GUIDANCE
BY GENOME DX

GUIDANCE UGX PROVIDES PATHOGEN IDENTIFICATION AND ANTIBIOTIC SENSITIVITY DETERMINATION FOR URINARY TRACT INFECTIONS (UTIs)

Superior accuracy and faster turn-around-time compared to culture

Contact the GenomeDx Customer Support Team
888.792.1601 or customersupport@genomedx.com

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GUIDANCE UGX IS A RAPID MOLECULAR TEST FOR PATHOGEN IDENTIFICATION AND ANTIBIOTIC SENSITIVITY DETERMINATION

Guidance UGx is intended for patients with any of these symptoms

- Experiencing recurrent UTI
- Interstitial cystitis
- Pyelonephritis
- Men with UTI
- Pregnant patients
- 55 years old and older
- Past urinary culture results were “contaminated”
- On chronic pain care regimens
- Immunosuppressed
- Diabetic

CHALLENGE: Missed Diagnosis—Standard urine culture misses up to 2/3 of all UTI positive patients[1]

SOLUTION: Guidance UGx—A novel, molecular test that provides increased diagnostic accuracy

	Guidance UGx	Urine Culture
Positive Cases	200	148
Percentage Sensitivity	97%	71%

Data on file

Guidance UGx demonstrates a 26% increase in sensitivity[2]

	Guidance UGx	Urine Culture
Number Misdiagnosed	7	142
Percentage Misdiagnosed	4%	69%

Data on file

Guidance UGx improves diagnostic accuracy by over 65%[2]

References

[1]Price TK, Dune T, Hilt EE, et al. The Clinical Urine Culture: Enhanced Techniques Improve Detection of Clinically Relevant Microorganisms. Forbes BA, ed. *J Clin Microbiol.* 2016;54(5):1216-1222.

[2]Data based on Pathnostics Laboratory internal studies comparing 300 cases of traditional urine culture vs. Guidance UGx.

[3]Karlowsky JA, Kelly LJ, Thornsberry C, Jones ME, Sahm DF. Trends in antimicrobial resistance among urinary tract infection isolates of Escherichia coli from female outpatients in the United States. *Antimicrob Agents Chemother.* 2002;46(8):2540-2545.

ABOUT GUIDANCE UGX FOR URINARY TRACT INFECTIONS (UTIs)

CLINICAL UTILITY

- Detects presence of microbial DNA from pathogens that can cause UTIs
- Provides antibiotic treatment recommendations

INTERPRETATION

- Organisms detected reported as cells/mL
- Antibiotic Resistance (ABR) listed as either "Sensitive" or "Resistant/Without Sensitivity"

SPECIMEN

- 10mL of urine or catheter urine
- Rejection Criteria: >5 days of collection time, frozen, samples collected in PreservCyt, or Foley Catheter Tips

TURNAROUND TIME

- 48-72 hours

	Guidance UGx	Urine Culture
Turn-around time	48-72 hours	Up to 5 days

Guidance UGx provides significant turn-around time advantage for efficient treatment

CHALLENGE: Antibiotic Resistance—

UTIs are increasingly caused by multidrug-resistant organisms due to overuse of broad-spectrum antibiotic therapy[3]

SOLUTION: Guidance UGx—

Identifies 25 pathogens simultaneously from urine samples and determines antibiotic sensitivity for more informed treatment

	Guidance UGx	Urine Culture
Number Detected	423	159
Percentage Detected	97%	36%

Guidance UGx detects 61% more organisms than culture[2]

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GUIDANCE UGX DELIVERS A COMPREHENSIVE AND ROBUST DIAGNOSIS

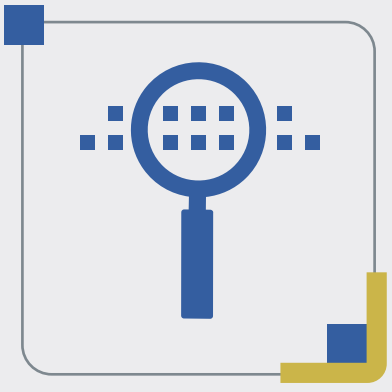
Simultaneously identifies 25 pathogens that are most commonly associated with UTIs

