

CLINIC INFORMATION

Name: Assurance Pathology
Laboratory
Address: 2868 Acton Road
Suite 207
BIRMINGHAM, AL 35243
Provider: Doctor Test

PATIENT INFORMATION

Name: TEST, TEST
DOB: 5/12/1965
Gender: M

SPECIMEN INFORMATION

Lab Accession Number: ASL-80103
Date Collected: 1/19/2020
Date Received by Lab: 1/20/2020
Date Accessioned: 1/20/2020
Date Reported: 1/20/2020
Faxed to: 18777966185

Controls

Patient Extraction Control ¹	PASS
Endogenous Positive Control ¹	PASS
Pathogen Positive Control ²	PASS
Pathogen Negative Control ³	PASS

- (1) Endogenous control confirms sample collection, DNA/RNA extraction, and assay enzyme activity
(2) Positive control is synthetic inactive pathogen
(3) Negative Control contains primers, probe, and enzymes with no DNA/RNA template
(4) A "Detected" result indicates the presence of a pathogen (99.99% confidence) above the assay cutoff. Assay cutoff is represented by CFU (bacteria), PFU (viruses) or Copy Number (DNA)

Test Performed	Lab Result(4) (Qualitative Low/Medium/High)	DNA Copy Number	Comments
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SUMMARY UTI Pathogens			Collection Type: Urine
Escherichia coli	DETECTED - HIGH	1.00E+06	[1/20/2020 9:30 AM] Shares homology with Shigella spp.
Proteus mirabilis	DETECTED - MEDIUM	1.00E+03	

Class (Gene Name)	Lab Result (Qualitative)	Resistance Gene Targets Identified	Associated Resistances
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SUMMARY Antibiotic Resistance Markers			
Sulfonamides	DETECTED	sul1; sul2; sul3	[1/20/2020 9:30 AM] Sulfadiazine, Sulfamethizole, Sulfamethoxazole, Sulfasalazine, Sulfisoxazole
Trimethoprim	DETECTED	dfrA1; dfrA5; dfrA11; dfrA17	[1/20/2020 9:30 AM] Primsol

Antibiotic Sensitivity Testing	Minimum Inhibitory Concentration (ug/ml)	Susceptibility	Notes
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Culture ID			
Organism Cultured:	E.coli		
Colony Count:	>100k CFU/mL		

Antibiotic Sensitivity Testing			
Gentamicin AST	<= 4 ug/mL	Susceptible	
Ceftriaxone AST	<= 1 ug/mL	Susceptible	
Ampicillin AST	<= 8 ug/mL	Susceptible	
Nitrofurantoin AST	<= 32 ug/mL	Susceptible	
Ciprofloxacin AST	<= 1 ug/mL	Susceptible	
Trimethoprim/sulfamethoxazole AST	> 2/38 ug/mL	Resistant	
Amoxicillin/clavulanic Acid AST (2:1)	<= 8/4 ug/mL	Susceptible	
Cefazolin AST	<= 4 ug/mL	Susceptible	

Culture ID - 2nd Organism			
Organism Cultured:	P.mirabilis		
Colony Count:	10-100k CFU/mL		

Antibiotic Sensitivity Testing - 2nd Organism			
Gentamicin AST	<= 4 ug/mL	Susceptible	
Ceftriaxone AST	<= 1 ug/mL	Susceptible	
Ampicillin AST	<= 8 ug/mL	Susceptible	

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This test detects the presence of pathogen and must be evaluated with clinical symptoms to diagnose disease. All tests established and validated by Laboratory and not FDA approved.

Methodology statement: Real-time PCR assays are designed to detect pathogens with clinical significance and analytical sensitivity and specificity greater than 99%.

Limitations: While these assays are very sensitive and specific, theoretically these assays could detect pathogens not listed, resulting in a false positive.

In addition, while these assays are very specific, there may be target pathogen sequences with unknown sequence variability which may not be detected, resulting in a false negative result.

