SWIFT DIAGNOSIS AND THERAPY OPTIONS THAT WORK THE FIRST TIME TAKE GUIDANCE
GUIDANCE POINTS THE WAY TO QUICK AND EFFECTIVE RESOLUTION OF CHRONIC INFECTIONS

Today’s standard of care simply isn’t good enough. Typical urine culture misses up to 2/3 of all UTI-positive patients and it detects organisms in only 4% of the cases to diagnose prostatitis.¹²

Now there’s a better way to test and treat chronic urologic infections. Guidance is a unique rapid molecular test for both pathogen identification and antibiotic sensitivity, backed by patented technology.

With quick 24-48 hour turnaround time, Guidance provides personalized therapy options that work the first time. So you can conquer your patients’ unresolved infections.

KNOW WHAT’S CAUSING THE PROBLEM

- Tests for more pathogens
- Higher sensitivity and accuracy
- Results in more accurate diagnosis

Organism identification

KNOW HOW TO SUCCESSFULLY TREAT

- Tests more antibiotics
- Leverages dual assessments
- Uncovers more effective, personalized therapy options

Genotype resistance + Antibiotic sensitivity

The difference is clear

<table>
<thead>
<tr>
<th></th>
<th>GUIDANCE</th>
<th>OTHERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pathogens Tested</td>
<td>45</td>
<td>≤16</td>
</tr>
<tr>
<td>Antibiotic Resistance Genes</td>
<td>38</td>
<td>≤27</td>
</tr>
<tr>
<td>Pooled Phenotypic Sensitivity</td>
<td>YES</td>
<td>NO</td>
</tr>
</tbody>
</table>

WHO NEEDS GUIDANCE

Patients with:
• Recurrent UTI
• Interstitial cystitis

At-risk groups:
• Pregnant
• Elderly
• Past urinary culture results were “contaminated”
• On chronic pain care regimens
• Immunosuppressed
• Diabetic
• Men with UTI

TESTING OPTIONS

GUIDANCE BASIC

Tests for:
• Simple cystitis

Includes detection of:
• Bacterial and yeast organisms
• Bacterial groups
• Antibiotic resistant genes detected

GUIDANCE COMPREHENSIVE

Tests for:
• Recurrent, persistent, or complicated UTI
• Interstitial cystitis
• Prostatitis

Includes detection of:
• Bacterial and yeast organisms
• Bacterial groups
• Viral particles
• Antibiotic resistant genes detected
**CLINICAL UTILITY**

**PATHOGEN IDENTIFICATION**
Polymerase chain reaction (PCR) amplification-based assay to test up to 45 pathogens

**THERAPEUTIC OPTIONS**
- Targeted detection of 38 resistance genes spanning 7 different antibiotic classes
- Phenotypic data showcasing antibiotic sensitivity for polymicrobial environment
- Personalized antibiotic options based on supportive evidence

**INTERPRETATION**

**DETECTED PATHOGENS**
Cells of organisms per milliliter of sample:

- 10,000-49,999
- 50,000-99,999
- ≥100,000

Detection range as low as 500 cells/mL (depending on organism) to 6,000,000 cells/mL. Viral and STD pathogens will be noted as “detected” or “not detected” only.

**ANTIBIOTIC RESISTANCE**
- **Sensitive**: antibiotic prevented growth of polymicrobial culture
- **Resistant**: antibiotic did not prevent growth in polymicrobial culture
- **RGI**: resistance gene identified

**SPECIMEN**

**URINE**
Voided urine or catheter urine collected within 5 days
Samples that were frozen, have PreservCyt, or were collected with Foly catheter tips will be rejected.

