Urinary Tract Infection Detection using PCR

The Molecular Approach by Wellness Labs
### URINARY TRACT INFECTION (UTI) IS ONE OF THE MOST COMMON HUMAN BACTERIAL INFECTIONS

- Patients are often misdiagnosed with a ‘bladder syndrome’ in attempt to explain their continued UTI symptoms.

### 26-44% WILL HAVE A UTI RECURRENT WITHIN 6 MONTHS

- One in 10 girls and one in 30 boys developing a UTI before the age of 16.

### ONCE ESTABLISHED, CHRONIC UTI (cUTI) AND RECURRENT UTI (rUTI) CANNOT BE ERADICATED WITH SHORT-TERM ANTIBIOTICS

### 7 OUT OF 10 DON’T BELIEVE THEIR UTI TREATMENT WILL WORK

### LEFT UNTREATED, cUTI CAUSES ONGOING, DEBILITATING AND LIFE-CHANGING SYMPTOMS

### UP TO 30% OF PATIENTS ACCORDING TO CURRENT GUIDELINES WILL FAIL TO RESPOND TO TREATMENT

### AT LEAST HALF OF ALL WOMEN WILL DEVELOP A UTI IN THEIR LIFETIME, WITH 20-30% GOING ON TO EXPERIENCE A RECURRENCE AND A SIGNIFICANT SUBSET DEVELOPING A CHRONIC FORM OF UTI

### DIAGNOSTIC TESTS FOR UTI HAVE BEEN WIDELY DISCREDITED IN PEER-REVIEWED PUBLICATIONS FOR OVER 30 YEARS

### 7 MILLION FEMALES EXPERIENCE A UTI EACH YEAR IN THE USA

### 80% OF cUTI SUFFERERS ARE FEMALE, IT IS ESPECIALLY PREVALENT AMONG ELDERLY WOMEN WHERE IT IS NOT ONLY CRUEL AND DEBILITATING, BUT ALSO LIFE-THREATENING
URINARY TRACT INFECTION MOLECULAR TEST PANEL
by Real-Time Polymerase Chain Reaction

What is UTI?

Urinary Tract Infection (UTI) is the general term for an infection occurring anywhere in the urinary system. Most UTIs involve the bladder and the urethra, but some can also involve the ureters and even the kidneys.

It is quite common for UTIs to be misdiagnosed, and this puts an extreme and unnecessary burden on the healthcare system and the healthcare economy. Over 150 million people worldwide will experience UTIs annually, with females four times more likely to get them than males. In fact, at least half of all women will get a UTI during their lifetime, and a third of these occur before the age of 24. A compounding factor is that approximately 25% of all patients will experience a reoccurrence within six months, in some cases developing a chronic form of urinary infection.

Children are also prone to UTIs, with one in 10 girls and one in 30 boys developing the infections before the age of 16. Chronic UTI (cUTI) is a largely misunderstood form of the disease that is particularly difficult to diagnose and treat under current guidelines. Chronic UTI is especially prevalent among elderly women, for whom it is not only painful and debilitating, but can also be life-threatening.

Data shows that UTIs are increasing due to multidrug-resistant pathogens that are spreading globally from the over-prescription and widespread use of broad-spectrum antibiotic therapy instead of a more controlled approach which would match the optimal antibiotics to specific pathogens. Ironically, it can be said that the very treatment of UTIs with broad-spectrum antibiotics has itself become a major contributing factor to its global spread.

Molecular UTI Panel by Wellness Laboratories offers an extremely fast turnaround time and far more sensitive identification of bacterial species than all other testing methods, which allows for diagnosis and treatment that are narrowly matched to appropriate antibiotic choices.

The Wellness Laboratories Urinary Tract Infection Molecular Test Panel simultaneously identifies, from a single specimen, 17 pathogens (gram positive, gram negative and fungi) that are most commonly associated with UTIs.

| GRAM NEGATIVE ORGANISMS | Acinetobacter baumannii | Klebsiella pneumoniae |
| Citrobacter freundii | Morganella morganii |
| Enterobacter aerogenes | Proteus mirabilis |
| Enterobacter cloacae | Proteus vulgaris |
| Escherichia coli | Providencia stuartii |
| Klebsiella oxytoca | Pseudomonas aeruginosa |

| GRAM POSITIVE ORGANISMS | Enterococcus faecalis | Staphylococcus saprophyticus |
| Enterococcus faecium | Streptococcus agalactiae |

| FUNGI | Candida albicans |

Next day turnaround and accurate detection of urinary tract pathogens provides the clinician with the critical information for more focused therapy and improved outcomes. Based upon published recommendations, use of the appropriate narrow spectrum antibiotic in treating UTIs reduces the incidence of treatment failure. Rapid diagnostic molecular methods can allow for earlier intervention and optimized therapy when appropriate.
ABOUT CHRONIC UTI

Chronic Urinary Tract Infection (cUTI) is a largely under-diagnosed condition that affects a significant percentage of the population. The majority of those living with an undiagnosed and untreated cUTI are women.

