

Name	UA, TEST	Accession#	3887096	Doctor	Marjorie Bon Homme
Date of Birth	08/22/2009	Sample ID	None	Organization	Testing and Verification – Acutis
Gender	Female	Matrix	Clean Catch Urine		
ID	6-491823	Collection Date	04/11/2023 01:00 AM		
		Received Date	04/11/2023 05:41 PM		
		Reported Date	04/11/2023 06:12 PM		

Urinary Tract Infection (UTI) - Detected by PCR

Organisms	Outcome; CFU/mL
<i>Enterococcus faecalis</i>	Positive, >10,000
<i>Escherichia coli</i>	Positive, >10,000

Possible Treatment Options & Resistance

Treatment	Organisms: <i>Enterococcus faecalis</i>			Organisms: <i>Escherichia coli</i>		
	Colony Count: <10,000 CFU/mL			Colony Count: >100,000 CFU/mL		
	EMP	AST	MIC	EMP	AST	MIC
Amoxicillin/Clavulanic Acid	EMP	S	<=2	EMP	S	4
Nitrofurantoin	EMP	S	<=16	EMP	S	<=16
Ciprofloxacin		S	<=0.5	EMP	S	<=0.25
Levofloxacin		S	0.5	EMP	S	<=0.12
Tetracycline	EMP	S	<=1		S	<=1
Trimethoprim/Sulfamethoxazole		S	<=20	EMP	S	<=20
Amikacin		S	<=2		S	<=2
Ampicillin		S	<=2		R	>=32
Ampicillin/Sulbactam		S	<=2		I	16
Aztreonam		S	<=1		S	<=1
Cefazolin (urine)		S	<=4		S	<=4
Cefepime		S	<=1		S	<=1
Cefotaxime		S	<=1		S	<=1
Cefotetan		S	<=4		S	<=4
Cefoxitin		S	<=4		S	<=4
Cefpodoxime		S	<=0.25		S	<=0.25
Ceftazidime		S	<=1		S	<=1
Ceftriaxone		S	<=1		S	<=1
Cefuroxime		S	4		S	2
Cefuroxime Axetil		S	4		S	2
Doripenem		S	<=0.12		S	<=0.12
Ertapenem		S	<=0.5		S	<=0.5
Erythromycin		R	>=8		-	-
ESBL		-	Neg		-	Neg
Gentamicin		S	<=1		S	<=1
Imipenem		S	<=0.25		S	<=0.25
Linezolid		S	1		-	-
Meropenem		S	<=0.25		S	<=0.25
Penicillin		S	4		-	-
Piperacillin		S	<=4		R	>=128
Piperacillin/Tazobactam		S	<=4		S	<=4



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Treatment	EMP	AST	MIC	EMP	AST	MIC
Tigecycline		S	<=0.12		S	<=0.5
Tobramycin		S	<=1		S	<=1
Vancomycin		R	>=32		-	-

EMP: Empiric antibiotics are noted by either a % or "EMP" and represent common treatment options prior to sensitivity results. Where available % sensitivity is provided based on general Acutis antibiogram data otherwise "EMP" is indicated. See important Test System Details.

AST: Antimicrobial Sensitivity Test (S: Susceptible / I: Intermediate / R: Resistant / NI: No Interpretation / -: Not Available) | MIC: Minimum Inhibitory Concentration

Sexually Transmitted Infection (STI) - Detected by PCR/NAAT

Organisms	Outcome
<i>Mycoplasma genitalium</i>	Detected

Urinalysis

Analyte	Outcome
Blood	Negative, Normal
Glucose	Negative, Normal
Leukocyte	2+, Abnormal
Nitrite	Negative, Normal
Protein	Negative, Normal

Urinary Tract Infection (UTI) - Not Detected by PCR

<i>Acinetobacter baumannii</i>	<i>Aerococcus urinae</i>	<i>Candida albicans</i>	<i>Candida parapsilosis / glabrata</i>
<i>Citrobacter freundii</i>	<i>Citrobacter koseri</i>	Coagulase Negative Staph Group	<i>Corynebacterium riegellii</i>
<i>Enterobacter aerogenes / cloacae</i>	<i>Enterococcus faecium</i>	<i>Klebsiella oxytoca</i>	<i>Klebsiella pneumoniae</i>
<i>Morganella morganii</i>	<i>Pantoea agglomerans</i>	<i>Proteus mirabilis</i>	<i>Providencia stuartii</i>
<i>Pseudomonas aeruginosa</i>	<i>Serratia marcescens</i>	<i>Staphylococcus aureus</i>	<i>Staphylococcus saprophyticus</i>
<i>Streptococcus agalactiae</i>	<i>Streptococcus anginosus / pasteurianus</i>	<i>Streptococcus oralis</i>	<i>Streptococcus pyogenes</i>

Sexually Transmitted Infection (STI) - Not Detected by PCR/NAAT

<i>Chlamydia trachomatis</i>	<i>Neisseria gonorrhoeae</i>	<i>Trichomonas vaginalis</i>
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STI Notes:

Chlamydia trachomatis / Neisseria gonorrhoeae Assays – First catch female urine specimens are acceptable but may detect up to 10% fewer infections when compared with vaginal swab specimens.