Organism Detected by Guidance UGx

Acinetobacter baumannii
Actinobaculum schaalii
Aerococcus urinae
Alloscardovia omnicolens
Candida albicans
Candida glabrata
Candida parapsilosis
Citrobacter freundii
Citrobacter koseri
Corynebacterium riegelii
Corynebacterium urealyticum
Enterbacter aerogenes
Enterococcus faecalis
Escherichia coli
Klebsiella oxytoca
Klebsiella pneumoniae
Morganella morganii
Mycoplasma genitalium
Proteus mirabilis
Pseudomonas aeruginosa
Serratia marcescens
Staphylococcus aureus
Staphylococcus saprophyticus
Streptococcus agalactiae
Streptococcus anginosus

Detection Range

Between 1,620 and 5,401 cell/mL (depending on organism) to 6,000,000 cells/mL or greater



GUIDANCE UGX DELIVERS EFFECTIVE AND PERSONALIZED TREATMENT OPTIONS

Helps individually tailor antibiotic therapy and improve effective selection of antibiotics

Antibiotic Resistance Reported by Guidance UGx

Ampicillin
Ampicillin/Sulbactam
Cefoxitin
Ceftazidime
Cefepime
Cefazolin
Ceftriaxone
Ciprofloxacin
Gentamicin
Levofloxacin
Meropenem
Nitrofurantoin
Piperacillin/Tazobactam
Tetracycline
Trimethoprim/ Sulfamethoxazole (TMP/SMX)
Vancomycin

TEST METHODOLOGY

Pathogen Identification
Quantitative, real-time PCR (Polymerase Chain Reaction) based assay

ABR Determination
Phenotypic assay for antibiotic sensitivity of polymicrobial infections

Guidance UGx REPORT

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10355 Science Center Drive, Suite 240
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Patient:
DOB:
Age:
Gender:
Phone:
MRN#:

Ordering Physician:
Faculty:

Phone:
Fax:

Case #:

Data Collected:
Date Received:
Date Reported:

Results:

Pathogenic DNA Detected

Organisms Tested - Detected:

Escherichia coli - >6,000,000 Cells/mL
Morganella Morganii - 1,018,127 Cells/mL
Klebsiella pneumoniae – 1,049,878 Cells/mL
Streptococcus anginosus – 5,398 Cells/mL

Antibiotics Recommended Based on Sensitivity Testing and Clinical Data†:

Cefepime
Ceftazidime
Ceftriaxone
Meropenem
Piperacillin/Tazobactam
Gentamicin

Organisms Tested - Not Detected:
Candida albicans, Candida glabrata, Candida tropicalis, Candida parapsilosis, Streptococcus agalactiae, Staphylococcus saprophyticus, Mycoplasma genitalium, Staphylococcus aureus, Enterococcus faecalis, Proteus mirabilis, Citrobacter freundii, Serratia marcescens, Pseudomonas aeruginosa, Klebsiella oxytoca, Acinetobacter baumannii. Corynebacterium urealyticum, Corynebacterium riegelii. Aerococcus urinae. Alloscardovia omnicolens, Enterobacter aerogenes, Citrobacter koseri

Antibiotics Tested with Sensitivity But Not Clinically Recommended:
Cefazolin, Cefepime, Nitrofuratoin, Ampicillin/Sulbactam

Antibiotics Tested Without Demonstrated Sensitivity:
Trimethoprim/Sulfamethoxazole, Levofloxacin, Ciprofloxacin, Cefoxitin, Ampicillin, Vancomycin, Tetracycline