**HERE’S HOW YOU ACCESS YOUR PERSONALIZED THERAPY OPTIONS**

**TEST PERFORMANCE**

<table>
<thead>
<tr>
<th></th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>PATHOGEN DETECTION</td>
<td>97%</td>
<td>100%</td>
</tr>
<tr>
<td>ANTIBIOTIC RESISTANCE</td>
<td>95%</td>
<td>89%</td>
</tr>
</tbody>
</table>
**GUIDANCE TEST DETAILS**

**ORGANISMS DETECTED:**

**BACTERIAL/YEAST ORGANISMS**
- Acinetobacter baumannii
- Actinobaculum schaalii
- Aerococcus urinae
- Alloscardovia omnicolens
- Candida albicans
- Candida glabrata
- Candida parapsilosis
- Citrobacter freundii
- Citrobacter koseri
- Corynebacterium riegelii
- Enterobacter aerogenes
- Enterococcus faecalis
- Escherichia coli
- Klebsiella oxytoca
- Klebsiella pneumoniae
- Morganella morganii
- Mycobacterium tuberculosis
- Mycoplasma genitalium
- Mycoplasma hominis
- Pantoea agglomerans
- Proteus mirabilis
- Providencia stuartii
- Pseudomonas aeruginosa
- Serratia marcescens
- Staphylococcus aureus
- Streptococcus agalactiae
- Streptococcus pyogenes
- Ureaplasma urealyticum
- Cefuroxime (PO)
- Cephalalexine (PO)
- Ciprofloxacin (PO/IV)
- Gentamicin (IM/IV)
- Levofloxacin (PO)
- Meropenem (IV)
- Nitrofurantoin (PO)
- Piperacillin/Tazobactam (IV)
- Sulfamethoxazole/Trimethoprim (PO/IV)
- Tetracycline (PO)
- Vancomycin (IV)

**SEXUALLY TRANSMITTED ORGANISMS**
- Chlamydia trachomatis
- Neisseria gonorrhoeae
- Trichomonas vaginalis

**POOLED GENOTYPE ANTIBIOTIC RESISTANCE GENES INCLUDE:**
- Ampicillin
- ß-Lactamase
- Carbapenem
- Macrolide
- Methicillin
- Quinolinone/Fluoroquinolone
- Vancomycin

**POOLED PHENOTYPE ANTIBIOTIC RESISTANCE/SENSITIVITY TESTING INCLUDES:**
- Ampicillin (PO/IV)
- Ampicillin/Sulbactam (IV)
- Amoxicillin/Clavulanate (PO)
- Cefaclor (PO)
- Cefazolin (IV)
- Cefepime (IV)
- Cefotaxin (IV)
- Ceftazidime (IV)
- Ceftriaxone (IM/IV)
- Cefuroxime (PO)
- Cephalalexine (PO)
- Ciprofloxacin (PO/IV)
- Gentamicin (IM/IV)
- Levofloxacin (PO)
- Meropenem (IV)
- Nitrofurantoin (PO)
- Piperacillin/Tazobactam (IV)
- Sulfamethoxazole/Trimethoprim (PO/IV)
- Tetracycline (PO)
- Vancomycin (IV)

- BK virus
- Adenovirus
- CMV
- HHV-6
- HHV-7
- HSV 1/2
- JC virus

**POOLED GENOTYPE ANTIBIOTIC RESISTANCE GENES INCLUDE:**
- Ampicillin
- ß-Lactamase
- Carbapenem
- Macrolide
- Methicillin
- Quinolinone/Fluoroquinolone
- Vancomycin

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*Coagulase neg. staphylococci: Staphylococcus epidermidis, Staphylococcus haemolyticus, Staphylococcus lugdunensis, Staphylococcus saprophyticus
**Viridans group streptococci: Streptococcus anginosus, Streptococcus oralis, Streptococcus pasteurius*
SEE WHY GUIDANCE IS SUPERIOR TO STANDARD CULTURE

Relying on urine culture to diagnose chronic urologic infections has significant shortcomings. By leveraging a novel molecular and antibiotic sensitivity test, Guidance points the way to more therapy options for better patient outcomes.
MISSED DIAGNOSIS
Does standard urine culture miss up to 2/3 of all UTI-positive patients?¹

