



CLIENT INFORMATION

Account: Qitek Labs
Address: 4375 River Green Pkwy
Suite 200
Duluth, GA 30096

Phone: 888-85-QITEK
Provider: Dr. Qitek

PATIENT INFORMATION

Name: John Doe
DOB: 11/26/2019
Gender: Male
Fasting: No

SPECIMEN INFORMATION

Accession: 0131200001
Specimen Type:
Swab
Collected: 01/29/20
Received: 01/30/20
Reported: 01/31/20

MEDICATIONS PRESCRIBED (as provided): No Medication List Provided

Controls

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

PASS
PASS
PASS
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).

Results

Test Performed	Lab Result (Qualitative)	Recommended Treatment
Pathogens		
A. baumannii	Not detected	N/A
C freundii/braakii	Not detected	N/A
C. koseri	Not detected	N/A
E. aerogenes	Not detected	N/A
E. cloacae	Not detected	N/A
Enterococcus spp. (E. faecalis/E. faecium)	Detected - HIGH	Ampicillin, vancomycin, cipro, levofloxacin
B. fragilis	Not detected	N/A
E. coli	Not detected	N/A
K. oxytoca/michiganensis	Not detected	N/A
K. pneumoniae	Not detected	N/A
M. morgani	Detected - HIGH	Ampicillin, amoxicillin, cefazolin, cefuroxime, ceftazidime, cefepime, trimethoprim, cipro
P. mirabilis	Not detected	N/A
P. aeruginosa	Not detected	N/A
S. epidermidis	Not detected	N/A
S. saprophyticus	Not detected	N/A
S. aureus	Not detected	N/A
MRSA	Not detected	N/A
S. pyogenes (Group A)	Not detected	N/A
S. marcescens	Not detected	N/A



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Test Performed	Lab Result (Qualitative)	Resistance Gene Targets	Associated Resistances
		ABX Resistance Markers	
Class A Beta-lactamase (CTX-M-Group 1)	Detected	blaCTX-M-1, 3, 10, 12, 15, 22, 23, 28, blaFEC-1	Cephalosporins, penicillins, aztreonam
Class A Beta-lactamase (blaKPC)	Not detected	KPC-2-8, 10, 11, 13-22, 24-33	N/A
Class B metallo Beta-lactamase (blaNDM)	Not detected	NDM 1-4	N/A
vanA Vancomycin	Not detected	vanA	N/A
vanB Vancomycin	Not detected	vanB	N/A
mecA	Not detected		N/A
Sulfonamides	Not detected	dhps1, sul2, sul3	N/A
Fluoroquinolones	Not detected	qnrS 1-4, 5, 7, 8, 9 qnrB Group 1: qnrB 1, 2, 3, 13, 14, 15, 16, 17, 18, 20, 23, 26, 29, 30, 41, 42, 43, 45, 48, 49, 52, 54, 57, 58, 64, 66, 75, 77, 80 qnrB Group 5: qnrB 5, 10, 19, 36, 40, 46, 47, 50, 56, 59, 61, 62, 67, 68, 70, 71, 72	N/A
Fluoroquinolones	Not detected	dfrA1, dfrA5, dfrA11, dfrA17	N/A

*This test detects the presence of pathogen and must be evaluated with clinical symptoms to diagnose disease. This test is 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.