Patient: **Case #:**

Reference Table Indicating Clinical Data for all Detected Organisms

Organisms Detected	Antibiotics															
	Ampicillin	Ampicillin/ Sulbactam	Piperacillin/ Tazobactam	Cefazolin	Cefoxitin	Ceftriaxone	Ceftazidime	Cefepime	Ciprofloxacin	Levofloxacin	Meropenem	Nitrofurantoin	Trimethoprim / Sulfamethoxazole	Tetracycline	Vancomycin	Gentamicin
Formulations	PO/IV	IV	IV	IV	IV	IV	IV	IV	PO/IV	PO/IV	IV	PO	PO/IV	PO	IV	IV
Escherichia coli	**CR**	**CR**	**CR**	**CR**	**CR**	**CR**	**CR**	**CR**	**CR**	**CR**	**CR**	**CR**	**CR**	**CNR**	**CNR**	**CR**
Klebsiella pneumoniae	**CNR**	**CR**	**CR**	**CR**	**CR**	**CR**	**CR**	**CR**	**CR**	**CR**	**CR**	**CR**	**CR**	**CNR**	**CNR**	**CR**
Morganella morganii	**CNR**	**CNR**	**CR**	**CNR**	**CR**	**CR**	**CR**	**CR**	**CR**	**CR**	**CR**	**CNR**	**CR**	**CNR**	**CNR**	**CR**
Streptococcus anginosus	**CR**	**CR**	**CR**	**CR**	**CR**	**CR**	**CR**	**CR**	**CR**	**CR**	**CR**	**CNR**	**CNR**	**CNR**	**CR**	**CR**

CR= Clinically Recommended **CNR= Clinically Not Recommended**

Clinically Recommended: Agent(s) are reliably active in vitro, clinically effective, guideline recommended as first-line agent(s) or acceptable alternative agent(s).
Clinically Not Recommended: Agent(s) are a poor alternative to other agents because resistance is likely to be present or occur. This is due to, poor drug penetration to site of infection, an unfavorable toxicity profile, or limited anecdotal or clinical data to support effectiveness.

Methodology and Clinical Significance: The Pathnostics Guidance UGx Report utilizes quantitative PCR technology in addition to traditional microbiological methods to detect the presence of bacterial and fungal organisms associated with urinary tract infections. An antibiotic drug resistance panel provides guidance to aid in the selection of appropriate antibiotics. Detected pathogens are reported as the number of organisms per milliliter of urine. Results <10,000 Cells/mL are considered below accurate range of detection by laboratory standards.
Unsanitary sample collection practices are common and can result in the presence of contaminants. An algorithm based on common laboratory practices helps to differentiate between a positive urinary tract infection and a likely contamination.

Disclaimer: This test was developed and its performance characteristics determined by Pathnostics. It has not been cleared or approved by the US Food and Drug Administration. The FDA has determined that such clearance or approvals is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity clinical testing. Urine specimens received greater than 5 days post collection may give unreliable Cells/mL counts due to overgrowth of microorganisms.

†Treatment options are based on sensitivity data (when available) and general recommendations from an aggregation of clinical guidelines and are not intended to be prescriptive for this patient. Appropriate medical judgement should be exercised by the attending physician before prescribing a course of treatment.

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DECIPHER AND GUIDANCE GENOMIC TESTS DELIVER CLINICALLY ACTIONABLE RESULTS TO UROLOGISTS AND THEIR PATIENTS

GUIDANCE UGX MOLECULAR TECHNOLOGY WITH PROPRIETARY ABR DETECTION GIVES YOU MORE:

- Diagnose MORE symptomatic cases than culture alone
- Resolve MORE recurring cases
- Provide MORE informed treatment options

GenomeDx Biosciences remains committed to bringing clinically actionable genomic information to clinicians and patients in the urology community.

ACCESS FOR ALL PATIENTS

- Covered by Medicare
- Private Insurance Coverage for multiple plans
- Proven and comprehensive financial assistance for patients

Contact Pathnostics at 800.493.4490 or email billing@pathnostics.com for additional billing questions

Contact the GenomeDx Customer Support Team
1.888.792.1601 (toll-free) or customersupport@genomedx.com

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PATHN2017901