



One Test for a Clean Bill of Urological Health

Cysto One PAP[®]

preventive genetic urinary screening

What is Cysto One PAP ?

The Cysto One PAP is a molecular test to screen and diagnose low and high grade urinary bladder malignancies as well as urinary tract infections and sexually transmitted diseases.

Boost effectiveness of patient testing

Urinary Tract Infections (UTIs) account for 83 million doctor visits, 1 million emergency department (ED) visits, and 100,000 hospitalizations annually with an estimated cost of \$1 billion annually in the US. Annually, there are over 84,000 new diagnoses of bladder cancer in the U.S.A and 430,000 globally, making it the fourth most prevalent malignancy in men and the fifth most prevalent in woman. Prognosis and mortality is strongly correlated with cancer staging at the time of diagnosis.

Why Cysto One PAP?

The Cysto One PAP screens for presence of Cytokeratin17. Keratin17 is an immunobiomarker which is involved in the replication cycle of malignant cells. Presence of keratin 17 is a highly specific immunobiomarker for presence of urinary bladder malignancy. In addition Cysto One PAP is designed to test for a host of other infectious urological conditions.

Urological UTI/STI Panel Menu

Performance:

98.5% sensitivity and 99.2% specificity

Sample Requirements:

Voided Urine

Run Time

~24 hours

UTI Molecular Panel

Acinetobacter baumannii
Actinotignum schaalii
Aerococcus urinae
Alloscardovia omnicolens
Candida albicans
Candida auris
Citrobacter freundii
Citrobacter koseri
Coagulase negative staphylococci
Corynebacterium riegelii
Enterobacter aerogenes
Enterobacter cloacae complex
Enterococcus faecalis
Enterococcus faecium
Erratia marcescens
Escherichia coli
Gardnerella vaginalis
Klebsiella oxytoca
Klebsiella pneumoniae
Morganella morgani i
Pantoea sp
Proteus mirabilis
Proteus vulgaris
Providencia stuartii
Pseudomonas aeruginosa
Staphylococcus aureus
Staphylococcus saprophyticus
Streptococcus agalactiae (group B)
Streptococcus dysgalactiae

STI Molecular Panel

Candida glabrata
Candida parapsilosis
Chlamydia Trachomatis
Herpes / HSV1
Herpes / HSV2
Mobiluncus curtisii
Mycoplasma genitalium
Mycoplasma hominis
Neisseria Gonorrhoeae
Treponema pallidum (Syphilis)
Trichomonas Vaginalis
Ureaplasma urealyticum

Antimicrobial Resistance Genes Panel

Antimicrobial Resistance Genes Solutions

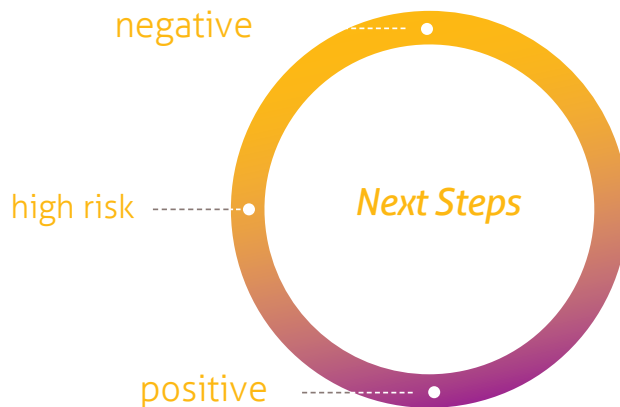
Antibiotics are just one type of antimicrobial, which are substances that kill microbes like bacteria, fungi, mold, viruses, and other microbes. Antimicrobial stewardship programs are efforts to combat antimicrobial resistance by optimizing the use of antimicrobial medications, including antibiotics. Antibiotics and other antimicrobials are vital and lifesaving, but it is their use—especially overuse and misuse—that contributes most to antimicrobial resistance.

Antimicrobial stewardship programs aim to reduce the number of unnecessary and inappropriate antimicrobial prescriptions to improve patient outcomes and curb resistance. Because these programs can play a key role in helping prevent and curb disease outbreaks, antimicrobial stewardship should be central to every institution's emergency preparedness efforts..


