



**Patient: First Last**

DOB: 01-01-1901	Provider: Doctor	Case#: PUG24-000580
Phone:	Facility: Test Client	Collection Method: Voided Urine
MRN#:	Irvine, CA 92618	Date Collected: 10-04-2024
	Phone: 123-456-7890	Date Received: 10-05-2024
	Fax: 123-456-7891	Date Reported: 10-06-2024

**RESULTS: PATHOGENIC DNA DETECTED**

**ORGANISM(S) TESTED - DETECTED:** (See last page for Organism(s) Tested - Not Detected)

- *Escherichia coli* ≥100,000 cells/mL
- *Staphylococcus aureus* 50,000-99,999 cells/mL
- *Ureaplasma urealyticum* 10,000-49,999 cells/mL

LEGEND																								
<b>S</b> = Pooled Susceptibility Detected																								
<b>I</b> = Pooled Intermediate Susceptibility Detected																								
<b>R</b> = Pooled Resistance Detected																								
<b>RGD</b> = Resistance Gene(s) Detected																								
	Doxycycline	Levofloxacin	Nitrofurantoin	Sulfamethoxazole / Trimethoprim	Fosfomycin	Linezolid	Clindamycin	Gentamicin	Meropenem	Cefaclor	Cephalexin	Ampicillin / Sulbactam	Cefepime/Enmetazobactam	Piperacillin / Tazobactam	Ciprofloxacin	Amoxicillin / Clavulanate	Ampicillin	Trimethoprim	Vancomycin	Ceftazidime	Ceftriaxone	Cefepime	Cefazolin	
<b>Formulations</b>	PO IV	PO IV	PO	PO IV	PO IV	PO IV	PO	IM IV	IV	PO	PO	IV	IV	IV	PO IV	PO	PO IV	PO	IV	SC IV	SC IM IV	IM IV	IV	
<b>Pooled Antibiotic Susceptibility Testing (P-AST™)</b>	S	S	S	S	S	S	S	S	S	S	S	S	S	S	I	I	I	R	R	R	R	R	R	R
<b>Resistance Gene(s) Detected</b>										RGD	RGD	RGD	RGD	RGD		RGD	RGD			RGD	RGD	RGD	RGD	
<b>Pooled MIC Results (µg/mL)</b>	4	0.5	32	2/38	64	2	0.5	2	1	8	16	8/4	8/8	8/4	0.5	16/8	16							

Organism(s) Tested - Detected: ✓ = Check marks are supportive data and are NOT patient specific.

<i>Escherichia coli</i>	✓	✓	✓	✓	✓			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓
<i>Staphylococcus aureus</i>	✓		✓	✓		✓		✓										✓	✓				
<i>Ureaplasma urealyticum</i>	✓	✓																					

✓ = Check marks indicate that (a) the FDA has determined the antibiotic is effective against the organism or notes in vitro data demonstrating that MIC levels are less than or equal to susceptibility breakpoints, (b) CLSI breakpoints for urine culture are reported, or (c) there is sufficient evidence proving the antibiotic's use. References available on request. Check mark information may change as new evidence on antibiotic efficacy is continuously being published. Note that in vitro results may not apply in vivo. The health care provider should exercise appropriate medical judgment before prescribing a course of treatment.



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## POOLED SUSCEPTIBILITY DETECTED (S):

- Ampicillin / Sulbactam (IV)
- Cefaclor (PO)
- Cefepime/Enmetazobactam (IV)
- Cephalexin (PO)
- Clindamycin (PO)
- Doxycycline (PO/IV)
- Fosfomycin (PO/IV)
- Gentamicin (IM/IV)
- Levofloxacin (PO/IV)
- Linezolid (PO/IV)
- Meropenem (IV)
- Nitrofurantoin (PO)
- Piperacillin / Tazobactam (IV)
- Sulfamethoxazole / Trimethoprim (PO/IV)

## POOLED INTERMEDIATE SUSCEPTIBILITY DETECTED (I):

- Amoxicillin / Clavulanate (PO)
- Ampicillin (PO/IV)
- Ciprofloxacin (PO/IV)