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Antibiotic Sensitivity Testing

 Minimum Inhibitory
 Concentration (ug/ml)

Susceptibility

Notes

Antibiotic Sensitivity Testing - 2nd Organism (cont'd)

Antibiotic Sensitivity Testing	Minimum Inhibitory Concentration (ug/ml)	Susceptibility	Notes
Nitrofurantoin AST	See comments.	Resistant	[1/20/2020 9:49 AM] Intrinsically resistant.
Ciprofloxacin AST	<= 1 ug/mL	Susceptible	
Trimethoprim/sulfamethoxazole AST	> 2/38 ug/mL	Resistant	
Amoxicillin/clavulanic Acid AST (2:1)	<= 8/4 ug/mL	Susceptible	
Cefazolin AST	<= 4 ug/mL	Susceptible	

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UTI Pathogens			
Acinetobacter baumannii	Not Detected	Not Detected	
Bacteroides fragilis	Not Detected	Not Detected	
Citrobacter freundii/braakii	Not Detected	Not Detected	
Citrobacter koseri	Not Detected	Not Detected	
Enterobacter cloacae	Not Detected	Not Detected	
Enterococcus spp.	Not Detected	Not Detected	
Escherichia coli	DETECTED - HIGH	1.00E+06	[1/20/2020 9:30 AM] Shares homology with Shigella spp.
Klebsiella aerogenes	Not Detected	Not Detected	
Klebsiella oxytoca/michiganesis	Not Detected	Not Detected	
Klebsiella pneumoniae	Not Detected	Not Detected	
Morganella morganii	Not Detected	Not Detected	
Proteus mirabilis	DETECTED - MEDIUM	1.00E+03	
Pseudomonas aeruginosa	Not Detected	Not Detected	
Serratia marcescens	Not Detected	Not Detected	
Staphylococcus aureus	Not Detected	Not Detected	
Staphylococcus epidermidis	Not Detected	Not Detected	
Staphylococcus saprophyticus	Not Detected	Not Detected	
Streptococcus pyogenes (Group A)	Not Detected	Not Detected	

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Antibiotic Resistance Markers			
Class A Beta-lactamase (blaKPC)	Not Detected	KPC-2-8,10,11,13-22,24-33	[1/20/2020 9:30 AM] Carbapenems, Cephalosporins, Penicillins, Beta-lactamase inhibitors, Aztreonam
Class A Beta-lactamase (CTX-M-Group 1)	Not Detected	blaCTX-M-1,3,10,12,15,22,23,28; blaFEC-1	[1/20/2020 9:30 AM] Cephalosporins, Penicillins, Aztreonam
Class B metallo Beta-lactamase (blaNDM)	Not Detected	NDM (1-21)	[1/20/2020 9:30 AM] Carbapenems, Cephalosporins, Penicillins, Beta-lactamase inhibitors
Fluoroquinolones	Not Detected	qnrS 1-5,7-9; qnrB Group 1; qnrB Group 5	[1/20/2020 9:30 AM] Ciprofloxacin, Gemifloxacin, Levofloxacin, Moxifloxacin, Norfloxacin, Ofloxacin
mecA (Methicillin/Oxacillin resistance)	Not Detected	mecA	[1/20/2020 9:30 AM] Oxacillin
Sulfonamides	DETECTED	sul1; sul2; sul3	[1/20/2020 9:30 AM] Sulfadiazine, Sulfamethizole, Sulfamethoxazole, Sulfasalazine, Sulfisoxazole
Trimethoprim	DETECTED	dfrA1; dfrA5; dfrA11; dfrA17	[1/20/2020 9:30 AM] Primsol
vanA (Vancomycin)	Not Detected	vanA	[1/20/2020 9:30 AM] Vancomycin
vanB (Vancomycin)	Not Detected	vanB	[1/20/2020 9:30 AM] Vancomycin

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