

EXAMPLE REPORT

Laboratory Information	Sample Information	Patient Information
CirrusDx, Inc.	Technician: TF	Accession #: 2019-1356-008
9901 Belward Campus Dr	Date Collected: 8/6/2019	Name: Opal Winesap
Rockville, MD 20850	Date Received: 8/7/2019	DOB: 4/12/1984
CLIA#21D2130541	Date Reported: 8/8/2019	MRN/SSN:
Dr. Todd Myers, Lab Director		Sex: Female
240-813-8801 or info@cirrusdx.com		

Practice Information	Test Information		
Name: Apple Urology	Test Name:	Urinary Tract Infection Panel (UTIP™) & polyMIC™	
Provider: Dr. Red Address: 123 Apple Way Farmtown, WI 12589	Test Method:	UTIP: Real-Time PCR (Molecular) polyMIC: Antibiotic Sensitivity Testing	
Phone: 123-456-0789	Specimen Type:	Urine Unknown Collection Method	
Fax: 987-654-3210	Antibiotic Usage:	Unknown	

Gram Negative Pathogens				
Tested Pathogen	Result	Detection Level (Organism/mL)#	Reference Range	
Escherichia coli	Detected	1 x 10^8	< 1x10 ⁴	
Acinetobacter baumannii	Not Detected		< 1x10 ⁴	
Morganella morganii	Not Detected		< 1x10 ⁴	
Mycoplasma genitalium	Not Detected		< 1x10 ⁵	
Klebsiella oxytoca	Not Detected		< 1x10 ⁴	
Citrobacter freundii	Not Detected		< 1x10 ⁴	
Klebsiella pneumoniae	Not Detected		< 1x10 ⁴	
Proteus mirabilis	Not Detected		< 1x10 ³	
Enterobacter aerogenes	Not Detected		< 1x10 ⁴	
Pseudomonas aeruginosa	Not Detected		< 1x10 ⁴	
Enterobacter cloacae	Not Detected		< 1x10 ⁴	
Serratia marcescens	Not Detected		< 1x10 ⁴	
	Gram Positiv	ve Pathogens		
Staphylococcus aureus	Not Detected		< 1x10 ⁴	
Staphylococcus spp. (CNS)	Not Detected		< 1x10 ⁵	
Enterococcus faecium	Not Detected		< 1x10 ⁴	
Enterococcus faecalis	Detected	1 x 10^7	< 1x10 ⁴	
Streptococcus agalactiae	Not Detected		< 1x10 ⁴	
Streptococcus pneumoniae	Not Detected		< 1x10 ⁴	
Streptococcus pyogenes	Not Detected		< 1x10 ⁵	
Fungal Pathogens				
Candida albicans	Not Detected		< 1x10 ⁴	
Candida glabrata	Not Detected		< 1x10 ³	
Candida krusei	Not Detected		< 1x10 ⁵	
Candida tropicalis	Not Detected		< 1x10 ⁴	
Candida parapsilosis	Not Detected		< 1x10 ⁴	

F-055.05 Page 1 of 3



EXAMPLE REPORT

Laboratory Information	Sample Information	Patient Information
CirrusDx, Inc.	Technician: TF	Accession #: 2019-1356-008
9901 Belward Campus Dr	Date Collected: 8/6/2019	Name: Opal Winesap
Rockville, MD 20850	Date Received: 8/7/2019	DOB: 4/12/1984
CLIA#21D2130541	Date Reported: 8/8/2019	MRN/SSN:
Dr. Todd Myers, Lab Director		Sex: Female
240-813-8801 or info@cirrusdx.com		

Tested Resistance Genes			
Drug Class	Gene	Result	Reference Range
Methicillin	MecA	Not Detected	Not Detected
Carbapenems	KPC	Not Detected	Not Detected
Vancomycin	Van A/Van B	Not Detected	Not Detected

polyMIC* Comments

Antibiotic sensitivity was determined.

Antibiotic Sensitivity						
Antibiotic	Appropriate for Detected Pathogen:	S = Sensitive Demonstrated effectiveness	I = Intermediate Incomplete effectiveness	R = Resistant No effectiveness	H = Halo** Partial demonstrated effectiveness	Reference Range:
Nitrofurantoin	E. coli, E. faecalis		I			S
Trimethoprim-Sulfamethoxazole	E. coli		I			S
Amoxilin / Clavulanic Acid	E. coli	S				S
Ofloxacin	E. coli		I			S
Ciprofloxacin	E. coli, E. faecalis	S				S
Levofloxacin	E. coli, E. faecalis	S				S
Imipenem	E. coli	S				S
Meropenem	E. coli		I			S
Ertapenem	E. coli			R		S
Piperacilillin /Tazobactam	E. coli	S				S
Fosmomycin	E. coli, E. faecalis	S				S
Cefazolin	E. coli			R		S
Cephalexin	E. coli			R		S
Cefpodoxime	E. coli			R		S
Cefdinir	E. coli			R		S
Ceftriaxone	E. coli			R		S
Cefepime	E. coli			R		S
Aztreonam	E. coli			R		S
Tetracycline	E. coli, E. faecalis			R		S
Doxycycline	E. coli, E. faecalis			R		S

Halo Comments

Not applicable; No Halos.

General Comments
None.

F-055.05 Page 2 of 3



EXAMPLE REPORT

Laboratory Information	Sample Information	Patient Information
CirrusDx, Inc.	Technician: TF	Accession #: 2019-1356-008
9901 Belward Campus Dr	Date Collected: 8/6/2019	Name: Opal Winesap
Rockville, MD 20850	Date Received: 8/7/2019	DOB: 4/12/1984
CLIA#21D2130541	Date Reported: 8/8/2019	MRN/SSN:
Dr. Todd Myers, Lab Director		Sex: Female
240-813-8801 or info@cirrusdx.com		

Notes

#Organisms/mL are based on the calculation of genome equivalents. One genome equivalent is theoretically equal to one colony forming unit (cfu).

- * polyMIC testing is performed with a direct inoculation of the urine into the culture system. As a result, when multiple organisms are detected in the patient sample, individual susceptibility zone size cutoffs are not established. The polyMIC profile is used for urines with one or more organisms detected, based upon the laboratory's established zone size cutoffs for susceptibilities.
- **Halo observation is the result of both Sensitive and Resistant organisms responding to an antibiotic. Halo(s) is/are the antibiotic(s) that demonstrated effectiveness on a portion of the organisms detected. Halos are only available for samples when no oral antibiotic was found to be sensitive AND Candida spp. is not detected the sample.

Sensitive (S): indicates the organism(s) is susceptible to the antibiotic.

Intermediate (I): indicates the organism(s) is susceptible to the antibiotic but not at a level required to ensure effectiveness.

Resistant (R): indicates the organism(s) is not susceptible.

It is the physician's responsibility to interpret the results provided and determine the appropriate (if any) treatment options including antibiotic selection.

Questions including Clinical Consultation on Results: 240-813-8801 or info@cirrusdx.com

<u>Notes:</u> The molecular tests and antibiotic sensitivity test were developed and their performance characteristics were determined by CirrusDx. They have not been cleared or approved by the US Food and Drug Administration. The FDA does not require these tests to go through premarket FDA review. This test is used for clinical purposes. It should not be regarded as investigational or for research.

This report has been reviewed and approved.

F-055.05 Page 3 of 3