

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-62975
 Date Collected: 7/10/2019 9:19 AM
 Date Received by Lab: 7/11/2019
 Date Accessioned: 7/11/2019
 Date Reported: 7/11/2019
 Faxed to: 18777966185

Controls

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

Pathogen	Lab Result	DNA Copy Number	Comments
Escherichia coli	DETECTED - LOW	1.00E+01	[7/11/2019 9:44 AM] Shares homology with Shigella spp.
Klebsiella pneumoniae	DETECTED - HIGH	1.00E+05	
Morganella morganii	DETECTED - MEDIUM	1.00E+03	
Proteus mirabilis	DETECTED - LOW	1.00E+01	

Class (Gene Name)	Lab Result (Qualitative)	Resistance Gene Targets Identified	Associated Resistances (Antibiotics to Avoid)
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SUMMARY Antibiotic Resistance Markers

Class A Beta-lactamase (blaKPC)	DETECTED	KPC-2-8,10,11,13-22,24-33	[7/11/2019 9:44 AM] Carbapenems, Cephalosporins, Penicillins, Beta-lactamase inhibitors, Aztreonam
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Page: 1

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.

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UTI Pathogens			
Test Performed	Lab Result(4) (Low/Medium/High)	DNA Copy Number	Comments
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 aerogenes	Not Detected	Not Detected	
Enterobacter cloacae	Not Detected	Not Detected	
Enterococcus spp.	Not Detected	Not Detected	
Escherichia coli	DETECTED - LOW	1.00E+01	[7/11/2019 9:44 AM] Shares homology with Shigella spp.
Klebsiella oxytoca/michiganesis	Not Detected	Not Detected	
Klebsiella pneumoniae	DETECTED - HIGH	1.00E+05	
Morganella morganii	DETECTED - MEDIUM	1.00E+03	
Proteus mirabilis	DETECTED - LOW	1.00E+01	
Pseudomonas aeruginosa	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	
Serratia marcescens	Not Detected	Not Detected	

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Page: 2

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Class (Gene Name)	Lab Result (Qualitative)	Resistance Gene Targets Identified	Associated Resistances (Antibiotics to Avoid)
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Antibiotic Resistance Markers			
Class (Gene Name)	Lab Result (Qualitative)	Resistance Gene Targets Identified	Associated Resistances (Antibiotics to Avoid)
Class A Beta-lactamase (CTX-M-Group 1)	Not Detected	blaCTX-M-1,3,10,12,15,22,23,28; blaFEC-1	[7/11/2019 9:44 AM] Cephalosporins, Penicillins, Aztreonam
Class A Beta-lactamase (blaKPC)	DETECTED	KPC-2-8,10,11,13-22,24-33	[7/11/2019 9:44 AM] Carbapenems, Cephalosporins, Penicillins, Beta-lactamase inhibitors, Aztreonam
Class B metallo Beta-lactamase (blaNDM)	Not Detected	NDM (1-21)	[7/11/2019 9:44 AM] Carbapenems, Cephalosporins, Penicillins, Beta-lactamase inhibitors
Fluoroquinolones	Not Detected	qnrS 1-5,7-9; qnrB Group 1; qnrB Group 5	[7/11/2019 9:44 AM] Ciprofloxacin, Gemifloxacin, Levofloxacin, Moxifloxacin, Norfloxacin, Ofloxacin
mecA (Methicillin/Oxacillin resistance)	Not Detected	mecA	[7/11/2019 9:44 AM] Oxacillin
Sulfonamides	Not Detected	sul1; sul2; sul3	[7/11/2019 9:44 AM] Sulfadiazine, Sulfamethizole, Sulfamethoxazole, Sulfasalazine, Sulfisoxazole
Trimethoprim	Not Detected	dfrA1; dfrA5; dfrA11; dfrA17	[7/11/2019 9:44 AM] Primisol
vanA (Vancomycin)	Not Detected	vanA	[7/11/2019 9:44 AM] Vancomycin
vanB (Vancomycin)	Not Detected	vanB	[7/11/2019 9:44 AM] Vancomycin

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