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Trichomonas vaginalis Assay – Specimens collected from patients with urogenital tract co-infections with high titers of Trichomonas tenax or Pentatrichomonas hominis, and low T. vaginalis titers may result in a false-negative or invalid results.

#### Test System Details:

Empirical antibiotic list, when presented, does not consider patient specific factors and is based on the presence of the pathogen alone. The list further does not incorporate resistance, amongst other criteria. 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:

This is a real-time polymerase chain reaction (PCR) diagnostic assay developed for the qualitative detection of select urinary pathogens from human samples. This is a multiplex test intended for the detection of DNA from uropathogens extracted from a urine specimen. 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. 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.

Organisms listed below have cut-off value = 100,000 CFU/mL. All other assay cut-off values = 10,000 CFU/mL.

*Acinetobacter baumannii*, *Citrobacter freundii*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Staphylococcus epidermidis/haemolyticus/lugdunensis*, *Streptococcus anginosus/pasteurianus*, *Streptococcus oralis*, *Candida parapsilosis/glabrata*

#### 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.

#### Sexually Transmitted Infection (STI):

The Acutis Reveal STI is a panel of qualitative tests that utilize nucleic acid amplification technology (NAAT) methodology to detect specific nucleic acid targets.

The following tests are FDA approved and may be collected using swabs: *C. trachomatis*, *N. gonorrhoeae*, *M. genitalium*, *T. vaginalis*, *Candida species group*, *Candida glabrata* and bacterial vaginosis. The herpes simplex virus types 1 & 2 tests are FDA approved and the only acceptable sample type is a lesion swab. Patient-collected vaginal swab specimens are not an acceptable sample for this test. The following assays are laboratory developed tests (LDT) and the acceptable sample type is urine: *C. trachomatis*, *N. gonorrhoeae*, *M. genitalium* and *T. vaginalis*. Urine should be collected in Aptima Urine Collection Kit and genital swabs should be collected in the Aptima Multitest Swab Specimen Collection Kit. The herpes test can also be collected in viral transport medium.

Results from this test should be interpreted in conjunction with all available laboratory and clinical data. Reliable results are dependent on adequate specimen collection. Therapeutic failure or success cannot be determined since nucleic acid may persist following appropriate antimicrobial therapy. A negative result does not preclude a possible infection because results are dependent on adequate specimen collection. Test results may be affected by improper specimen collection or target levels below the assay limit of detection. Whole blood, mucus, vaginal moisturizing cream/gel, tioconazole and glacial acetic acid may potentially interfere with these tests. *Candida famata* at concentrations higher than 5 x 10<sup>5</sup> cfu/mL will cross-react with the CV/TV assay. Competitive interference was observed in co-infected samples for the combination of low *C. glabrata* and high *T. vaginalis* (1 x 10<sup>5</sup> or 1 x 10<sup>4</sup> cells/mL). If negative results from the specimen do not fit with the clinical impression, a new specimen may be necessary. A positive test result does not necessarily indicate the presence of viable organisms. Public health recommendations should be consulted regarding testing for additional sexually transmitted infections for positive patients. This assay is not intended for the evaluation of suspected sexual abuse or for other medico-legal indications. For those patients for whom a false positive result may have adverse psycho-social impact, the CDC recommends retesting. This test has not been evaluated in adolescents less than 15 years of age.

#### Urinalysis (UA):

This assay is CLIA-waived. Clinical diagnosis should not be based solely on a single test result. The test is a colorimetric assay and heavily pigmented, bloody, or discolored samples may interfere with the instruments ability to correctly interpret test results. Tetracycline interferes with the leukocyte panel, and high levels of the drug may cause a false negative result. Any trace results are considered indeterminate, and it is recommended that a fresh sample be collected for retesting.

Panel cutoffs: blood = 0.01 mg/dL hemoglobin, glucose = 75 mg/dL, leukocyte esterase = 10 cells/μL, nitrites ions = 0.06 mg/dL, protein = 15 mg/dL

Laboratory Director: Marjorie Bon Homme, PhD, DABCC

Acutis Diagnostics; 400 Karin Lane, Hicksville, NY 11801. CLIA ID# 33D2087537