Chronetyx LABORATORIES

EXAMPLE

3171 Players Club Parkway
Memphis, TN 38125
800.454.2137

Laboratory Testing Results Report

ORDER: CYX100-008881-005610

Patient	Specimen	Ordering
Smith, Johnathan **DOB:** 12/29/1936 **Gender:** Male **Address:** 1234 Main St. Anytown, TN 38123 **Phone:** (555) 867-5309	**Lab ID:** SPCR-240710-001116 **Client ID:** 231843340 **Reference:** MRN: 20987654321 **Collected:** 07/09/24 00:00 **Received:** 07/10/24 13:41 **Reported:** 07/10/24 16:09	Dr. Deforest Kelly General Clinics of America 1701 Enterprise Dr. Suite 42 Anytown, TN 38123 Phone: (555) 987-6543

ORDERED ITEMS

CYX100 - Urine PCR Quantitative – Basic Panel w/ Anti-Microbial Resistance Reflex Testing

PATHOGEN RESULTS

Pathogens	Presence	Copies/µl
Escherichia coli	DETECTED	1,000 - 9,999
Klebsiella pneumoniae	Not Detected	
Proteus mirabilis	Not Detected	
Pseudomonas aeruginosa	Not Detected	
Enterococcus faecalis or faecium	Not Detected	
Staphylococcus aureus	Not Detected	
Staphylococcus saprophyticus	Not Detected	
Streptococcus agalactiae	Not Detected	

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ANTIMICROBIAL RESISTANCE

Resistance Class/Target	Resistant Gene	Presence
Sulfonamide	Sul1, Sul2	DETECTED
Confers resistance to Sulfonamide antibiotics		
Extended Spectrum Beta Lactamase (ESBL)	TEM	DETECTED
Confers resistance to most Beta-Lactam antibiotics, including expanded spectrum Cephalosporins and Monobactams		

This assay detects the following microbial pathogens: *Pseudomonas aeruginosa, Enterococcus faecalis, Enterococcus faecium, Staphylococcus aureus, Proteus mirabilis, Escherichia coli, Klebsiella pneumoniae, Streptococcus agalactiae* and *Staphylococcus saprophyticus*. Upon detection of one or more microbial pathogens reflex testing is performed for the following antimicrobial resistance gene targets: Sul1, Sul2, TetM, TetB, CTX-M (4 genes), SHV (3 genes), FOX, ACT /AmpC, MIR, ACC, IMP, VIM, NDM, TEM, mecA, Mef(A), ermB, ermA, ermC, QnrS, QnrA, DfrA5, DfrA1, AaA1, AAC(3)-Ia, AAC(6)-Ib-cr, AAC(6)-Ib, VanA, VanB and VanC.

The reference interval for this assay is Not Detected. This laboratory is regulated under the Clinical Laboratory Improvement Amendment (CLIA) of 1988 as qualified to perform high complexity clinical testing. This test is used for clinical purposes. It should not be regarded as investigational or for research. Laboratory specimens were analyzed for the indicated pathogens and antimicrobial resistance genes using specific real-time quantitative polymerase Chain Reaction (qPCR) assays. DNA was extracted from the submitted specimens and amplified by qPCR using consensus oligonucleotide primers specific for the analytes specific for the detection of each pathogen. The Analyte Specific Reagents (ASR) are not approved by the Food and Drug Administration (FDA). FDA approval is not required for the use of these ASRs. Rare diagnostic errors may occur due to primer site similarities in the DNA Structure of non-specific organisms. Absence of the test analyte indicates only the absence of the analyte tested and does not imply that other infections analytes or other antimicrobial genes are not present. This assay is intended to detect common clinically significant urinary pathogens and their associated antibiotic resistance genes. Additional pathogens or antimicrobial resistance genes may be present that are not reflected in this report. The presence of three or more organisms may suggest contamination during specimen collection. False negatives can occur due to the presence of inhibitors or low bacterial load. This assay is not intended to be used as the sole basis for diagnosis and clinical judgment should be exercised. This assay cannot comprehensively detect all mechanisms of antimicrobial resistance and antibiotic failure. Urine culture with phenotypic antibiotic susceptibility analysis is recommended to be used in conjunction with this assay.