Accurate results within 24 hours after lab arrival

No more, complicated, redundant paperwork or late reports. As a service oriented, independent and fully certified provider, PCG Molecular can streamline the process and put the focus where it belongs—on you, the client. Our policy of speedy and efficient turnaround for our clients means fast access to the information you need via all forms of electronic transmittal and increased efficiency in the day to day operations of your own practice.

Sample Cysto One PAP® Kit



Sample Cysto One PAP® Report



preventive care innovation

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 Laboratory Director: Armando Mancada MD FCAP
 CLIA #11D2124751

Cysto One PAP® ANTIMICROBIAL RESISTANCE GENES & UTI/STI PANEL

Last name, First Name	John Mullin MD FCAP	CASE: CY-22-1000
Sex:	NPI: 1639246355	REQ: 000000
PID: 000000	Peachtree Medical 123 Atlanta Hwy Suite 340 Atlanta, GA 30031	DATE COLLECTED: 00/00/00
DOB: 00/00/0000		RECEIVED DATE: 00/00/00
		REPORT DATE: 00/00/00

LABORATORY RESULTS
Methodology: Real-Time PCR
Sample Type: Voided Urine

PATHOGENS DETECTED	RESISTANCE GENES DETECTED & POTENTIAL MED CLASS AFFECTED
Escherichia coli	DETECTED
	tetM Tetracycline
	SHV Beta-lactams
	ErmB Macrolides

RECOMMENDATIONS
John Hopkins ABX Guide

Consider pregnancy status, history of recurrent infection, and any known, specific drug resistance in the treatment of infections.

FIRST LINE >>>	Nitrofurantoin	Oral	100mg BID x 5-7 days
SECOND LINE >>>	Fosfomycin	Oral	3g x 1 dose (uncomplicated) or 3g q 3 days x 3 doses up to a maximum of 7 doses (complicated)
ALTERNATIVE >>>	Cefepime	Intramuscular	100mg BID x 5-7 days

Disclaimer: These tests were developed, characterized and interpreted by PCG Molecular, 755 Mount Vernon Hwy Suite 270 Atlanta, GA 30328. The tests cytology and UTI/STI panel have not been approved by the Food and Drug Administration. The FDA has determined that such approval is not necessary, provided that the laboratory both (1) maintains its good standing as a clinical testing laboratory with all mandatory accrediting bodies, and (2) continually demonstrates that its testing protocols and procedures achieve a high degree of analytical accuracy.

Cysto One PAP[®] STI & UTI MOLECULAR PANEL

Last name, First Name	Armando Moncada MD FCAP NPI: 1639246366	CASE: COP-000-0000
Sex:		REQ: 000000
PID: 000000	PCG Molecular 755 Mount Vernon Hwy Suite 270 Atlanta, GA 30328	DATE COLLECTED: 00/00/00
DOB: 00/00/0000		RECIEVED DATE: 00/00/00
		REPORT DATE 00/00/00

LABORATORY RESULTS Methodology: Real-Time PCR Sample Type: Urine Sample 30 ml

DETECTED PATHOGENS

UTI ARRAY RESULTS

+	Candida albicans	DETECTED

STI ARRAY RESULTS

		NOT DETECTED

NEGATIVE RESULTS

UTI Pathogens

-	Acinetobacter baumannii	Negative
-	Actinotignum schaalii	Negative
-	Aerococcus urinae	Negative
-	Alloscardovia omnicolens	Negative
-	Candida auris	Negative
-	Citrobacter freundii	Negative
-	Citrobacter koseri	Negative
-	Coagulase negative staphylococci	Negative
-	Corynebacterium riegelii	Negative
-	Enterobacter aerogenes	Negative
-	Enterobacter cloacae complex	Negative
-	Enterococcus faecalis	Negative
-	Enterococcus faecium	Negative
-	Erratia marcescens	Negative
-	Escherichia coli	Negative
-	Gardnerella vaginalis	Negative
-	Klebsiella oxytoca	Negative
-	Klebsiella pneumoniae	Negative
-	Morganella morgani i	Negative
-	Pantoea sp	Negative
-	Proteus mirabilis	Negative
-	Proteus vulgaris	Negative
-	Providencia stuartii	Negative
-	Pseudomonas aeruginosa	Negative
-	Staphylococcus aureus	Negative
-	Staphylococcus saprophyticus	Negative
-	Streptococcus agalactiae (group B)	Negative
-	Streptococcus dysgalactiae	Negative