GUIDANCE demonstrates a 26% increase in sensitivity.³

<table>
<thead>
<tr>
<th>GUIDANCE</th>
<th>URINE CULTURE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive Cases</td>
<td>200</td>
</tr>
<tr>
<td>Percentage Sensitivity</td>
<td>97%</td>
</tr>
<tr>
<td>Positive Cases</td>
<td>148</td>
</tr>
<tr>
<td>Percentage Sensitivity</td>
<td>71%</td>
</tr>
</tbody>
</table>

GUIDANCE improves diagnostic accuracy by more than 65%.³

<table>
<thead>
<tr>
<th>GUIDANCE</th>
<th>URINE CULTURE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number Misdiagnosed</td>
<td>7</td>
</tr>
<tr>
<td>Percentage Misdiagnosed</td>
<td>4%</td>
</tr>
<tr>
<td>Number Misdiagnosed</td>
<td>142</td>
</tr>
<tr>
<td>Percentage Misdiagnosed</td>
<td>69%</td>
</tr>
</tbody>
</table>

POLYMICROBIAL INFECTIONS
In populations 65 and older, the mortality rate for those patients with symptomatic UTIs is as high as 33%⁴ And the rate of polymicrobial UTIs is as high as 39%⁵

GUIDANCE detects 61% more organisms than culture. (actual exposure of patient specimen to antibiotic).³

<table>
<thead>
<tr>
<th>GUIDANCE</th>
<th>URINE CULTURE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number Detected</td>
<td>423</td>
</tr>
<tr>
<td>Percentage Detected</td>
<td>97%</td>
</tr>
<tr>
<td>Number Detected</td>
<td>159</td>
</tr>
<tr>
<td>Percentage Detected</td>
<td>36%</td>
</tr>
</tbody>
</table>

SLOW-GROWING PATHOGENS
Urine culture is less likely to detect pathogens that are difficult or slow to grow in culture, making treatment unnecessarily challenging.

GUIDANCE identifies antibiotic resistance genes from DNA through genotype testing (identification of pathogen DNA within pool of DNA isolated from detected organisms).

§ Data based on Pathnostics Laboratory internal studies comparing 300 cases of traditional urine culture vs. Guidance.
GUIDANCE IS THE BEST OF BOTH WORLDS

Only Guidance combines both genotype resistance testing and antibiotic sensitivity on the collection of pathogens to identify the most effective therapy choices in a polymicrobial environment.

Three reasons why genotype resistance testing alone isn’t enough:

1. **Too many resistance genes to put in one assay.** Scientists have identified tens of thousands of resistance genes, impacting hundreds of antibiotics in hundreds of organisms. Unfortunately, there is a limited number of resistance genes that can be identified via molecular assay.

2. **Resistance genes continuously evolve and are shared.** Bacteria generate new resistance genes and then transfer those genes to other bacteria on a regular basis. So the ability to identify and characterize new resistance genes will always lag behind bacteria’s capability to create them.

3. **Resistance gene may not be functional.** Even after the gene is characterized, the actual presence of the resistance gene doesn’t guarantee the gene is functional and exerting resistance within the detected pool of bacteria.

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More pathogens means more chances to evade treatment.

With a superior phenotype testing process for antibiotic resistance, Guidance results in improved treatment for polymicrobial infections.

Antibiotic Resistance in Mono- vs. Polymicrobial Infections

- **Escherichia coli** only: 55% Ampicillin, 11% Nitrofurantoin
- **Enterococcus faecalis** only: 32% Ampicillin, 17% Nitrofurantoin
- **Escherichia coli** + **Enterococcus faecalis**: 69% Ampicillin, 28% Nitrofurantoin

**MUTUALISM 101**

In elderly patients’ UTIs, polymicrobial infections typically consist of up to five organisms. These infections create an ecological environment in which the organisms enhance each other’s proliferation rates and overall survival in the presence of antibiotics. \(^9\)\(^-\)\(^13\)

Bacterial communities thrive due to cross-feeding because organisms produce metabolites that nourish the other members of the community. \(^10\)

