TruGenX
Precision Medicine

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Name: Tom Jones

Date of Birth: 11/26/1952 | Sex: F | Age: 64
Accession Number: UTI18-MOCK
Collection Date: 02/09/2017
Received Date: 02/10/2017
Reported Date: 02/10/2017
Specimen Type: Urine sample

Physician Information

Physician Name: Dr. Todd Dusseldorf
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Summary

***Escherichia coli* and *Candida albicans* positive. Gene marker *CTX-M group 1* positive indicative of Extended-Spectrum-Betalactamase resistance.**

Results

Target	Results	Target	Results
Acinetobacter baumannii	Target not detected	*Morganella morganii*	Target not detected
Citrobacter freundii	Target not detected	*Proteus mirabilis*	Target not detected
Enterobacter aerogenes	Target not detected	*Proteus vulgaris*	Target not detected
Enterobacter cloacae	Target not detected	*Pseudomonas aeruginosa*	Target not detected
Enterococcus faecalis	Target not detected	*Staphylococcus saprophyticus*	Target not detected
Enterococcus faecium	Target not detected	*Streptococcus agalactiae*	Target not detected
Escherichia coli	**Positive**	*Candida albicans*	**Positive**
Klebsiella oxytoca	Target not detected		
Klebsiella pneumoniae	Target not detected	Positive control	Pass

Resistance Gene Markers

Resistance Type	Gene	Results
Carbapenem resistance	*KPC*	Target not detected
Extended-Spectrum-Betalactamase	*CTX-M group 1*	**Positive**
Vancomycin resistance	*vanA1*	Target not detected
Vancomycin resistance	*vanA2*	Target not detected
Vancomycin resistance	*vanB*	Target not detected

Dai J. Li, MD, Ph.D

Interpretive Comments on Test

E. Coli detected with CTX-M group resistance gene marker for Extended-Spectrum-Beta-lactamase resistance: Treat with the combination drug Sulfamethoxazole-Trimethoprim first. Monitor for treatment efficacy.

Candida albicans positive: Fluconazole is the antifungal agent of choice, achieving high urine concentrations with the oral formulation.

Intended Use

The detection and identification of specific pathogens and drug resistance markers from individuals exhibiting signs and symptoms of urinary tract infection (UTI). This test aids in the diagnosis of UTI if used in conjunction with other clinical and epidemiological information. This UTI test is a Laboratory Derived (LDT) qualitative nucleic acid multiplex diagnostic test intended for use on an Applied Biosystems™ QuantStudio™ 12K Flex Real-Time PCR System for the simultaneous detection and identification of multiple pathogen nucleic acids in urine samples obtained from individuals exhibiting signs and symptoms of UTI. The following pathogens are identified using this UTI test: *Acinetobacter baumannii, Citrobacter freundii, Enterobacter aerogenes, Enterobacter cloacae, Enterococcus faecalis, Enterococcus faecium, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Staphylococcus saprophyticus, Streptococcus agalactiae,* and *Candida albicans,* The following genes that have been shown to correlate as drug resistance markers are identified using this UTI test: *vanA1, vanA2, vanB, CTX-M group 1, KPC*.

Drug(s)*	Resistance Type*	Gene*
carbapenem, cephalosporin, cephamycin, penicillin	Carbapenem resistance	*KPC*
ceftazidime; cephalosporin_i; cephalosporin_ii; cephalosporin_iii; monobactam; penicillin	Extended-Spectrum-Betalactamase	*CTX-M group 1*
vancomycin	Vancomycin resistance	*vanA1*
vancomycin	Vancomycin resistance	*vanA2*
vancomycin	Vancomycin resistance	*vanB*

*Nomenclature based on ARDB-Antibiotic Resistance Genes Database

Methodology

Real-Time PCR was performed on genomic DNA extractions using TaqMan Open Array™ plates, analyzed on a QuantStudio™ 12K Flex Platform. Data was obtained for each assay to detect species specific sequences within a sample, During amplification, sequence specific oligonucleotides probes (dually labeled with a fluorophore and quencher) hybridize to a specific DNA template. The 5'-3' exonuclease activity of DNA polymerase during elongation cleaves the fluorophore from being quenched on the oligonucleotide probe, causing the fluorophore to be excited; emitting fluorescence. The accumulation of fluorescence for each sample, in each well of the OpenArray™ plate, is measured by the instrument software during each cycle of amplification, directly corresponding to amplification of target sequence. The Applied Biosystems™ QuantStudio™ 12K Flex system software analyzes the data generated, producing quality scores and confidence values for each assay in each well, for each sample. The Applied Biosystems™ QuantStudio™ 12K Flex system software provides a qualitative result, the presence (Positive) or absence (Undetermined) of the pathogens or drug resistance markers contained in the panel, along with the internal controls, based upon whether the amplification is above or below the threshold of detection, in conjunction with the quality and confidence values.

Limitations

Negative results do not preclude a UTI infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Positive results do not rule out infection, or co-infection with other pathogens not on our panel. The agent detected may not be the definite cause of disease. The use of additional laboratory testing (e.g. bacterial and viral culture, immunofluorescence and radiography) and clinical presentation must be taken into consideration in the final diagnosis of a UTI. Detection of a marker of antibiotic resistance does not preclude other antibiotic resistance

mechanisms not tested for in the panel. Positive detection of an antibiotic resistance marker only indicates that marker is present in the flora in the sample tested and may not indicate potential for use in UTI.

Assay performed at NEXT Molecular Analytics, 11601 Ironbridge Road, Suite 101, Chester, Virginia 23831. 804-977-6600.
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