Molecular UTI Pathogen Identification Test

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Patient:	Physician:	Date Collected: 10/01/2024
DOB:	NPI #:	Date Received: 10/02/2024
Gender:	Practice:	Date Reported: 10/3/2024
Sample ID:	Phone:	Specimen Type: Urine - Clean Catch

RESULTS: PATHOGEN(S) DETECTED

ORGANISM(S) DETECTED:

- Enterococcus faecalis : 10,000-99,999 cells/mL
- Escherichia coli : 10,000-99,999 cells/mL

RESISTANCE GENE(S) DETECTED:

- QnrA/QnrB - Quinolone and Fluoroquinolone Resistance Marker

SUMMARY OF SENSITIVE AGENTS ON MOLECULAR ANTIBIOTIC SUSCEPTIBILITY TESTING

Sensitive Antibiotic	Result
Ampicillin	S
Doxycycline	S
Fosfomycin	S
Nitrofurantoin	S
Vancomycin	S

MOLECULAR ANTIBIOTIC SUSCEPTIBILITY ANALYSIS (Enterococcus faecalis)

Sensitive Antibiotic	Result
Ampicillin	S
Ciprofloxacin	S
Doxycycline	S
Fosfomycin	S
Levofloxacin	S
Nitrofurantoin	S
Vancomycin	S

MOLECULAR ANTIBIOTIC SUSCEPTIBILITY ANALYSIS (Escherichia coli)

Sensitive Antibiotic	Result
Ampicillin	S
Amoxicillin/Clavulanate	S
Cefazolin	S
Cefepime	S
Cefoxitin	S
Ceftriaxone	S
Doxycycline	S
Fosfomycin	S
Gentamicin	S
Nitrofurantoin	S
Meropenem	S
Piperacillin/Tazobactam	S
Sulfamethoxazole/Trimethoprim	S

Resistant Antibiotic	
Ciprofloxacin	R
Levofloxacin	R

Disclaimer: This test was developed and its performance characteristics determined by Mokan Labs, LLC. It has not been cleared or approved by the US Food and Drug Administration (FDA). The FDA has determined that such clearance or approval 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. Urine specimens received and/or processed greater than 5 days post-collection may give unreliable results due to overgrowth of microorganism(s). If 3 or more pathogens are detected, recollection of the specimen may be beneficial. A negative report does not rule out the presence of pathogens below the level of detection of this assay or in the presence of inhibitors. New evidence on the antibiotic efficacy against these pathogens may change and are continuously updated/published. Also of note, in vitro results may not apply in vivo results. Healthcare providers should utilize their medical judgment before prescribing medications based on these results.

Methodology: Microbes and resistance genes are detected through multiplex PCR. Pathogens are reported semi-quantitively as No pathogenic DNA detected, <10,000 cells/mL, 10,000 - 99,999 cells/mL, or >100,000 cells/mL of urine. Resistance genes are reported as detected or not detected. For specimens with >10,000 cells/mL of appropriate bacterial pathogen, the urine is exposed to a panel of antimicrobial agents per CLSI guideline breakpoints, with antibiotics reported as sensitive or resistant.

Organisms Tested: Acinetobacter baumannii, Candida albicans, Candida glabrata, Candida parapsilosis, Citrobacter freundii, Enterobacter cloacae, Enterococcus faecalis, Enterococcus faecium, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Mycoplasma hominis, Proteus mirabilis, Proteus vulgaris, Providencia stuartii, Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus aureus, Staphylococcus saprophyticus, Streptococcus agalactiae (Group B Strep), Ureaplasma urealyticum.

Resistance Genes Tested: Ampicillin Resistance Marker: ampC; Carbapenem Resistance Markers: Oxa-48, KPC, VIM/IMP-7/NDM; ESBL Resistance Markers: SHV, TEM, CTX-M Group 1/2; Methicillin Resistance Markers: mecA, femA; Quinolone and Fluoroquinolone Resistance Marker: QnrA/QnrB; Vancomycin Resistance Markers: VanA1/vanA2, VanB.

References: References are available upon request