STI Pathogens

-	Candida glabrata	Negative
-	Candida parapsilosis	Negative
-	Chlamydia Trachomatis	Negative
-	Herpes / HSV1	Negative
-	Herpes / HSV2	Negative
-	Mobiluncus curtisii	Negative
-	Mycoplasma genitaliumm	Negative
-	Mycoplasma hominis	Negative
-	Neisseria Gonorrhoeae	Negative
-	Treponema pallidum	Negative
-	Trichomonas Vaginalis	Negative
-	Ureaplasma urealyticum	Negative

Cysto One PAP[®] CYTOLOGY RESULTS

Last name, First Name	Armando Moncada MD FCAP NPI: 1639246366	CASE: COP-000-0000
Sex:		REQ: 000000
PID: 000000	PCG Molecular 755 Mount Vernon Hwy Suite 270 Atlanta, GA 30328	DATE COLLECTED: 00/00/00
DOB: 00/00/0000		RECIEVED DATE: 00/00/00
		REPORT DATE 00/00/00

CLINICAL INDICATION

Hematuria & Recurrent UTI

Specimen source

Voided Urine

Methodology

Immunocytochemistry (ICC)
Cytology Cellular Enhancement Technique

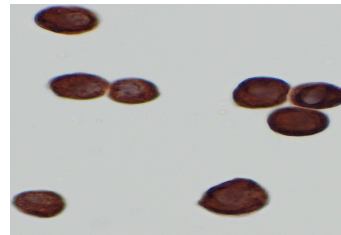
Risk stratification

Positive Cytology/ High CK17 Expression

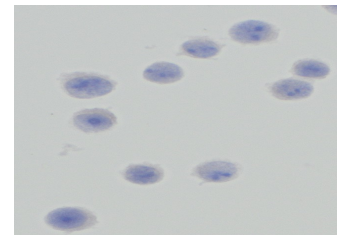
Clinical significance

This patient atypical urine cytology showed more than five (5) malignant appearing urothelial cells in a background of heavy hematuria with positive CK17 . The findings are considered to be highly suspicious for low and high grade Urothelial Malignancy

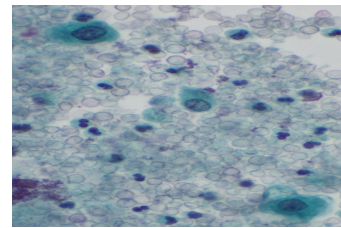
MICROPHOTOGRAPHS



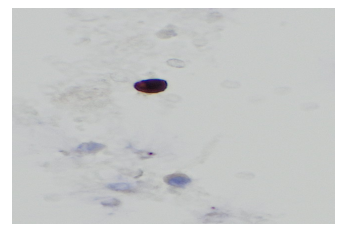
CK17 Positive Control
Urothelial Cells.



CK17 Negative Control
Urothelial Cells.



Malignant Urothelial Cells
with Hematuria Background.
Papanicolau Stain. 40X



CK17 Positive Malignant
Urothelial Cells. 40X

References:

Sruthi Babu, Daniel C. Mockler, Lucia Roa-Peña Agnieszka Szygalowicz, Nam W. Kim, Sholeh Jahanfard, Shahram S. Gholami, Richard Moffitt, John P. Fitzgerald, Luisa F. Escobar-Hoyos, Kenneth R. Shroyer, Modular Pathology (2018). Keratin 17 is a sensitive and specific biomarker of urothelial neoplasia. Vasdev N, Hampson A, Agarwal S, et al. e role of URO17TM biomarker to enhance diagnosis of urothelial cancer in new hematuria patients—First European Data. BJUI Compass. 2020;00:1–7. <https://doi.org/10.1111/bco2.50> Sruthi Babu, MD, PhD, Nam W. Kim, PhD, Maoxin Wu, MD, PhD, Ina Chan, Luisa F. Escobar-Hoyos, PhD, and Kenneth R. Shroyer, MD, PhD, AJCP. (2021) Keratin 17 Is a Novel Cytologic Biomarker for Urothelial Carcinoma Diagnosis

RECOMMENDATIONS

Standard Diagnostic workup with urological consultation is highly recommended.

Armando M.D.

Pathologist Electronic Signature
Armando Moncada Jr. M.D. FCAP