON THE 4 PRINCIPLES BELOW

- Pooled Phenotypic Sensitivity: "S" denotes antibiotics that work and are listed first; "R" denotes antibiotics that are resistant and are listed second. This allows physicians to quickly identify the optimal antibiotic for treating their patient.
- **Formulations:** Within each "S" and "R" group (with and without RGD), the antibiotics are prioritized by formulation. PO is listed first, IM is listed second, and IV is listed third. PO formulations are bolded to help identify pill/oral antibiotics.
- Resistance Gene(s) Detected: Antibiotics that have a resistance gene are stacked to the right of each "S" or "R" category and denoted by "RGD".
- Supporting evidence: Lastly, antibiotics are subcategorized by the number of checkmarks (greatest to least). Higher volume of checkmarks are left-stacked. The checkmarks section is separated from the top section to distinguish from patient-specific and non-patient-specific information.

Test details



ORGANISMS DETECTED:

BACTERIAL/YEAST ORGANISMS

- Acinetobacter baumannii
- Actinotignum schaalii
- Aerococcus urinae
- Alloscardovia omnicolens
- Candida albicans
- Candida auris
- Candida glabrata
- Candida parapsilosis
- Citrobacter freundii

- Citrobacter koseri
- Corynebacterium riegelii
- Enterococcus faecalis
- Enterococcus faecium
- Escherichia coli
- Klebsiella oxytoca
- Klebsiella pneumoniae
- Morganella morganii
- Mycobacterium tuberculosis

- Mycoplasma hominis
- Pantoea agglomerans
- Proteus mirabilis
- Providencia stuartii
- Pseudomonas aeruginosa
- Serratia marcescens
- Staphylococcus aureus
- Streptococcus agalactiae
- Ureaplasma urealyticum

BACTERIAL GROUPS

- Coagulase-Negative staphylococci*
- Viridans group *streptococci*†
- Enterobacter group[‡]

SEXUALLY TRANSMITTED ORGANISMS

- Chlamydia trachomatis
- Neisseria gonorrhoeae
- Trichomonas vaginalis

VIRAL PARTICLES

- BK virus
- HHV-1, HHV-2 (HSV 1/2)
- HHV-5 (CMV)HHV-6
- JC virus

POOLED ANTIBIOTIC SUSCEPTIBILITY TESTING (P-AST**) INCLUDES:

- Ampicillin (PO/IV)
- Ampicillin/Sulbactam (IV)
- Amoxicillin/Clavulanate (PO)
- Cefaclor (PO)
- Cefazolin (IV)
- Cefepime (IV)
- Cefoxitin (IV)

- Ceftazidime (IV)
- Ceftriaxone (IM/IV)
- Ciprofloxacin (PO/IV)
- Fosfomycin (PO/IV)
- Gentamicin (IM/IV)
- Levofloxacin (PO)
- Meropenem (IV)

- Nitrofurantoin (PO)
- Piperacillin/Tazobactam (IV)
- Sulfamethoxazole/Trimethoprim (PO/IV)
- Tetracycline (PO)
- Vancomycin (IV)

GENOTYPE ANTIBIOTIC RESISTANCE GENES INCLUDE:

- Ampicillin
- Carbapenem

- Extended Spectrum Beta-Lactamase
- Methicillin

- Quinolone/Fluoroguinolone
- Vancomycin

KEY

Guidance® UTI

Add-on tests

* Coagulase-Negative staphylococci: Staphylococcus epidermidis, Staphylococcus haemolyticus, Staphylococcus lugdunensis, Staphylococcus saprophyticus

[†] Viridans group *streptococci*: *Streptococcus anginosus*, *Streptococcus oralis*, *Streptococcus pasteuranus*

[†] Enterobacter group: Klebsiella aerogenes (formally known as Enterobacter aerogenes), Enterobacter clocacae