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

Acutis Reveal™ Report

Status - **FINAL**

Pathogen Detected

Name	UA, TEST	Accession#	3887098	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 05:42 PM		
		Reported Date	04/11/2023 06:40 PM		

Urinary Tract Infection (UTI) - Detected by PCR

Organisms	Outcome; CFU/mL
Enterococcus faecalis	***Positive, >100,000***
Escherichia coli	***Positive, >100,000***

Possible Treatment Options & Resistance

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

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Treatment	EMP/RGD	AST	MIC	EMP/RGD	AST	MIC
Tigecycline		S	<=0.12		S	<=0.5
Tobramycin		–	–		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.
RGD: Resistance Gene Detected
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
Trichomonas vaginalis	***Detected***

Urinalysis

Analyte	Outcome
Blood	*Negative, Normal*
Glucose	*Negative, Normal*
Leukocyte	*Negative, Normal*
Nitrite	*Negative, Normal*
Protein	*Negative*

Urinary Tract Infection (UTI) - Not Detected by PCR

Acinetobacter baumannii	*Actinobaculum schaalii*	*Aerococcus urinae*	*Alloscardovia omnicolens*
Candida albicans	*Candida auris*	*Candida glabrata*	*Candida parapsilosis*
Citrobacter freundii	*Citrobacter koseri*	*Coagulase Negative Staph*	*Corynebacterium riegelii*
Enterobacter aerogenes	*Enterobacter cloacae*	*Enterococcus faecium*	*Klebsiella oxytoca*
Klebsiella pneumoniae	*Morganella morganii*	*Mycoplasma hominis*	*Pantoea agglomerans*
Proteus mirabilis	*Proteus vulgaris*	*Providencia stuartii*	*Pseudomonas aeruginosa*
Serratia marcescens	*Staphylococcus aureus*	*Streptococcus agalactiae*	*Ureaplasma urealyticum*
Viridans Group Strep			

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

Chlamydia trachomatis	*Mycoplasma genitalium*	*Neisseria gonorrhoeae*

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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.

Mycoplasma genitalium Assay – In rare cases, specimens collected from patients with urogenital tract co-infections with low M. genitalium titer and high Mycoplasma pneumoniae titer 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 CLIA 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 105 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 105 or 1 x 104 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

Urinalysis and UTI by PCR are performed at the New Jersey Location. Laboratory Director: John Greene, PhD, NRCC (TC)
Acutis Diagnostics; 68 Culver Road; Suite# 150B; Monmouth Junction, NJ 08852. CLIA ID# 31D2257243

AST, bacterial vaginosis, and HSV types 1 & 2 tests are performed at the New York Location. Laboratory Director: Marjorie Bon Homme, PhD, DABCC
Acutis Diagnostics; 400 Karin Lane, Hicksville, NY 11801. CLIA ID# 33D2087537