## POOLED RESISTANCE DETECTED (R):

- Cefazolin (IV)
- Cefepime (IV/IM)
- Ceftazidime (IV/SC)
- Ceftriaxone (IM/IV/SC)
- Trimethoprim (PO)
- Vancomycin (IV)

## RESISTANCE GENE GROUP(S) DETECTED (RGD):

- Ampicillin Resistance

## RESISTANCE GENE(S) TESTED - NOT DETECTED:

- Carbapenem Resistance
- ESBL Resistance
- Methicillin Resistance
- Quino / Fluoroquinolone
- Vancomycin Resistance

## ORGANISM(S) TESTED - NOT DETECTED:

### BACTERIA:

- *Acinetobacter baumannii*
- *Actinotignum schaalii*
- *Aerococcus urinae*
- *Alloscardovia omnicolens*
- *Citrobacter freundii*
- *Citrobacter koseri*
- *Coagulase Negative Staph Group*
- *Corynebacterium riegelii*
- *Enterobacter Group*
- *Enterococcus faecalis*
- *Enterococcus faecium*
- *Gardnerella vaginalis*
- *Klebsiella oxytoca*
- *Klebsiella pneumoniae*
- *Morganella morganii*
- *Mycoplasma hominis*
- *Proteus mirabilis*
- *Providencia stuartii*
- *Pseudomonas aeruginosa*
- *Serratia marcescens*
- *Streptococcus agalactiae*
- *Viridans Group Strep*

### YEAST:

- *Candida albicans*
- *Candida glabrata*
- *Candida parapsilosis*

### References:

\* ESBL Positive for extended-spectrum beta-lactamases (ESBL) which are enzymes that confer resistance to most beta-lactam antibiotics, including penicillins, cephalosporins, and the monobactam aztreonam. Infections with ESBL producing organisms have been associated with poor outcomes

\*\* Coagulase Negative Staphylococcus Group includes: *Staphylococcus epidermidis*, *Staphylococcus haemolyticus*, *Staphylococcus lugdunensis*, and *Staphylococcus saprophyticus*.

\*\*\* Enterobacter Group includes: *Enterobacter cloacae*, and *Klebsiella aerogenes* (formerly *Enterobacter aerogenes*)

\*\*\*\* Viridans Group Streptococcus includes: *Streptococcus anginosus*, *Streptococcus oralis*, and *Streptococcus pasteurianus*

**Disclaimer:** This test was developed, and its performance characteristics determined by Pathnostics. It has not been cleared or approved by the US Food and Drug Administration. The FDA has determined that such clearance or approvals is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity clinical testing.

**Methodology and Clinical Significance:** Microbes and resistance genes are detected through multiplex PCR. Guidance<sup>®</sup> UTI results are reported as: "No pathogenic DNA detected", "Incidental finding: Low cell density pathogenic DNA detected", and "Pathogenic DNA detected". When pathogenic DNA is detected in undiluted mid-stream voided or catheterized samples, cell counts are reported as semi-quantitative values of: "<10,000", "10,000-49,999", "50,000-99,999", or "≥100,000" cells/mL of urine. Sample types such as bladder wash liquid will result with identification of organisms without semi-quantitative values. Resistance genes are either detected or not detected. Pooled minimum inhibitory concentration (MIC) is determined by subjecting the pool of organisms to a panel of antimicrobial agents. Pooled Antibiotic Susceptibility Testing (P-AST™) is a proprietary method to determine the antibiotic susceptibility for multiple antibiotics against the pool of organisms in the urine sample and is reported in those samples that are positive by M-PCR for non-fastidious bacteria. For full methodology visit pathnostics.com/methodology.

**Test Limitations:** The syndromic panel is limited to only include primers that identify UTI-associated uropathogens previously reported in the scientific literature. Organisms not listed on the test panel will not be detected. In vitro test results may not apply in vivo. Microbial DNA detection may not be indicative of live microbial infection and results must always be considered in the context of the patient's clinical presentation. Antibiotic-resistance (ABR) genes were selected based on prior evidence of their impact on antibiotic resistance. New or unknown resistance genes not included on the panel will not be detected. P-AST™ is not performed on fastidious organisms and does not test for antifungals.

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