ELITE CLINICAL LABORATORY

Elite Clinical Laboratory
6776 Southwest Freeway,
Suite 620 Houston,TX,77074 USA,
Phone: 281.378.2116, Fax : 281.466.2483,
CLIA #45D1061571,
Lab Director : Dr. Albert Chen MD.

UTI qPCR Report

Patient		Test Details		Specimen	
First Name:	Jane	Indication For:	Urinary Pathogen Detection	Collection Date:	03-02-2022
Last name:	Doe	Analysis ID:	8943	Received Date:	03-03-2022
Patient ID:	E22030XXXXX	Specimen type:	Urine	Reported Date:	03-04-2022
DOB:	09/29/19XX	Ref. Physician :	Test Patient		
Gender:	Female	Facility Name :	Test Patient		

SUMMARY OF RESULT — POSITIVE

Pathogens Detected

PATHOGEN	TYPE	LEVEL	MEDICATION RECOMMENDATION
Escherichia coli	Bacterium	Very High >100K Cfu/mL	Amikacin, Oral

AR genes Detected

None

Medication Recommendation

None

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Pathogen	Type
Klebsiella aerogenes (KA)	Bacterium
Pseudomonas aeruginosa (PA)	Bacterium
Klebsiella oxytoca (KO)	Bacterium
Klebsiella pneumoniae (KP)	Bacterium
Enterobacter cloacae complex (ECC)	Bacterium
Serratia marcescens (SM)	Bacterium
Proteus vulgaris (PV)	Bacterium
Proteus mirabilis (PM)	Bacterium
Enterococcus faecalis (Efs)	Bacterium
Streptococcus agalactiae (GBS)	Bacterium
Streptococcus anginosus (SAN)	Bacterium
Staphylococcus aureus (SA)	Bacterium
Enterococcus faecium (Efm)	Bacterium
Staphylococcus saprophyticus (SS)	Bacterium
Actinobaculum schaalii (AS)	Bacterium
Staphylococcus epidermidis (SE)	Bacterium
Citrobacter freundii (CF)	Bacterium
Aerococcus urinae (AU)	Bacterium
Citrobacter koseri (CK)	Bacterium
Corynebacterium urealyticum (CU)	Bacterium
Morganella morganii (MM)	Bacterium
Acinetobacter baumannii (AB)	Bacterium
Pantoea agglomerans (Pag)	Bacterium
Providencia stuartii (PS)	Bacterium
Candida glabrata Candida tropicalis Candida parapsilosis Candida krusei (CO)	Fungi
Candida albicans (CA)	Fungus

AR Genes

NDM, KPC, OXA48, VIM, IMP	**Carbapenems**	**Not Detected**
Extended Spectrum CTX-M	Extended - Spectrum - Betalactamase	Not Detected
IMP	Metallo-beta lactamase (MBL)	Not Detected
Van-A, Van-B	Macrolides	Not Detected

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Accession Number	Patient Name	Gender

Methodology:

This UTI (Urinary Tract Infection Pathogen Panel) test is a laboratory developed test. It is a real time RT-PCR which specifically detects pathogens listed on the report in patient's specimens. Patient's urine specimen is treated to extract RNA/DNA and processed to detect the presence of various urinary pathogens listed on the panel (see above) using specific primers on a real time PCR machine. The results are compared to contrived positive controls, internal controls, and Negative Template Controls (Quality Control Samples) run alongside the patient's samples for the diagnosis of urinary infections.

Limitations:

All molecular tests have limitations. If a patient is found 'NOT DETECTED or NEGATIVE' implies that he/she is not infected with the list of pathogens mentioned in the report at the sample collection time. On the other hand, this does not discount the fact that the patient having symptoms before this test may be due to the pathogens beyond the scope of Elite Clinical Laboratory Urinary Tract Pathogen Panel.

Laboratory Statement:

This test was validated, and performance characteristics have been determined by Elite Clinical Laboratory, 6776 Southwest Freeway Suite 620,Houston,TX 77074, CLIA(#45D1061571), Laboratory Director- Dr. Albert Chen MD. This test is used for clinical purposes (see Eligibility for testing). Its use should not be regarded as investigational or for research and tests only the listed pathogens on the report. Hence, we strongly recommend undergoing this test when the patient experiences symptoms consistent with infectious Urinary disease etiology with the clinician's advice and prescription. This laboratory is certified under Clinical Laboratory Improvements and Amendments of 1988 (CLIA 88) as qualified to perform high complexity clinical laboratory testing. This test has not been cleared or approved by the FDA. The FDA has determined that such approval is not necessary, provided that the laboratory both (1) maintains its good standing as a clinical testing laboratory with all mandatory accrediting bodies, and (2) continually demonstrates that its testing protocols and procedures achieve a high degree of analytical accuracy. Medication Recommendations/pharmacy guidance are given for information purpose only. The final prescription is given by the physician will be given based on patient's clinical history and correlation. Elite Clinical Laboratory is not responsible for adverse drug reactions if the patient takes medications based on the guidelines provided without physician's prescription. Final medications are under physician's discretion. The laboratory is regulated under CLIA as qualified to perform high-complexity testing. This test is used for clinical purposes and should not be regarded as investigational or for research.

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Eligibility for Testing:

This test should be used for diagnostic use only and is limited to patients suspected of Urinary infections by their healthcare provider. The eligibility determination ultimately rests on the clinician's judgment.

Conduct of the Test:

This test is performed under strict compliance and guidelines of Elite Clinical Laboratory R&D team, including the instruments, reagents, and other recommended procedures. This includes- the safety protocols where- all laboratory personnel are appropriately trained in RT-qPCR techniques and use appropriate laboratory and personal protective equipment when handling this kit/test and use this test in accordance with the authorized labeling.

Result Reports for Healthcare Providers and Patients:

We have a process for reporting test results to healthcare providers as appropriate. Result reports will be provided to healthcare providers and patients.

Performance Data and Reporting:

We collect information on the performance of the test and report any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which we become aware to concerned authorities.

Recordkeeping:

As an authorized laboratory we ensure all records associated with this test are maintained until otherwise notified. Such records are available to regulatory bodies for inspection upon request at any time