Acūtis
1-844-522-8847
service@acutis.com
acutis.com

# Acutis Reveal™ Report

Status - **FINAL**

**Pathogen Detected**

| | | |
|---|---|---|
| Name | Accession# | Doctor |
| Date of Birth | Sample ID | Organization |
| Gender | Matrix: Clean Catch Urine | |
| ID | Collection Date: 07/01/2024 04:40 PM | |
| | Received Date: 07/03/2024 11:34 AM | |
| | Reported Date: 07/06/2024 09:21 AM | |

## Urinary Tract Infection (UTI) - Detected by PCR

| Organisms | Outcome; CFU/mL |
|---|---|
| ***Enterococcus faecalis*** | ***Positive, >10,000 - <100,000*** |
| ***Coagulase Negative Staph*** | ***Positive, 100,000*** |

## Antimicrobial Sensitivity Results

**EMP+:** Empiric antibiotic option | **+:** Indicated for use by FDA | **ARG:** Antibiotic Resistance Gene detected
**AST:** Antimicrobial Sensitivity Test (S: Susceptible / I: Intermediate / R: Resistant / NI: No Interpretation / –: Not Available) | **MIC:** Minimum Inhibitory Concentration

| Organisms: | *Enterococcus faecalis* | | | *Coagulase Negative Staph* | | |
|---|---|---|---|---|---|---|
| Colony Count: | 10,000 CFU/mL | | | 20,000 CFU/mL | | |
| Treatment | EMP/ARG | AST | MIC | EMP/ARG | AST | MIC |
| Tetracycline | ARG | R | <=1 | EMP+ | R | >=16 |
| Clindamycin | + | – | – | EMP+ | R | <=0.25 |
| Levofloxacin | + | S | 2 | EMP+ | I | 4 |
| Nitrofurantoin | EMP+ | S | <=16 | + | S | <=16 |
| Trimethoprim/Sulfamethoxazole | + | – | – | EMP+ | S | <=10 |
| Ciprofloxacin | + | S | 1 | + | R | >=8 |
| Erythromycin | + | – | – | + | – | – |
| Gentamicin | + | – | – | + | S | <=0.5 |
| Linezolid | + | S | 2 | + | S | 2 |
| Penicillin | + | S | 2 | + | R | >=0.5 |
| Quinupristin/Dalfopristin | + | – | – | + | – | – |
| Tigecycline | + | S | <=0.12 | + | S | <=0.12 |
| Vancomycin | + | S | 1 | + | S | 1 |
| Ampicillin | + | S | <=2 | | – | – |
| Moxifloxacin | | – | – | + | S | 1 |
| Oxacillin | | – | – | + | S | <=0.25 |
| Rifampicin | | – | – | + | S | <=0.5 |
| Cefoxitin Screen | | – | – | | - | Neg |
| Inducible Clindamycin Resistance | | – | – | | + | Pos |

UTI Notes:
This assay detects the following species "Staphylococcus saprophyticus, Staphylococcus haemolyticus and Staphylococcus epidermidis".

## Antibiotic Resistant Genes - Detected by PCR

| |
|---|
| *tetM* |

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## Urinary Tract Infection (UTI) - Not Detected by PCR

| | | | |
|---|---|---|---|
| *Acinetobacter baumannii* | *Aerococcus urinae* | *Candida albicans* | *Candida glabrata* |
| *Candida parapsilosis* | *Citrobacter freundii* | *Citrobacter koseri* | *Corynebacterium riegelii* |
| *Enterobacter aerogenes* | *Enterobacter cloacae* | *Enterococcus faecium* | *Escherichia coli* |
| *Klebsiella oxytoca* | *Klebsiella pneumoniae* | *Morganella morganii* | *Pantoea agglomerans* |
| *Proteus mirabilis* | *Providencia stuartii* | *Pseudomonas aeruginosa* | *Serratia marcescens* |
| *Staphylococcus aureus* | *Streptococcus agalactiae* | *Viridans Group Strep* | |

## Antibiotic Resistant Genes - Not Detected by PCR

| | | | |
|---|---|---|---|
| *ACT* | *CMY* | *CTX-M group* | *dfrA* |
| *DHA* | *FOX* | *KPC* | *mecA* |
| *OXA-1 / GES* | *PER* | *qnr Group* | *SHV* |
| *Sul1/Sul2* | *TEM* | *van Group* | *VEB* |
| *VIM* | | | |

Test System Details:

Antimicrobial resistance gene information is incorporated when ordered and where it is available. Empirical antibiotic list and drugs indicated for potential use (+), when presented, does not consider patient specific factors and is based on the presence of the pathogen alone. All standard criteria for antibiotic selection must be considered independent of the provided list. The empiric antibiotic list presented should be cross-referenced with other sources including FDA.gov and Sanfordguide.com.

Urinary Tract Infection (UTI) by PCR:
The Acutis UTI Panel is a multiplex, real-time polymerase chain reaction (PCR) diagnostic assay developed for the semi-quantitative detection of select pathogens/ABRG from urine samples. Test results are presumptive and must be considered in conjunction with the clinical history and other available data for the clinical management of the patient. This test cannot rule out infections caused by pathogens not present in this panel. The performance of this assay has not been evaluated in asymptomatic patients. The presence of antibiotic resistance genes does not always result in phenotypic expression of resistance. Additionally, it is not always possible to determine which specific organism is contributing to the presence of these genes. This test was developed, and its performance characteristics were determined by Acutis in a manner consistent with NYS Department of Health requirements and CLSI guidelines. The FDA has not approved or cleared this test. The following organisms have a cut-off value = 100,000 CFU/mL: *Acinetobacter baumannii, Citrobacter freundii, Klebsiella pneumoniae, Pseudomonas aeruginosa,* coagulase negative staph *(Staphylococcus epidermidis, Staphylococcus saprophyticus and Staphylococcus haemolyticus),* viridians streptococci *(Streptococcus pasteurianus and Streptococcus oralis), Candida parapsilosis/glabrata*. All other assay cut-off values = 10,000 CFU/mL

Antimicrobial Sensitivity Testing (AST):
AST is performed using a culture-based methodology. Results are reported separately when ordered. Preliminary report status may indicate that AST results are pending.

Laboratory Director: Marjorie Bon Homme, PhD, DABCC
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