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**GUIDANCE REPORTS DELIVER EFFECTIVE, PERSONALIZED THERAPY OPTIONS**

**GUIDANCE BASIC/COMPREHENSIVE**  
Example Report

### ORGANISM(S) DETECTED

<table>
<thead>
<tr>
<th>ORGANISM(S) DETECTED</th>
<th>Gentamicin</th>
<th>Meropenem</th>
<th>Trinemophyn/Sulfamethoxazole</th>
<th>Amoxicillin/Clavulante</th>
<th>Ampicillin/Subactam</th>
<th>Piperacillin/Tazobactam</th>
<th>Ceftriaxone</th>
<th>Ceftazidime</th>
<th>Ciprofloxacin</th>
<th>Ampicillin</th>
<th>Nitrofurantoin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formulations</td>
<td>IM/IV</td>
<td>IV</td>
<td>PO/IV</td>
<td>PO</td>
<td>IV</td>
<td>PO/IV</td>
<td>IV</td>
<td>PO</td>
<td>PO/IV</td>
<td>PO/IV</td>
<td>PO</td>
</tr>
<tr>
<td>Pooled Phenotype Sensitivity</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>R</td>
<td>S</td>
<td>S</td>
<td>RGI</td>
</tr>
<tr>
<td>MIC Results (ug/mL)</td>
<td>40</td>
<td>10</td>
<td>20</td>
<td>80</td>
<td>40</td>
<td>40</td>
<td>40</td>
<td>40</td>
<td>160</td>
<td>80</td>
<td>320</td>
</tr>
<tr>
<td>Pooled Resistance Gene(s) Identified</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

- **Escherichia coli**
- **Enterococcus faecalis**
- **Streptococcus anginosus**

**Formulations**
- IM/IV
- IV
- PO/IV
- PO
- IV PO
- IV PO/IV
- IV PO/IV
- PO/IV
- PO

**MIC Results (ug/mL)**
- 40
- 10
- 20
- 80
- 40
- 40
- 40
- 160
- 80
- 320

**Pooled Resistance Gene(s) Identified**
- **RGI** = Resistance Gene Identified

- **S** = Sensitive
- **R** = Resistant
- **=** Supportive Evidence

Other Non-Bacterial Pathogens Detected:
- **Candida albicans** > 10,000 cells/mL

Antibiotic Resistance Genes Detected:
- Quinolinone/Fluoroquinolone
- Vancomycin

Antibiotic Resistance Detected:
- Cefaclor (PO)
- Levofloxacin (PO/IV)
- Cefazolin (IV)
- Tetracycline (PO)
- Cefoxitin (IV)
- Vancomycin (IV)
- Cefepime (IV)

**42 organisms tested, see second page for those not detected**
MIC (Minimum Inhibitory Concentration) results provide the concentration (ug/mL) of antibiotic the bacteria would be considered sensitive.

Highlighted boxes indicate situations where:
- organism(s) detected in patient specimen are sensitive to antibiotic
- targeted resistance gene for that antibiotic NOT detected
- antibiotic has supportive evidence for all organisms detected in patient specimen

Antibiotics and formulations with demonstrated sensitivity

Other non-bacterial pathogens (fungi, STDs, viruses, etc.) detected

Antibiotic resistance genes detected that could indicate resistance against classes of antibiotic

Drug resistance detected based on phenotype testing (actual exposure of patient specimen to antibiotic)
TURN TO PATHNOSTICS TO HELP PROVIDE SUPERIOR PATIENT CARE

Pathnostics is dedicated to providing the highest level of customer service and convenience. Whether your urology practice is growing or large and established, we have options to help you conquer your patient’s unresolved infections.

If you send patient samples to Pathnostics:
• count on us as a committed partner
• expect consistent turnaround time of 24-48 hours

By internalizing lab operations, you can:
• further reduce turnaround time
• improve specimen handling
• realize greater clinical workflow efficiency
• raise your patient satisfaction

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