



Patient: First Last

DOB: Provider: Case#: Collection Method: Post Prostate Massage Urine
 Phone: Facility: Date Collected:
 MRN#: Phone: Date Received:
 Fax: Date Reported:

RESULTS: PATHOGENIC DNA DETECTED & ESBL Positive*

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

- *Escherichia coli* ≥100,000 cells/mL
- *Pseudomonas aeruginosa* 10,000-49,999 cells/mL
- *Proteus mirabilis* <10,000 cells/mL

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

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

<i>Escherichia coli</i>	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
<i>Pseudomonas aeruginosa</i>	✓	✓				✓		✓					✓		✓	
<i>Proteus mirabilis</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.

ESBL Phenotype Positive: Extended-spectrum beta-lactamases (ESBL) are enzymes that confer resistance to most beta-lactam antibiotics, including penicillins, cephalosporins, and aztreonam.



Patient:

DOB:

Case#:

POOLED SUSCEPTIBILITY DETECTED (S):

- Fosfomycin (PO/IV)

POOLED INTERMEDIATE SUSCEPTIBILITY DETECTED (I):

- Amoxicillin/Clavulanate (PO)
- Ciprofloxacin (PO/IV)
- Doxycycline (PO/IV)
- Gentamicin (IM/IV)
- Levofloxacin (PO/IV)
- Meropenem (IV)
- Piperacillin/Tazobactam (IV)

POOLED RESISTANCE DETECTED (R):

- Ampicillin (PO/IV)
- Cefazolin (IV)
- Cefepime (IV/IM)
- Ceftazidime (IV/SC)
- Ceftriaxone (IM/IV/SC)
- Cephalexin (PO)
- Sulfamethoxazole/Trimethoprim (PO/IV)
- Trimethoprim (PO)

RESISTANCE GENE GROUP(S) DETECTED (RGD):

- Methicillin Resistance

RESISTANCE GENE(S) TESTED - NOT DETECTED:

- Ampicillin Resistance
- Carbapenem Resistance
- ESBL Resistance
- Quino/Fluoroquinolone

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*
- *Klebsiella oxytoca*
- *Klebsiella pneumoniae*
- *Morganella morganii*
- *Mycoplasma hominis*
- *Providencia stuartii*
- *Serratia marcescens*
- *Staphylococcus aureus*
- *Streptococcus agalactiae*
- *Ureaplasma urealyticum*
- *Viridans Group Strep*

YEAST:

- *Candida albicans*
- *Candida auris*
- *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® Prostatitis 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 voided post prostatic massage urine, 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. Semi-quantitative ranges are not provided for semen ejaculate specimen type. 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 prostatitis-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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