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

Acutis reveal™
Pathogen Detected
Status - FINAL COPY

Patient

Name	TEST, TEST test
Birth	1/1/2001
Gender	Female
ID	1-007

Matrix - Clean Catch Urine

Accession #	1234567
Sample ID	None
Collection Date	6/19/2021 9:00 AM
Received Date	6/20/2021 11:36 AM
Reported Date	6/21/2021 11:43 AM

Provider

Doctor	test, test
Organization	Acutis Diagnostics

Urinalysis

Test Name	Outcome
Blood	**1+, Abnormal**
Glucose	Negative, Normal
Leukocyte	Negative, Normal
Nitrite	Negative, Normal
Protein	Negative, Normal

Sexually Transmitted Infection (STI) - PCR/NAAT

Test Name	Outcome
Chlamydia trachomatis	**Detected**

STI Organisms Tested by PCR/NAAT but Not Detected

Mycoplasma genitalium, Neisseria gonorrhoeae

Urinary tract infection (UTI) - PCR

Test Name	Outcome, CFU/mL
Enterococcus faecium	**Positive, >10,000**

UTI Organisms Tested by PCR but Not Detected

Acinetobacter baumannii, Aerococcus urinae, Candida albicans, Candida parapsilosis / glabrata*, Citrobacter freundii*, Citrobacter koseri, Corynebacterium riegelii, Enterobacter aerogenes / cloacae, Enterococcus faecalis, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae*, Morganella morganii, Pantoea agglomerans, Proteus mirabilis, Providencia stuartii, Pseudomonas aeruginosa*, Serratia marcescens, Staphylococcus aureus, Staphylococcus epidermidis / haemolyticus / lugdunensis*, Staphylococcus saprophyticus, Streptococcus agalactiae, Streptococcus anginosus / pasteurianus*, Streptococcus oralis, Streptococcus pyogenes*

Antimicrobial Sensitivity results are presented on the next page.

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.

- - -

Patient		Matrix - Clean Catch Urine		Provider	
Name	TEST, TEST test	Accession #	1234567	Doctor	test, test
Birth	1/1/2001	Sample ID	None	Organization	Acutis Diagnostics
Gender	Female	Collection Date	6/19/2021 9:00 AM		
ID	1-007	Received Date	6/20/2021 11:36 AM		
		Reported Date	6/21/2021 11:43 AM		

Antimicrobial Sensitivity Results

Section presents AST for organisms that are suitable for growth in culture. Some organisms detected by PCR are not able to grow in vitro despite presence.

Antimicrobial Sensitivity Test (AST)

Source:
Urine clean catch

Isolate 1: Enterococcus faecium

Sensitivities	Isolate 1
Ampicillin	R
Ampicillin MIC	>8.0000
Ciprofloxacin	I
Daptomycin	S
Daptomycin MIC	2.0000
Gentamicin	R
Levofloxacin	S
Levofloxacin MIC	2.0000
Linezolid	S
Linezolid MIC	2.0000
Nitrofurantoin	S
Penicillin	R
Penicillin MIC	>8.0000
Rifampin	R
Tetracycline MIC	R
Vancomycin	R
Vancomycin MIC	>16.0000

Test system details

Organisms Detected by PCR:
This is a real-time 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 clean-catch 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. This is a multiplex test intended for the detection of DNA from uropathogens extracted from a clean-catch urine specimen. The FDA has not approved or cleared this test.
* Indicates cut-off value is = 100,000 CFU/mL. 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 and when an organism is detected by PCR. Preliminary report status may indicate that AST results are pending.
MIC (Minimum Inhibitory Concentration) values are reported in µg/mL. I = Intermediate, R = Resistant, S = Susceptible

Urinalysis:
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 leukocytes/µL, Nitrites = 0.06 mg/dL ions, Protein = 15 mg/dL total protein.

STI:
The Acutis Reveal STI Panel is FDA approved. This is qualitative test that utilize nucleic acid amplification technology (NAAT) methodology to detect specific nucleic acid targets. The acceptable samples type for this test are urine collected in Aptima Urine Collection Kit and vaginal swabs

Patient		Matrix - Clean Catch Urine		Provider	
Name	TEST, TEST test	Accession #	1234567	Doctor	test, test
Birth	1/1/2001	Sample ID	None	Organization	Acutis Diagnostics
Gender	Female	Collection Date	6/19/2021 9:00 AM		
ID	1-007	Received Date	6/20/2021 11:36 AM		
		Reported Date	6/21/2021 11:43 AM		

Test system details

collected in the Aptima Multitest Swab Specimen Collection Kit. Patient-collected vaginal swab specimens are not an acceptable sample for this test.
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. Mucus, vaginal moisturizing cream/gel and tioconazole may potentially interfere with this test. 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.

Laboratory Director: Marjorie Bon Homme, PhD, DABCC
Acutis Diagnostics; CLIA ID # 33D2087537; 400 Karin Ln., Hicksville, NY 11801