Anyone can develop cUTI, and researchers suggest that the most significant risk factor for an cUTI is having been diagnosed with a UTI previously. Between 20–30 percent of all patients treated for an acute UTI are not fully cured and go on to develop a complicated, embedded infection which is extremely difficult to diagnose and treat.

When patients experience UTI symptoms, but their tests say otherwise, there is a good reason to question those tests. Since the 1980s, peer-reviewed research has shown that MSU cultures (used by labs to diagnose UTIs) miss at least 50 percent of the infections for which they test. Urinary dipsticks (commonly used in the clinic or doctor’s office to screen samples) are even less effective and have been known for at least a decade to be completely unreliable in ruling out infections.

URINARY DIPSTICK TEST

Today, dipsticks are often the first diagnostic tool GPs use to confirm an infection. These tests look for signs of infection, such as white blood cells (leucocytes or pus cells), blood, pH levels and nitrites. Although they are useful in confirming a clearly positive diagnosis, studies in the early 1990s concluded that they are highly insensitive and unreliable at excluding infection in most clinical settings. About a decade later, another team of researchers comprehensively studied the reliability of urinary dipsticks and determined that these first-line screening tests were not up to the job of excluding significant UTIs. It found dipsticks identified white blood cells just 55 percent of the time, and nitrites (another positive indicator of infection) only 10 percent of the time. A negative result offers no useful information in ruling out a UTI. Given the proven shortcomings of urinary dipsticks, physicians should be extremely cautious when relying on this test to rule out a UTI.

MID-STREAM URINE CULTURES

MID-STREAM URINE CULTURES (MSU) cultures are considered the gold standard for diagnosing UTI and have been in use since the late 1950s. For over 30 years, researchers have warned of serious deficiencies that lead to these tests missing at least 50 percent of infections. Studies have been repeated and calls for the abandonment of MSU culturing have been heard repeatedly, but these warnings have been ignored, and MSU culturing remains the main diagnostic tool for UTIs around the world.

FACT

At least half of all women will develop a UTI in their lifetime, with 20-30% going on to experience a recurrence.
PANEL DETAILS

<table>
<thead>
<tr>
<th>TEST ORDERING CODE</th>
<th>MOL-UTI</th>
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<tbody>
<tr>
<td>METHODOLOGY</td>
<td>Real-Time Polymerase Chain Reaction (PCR).</td>
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<tr>
<td>SPECIMEN REQUIREMENTS</td>
<td>Clean catch urine specimen.</td>
</tr>
<tr>
<td>MINIMUM VOLUME</td>
<td>1.0 ml</td>
</tr>
<tr>
<td>TEMPERATURE</td>
<td>Refrigerated 7 days</td>
</tr>
<tr>
<td>STABILITY</td>
<td>Room temperature 48 hours</td>
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<tr>
<td>TURNAROUND TIME</td>
<td>1 business day with Susceptibility included.</td>
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NOTES:
* Proper sample collection is critically important for test accuracy.
** The patient should not have urinated for at least an hour before the urine specimen is collected.
*** Send urine in a sterile container to Wellness Laboratories.

CLINICAL BENEFITS
- Same day results
- Identifies bacteria regardless of recent antibiotic use
- Identifies difficult to culture pathogens
- Offers simplicity and convenience of single specimen collection Yields > 95% analytical sensitivity and specificity
- Identifies of 30 pathogens from a single specimen

INDICATIONS FOR MOLECULAR UTI PANEL
- Recurring UTIs
- Interstitial cystitis
- Pyelonephritis
- Pregnancy
- Over 50 years of age
- Chronic pain care patients
- Immunocompromised patients

FACT
UTI is one of the most common human bacterial infections with over 150 million people worldwide affected each year.

FACT
Patients are often misdiagnosed with a ‘bladder syndrome’ in attempt to explain their continued UTI symptoms.
ADVANTAGES AND CHALLENGES
OF THE MOLECULAR UTI TEST

ADVANTAGES

A molecular assay is highly sensitive, which helps identify slow growers in urine samples which would otherwise take more than 48 hours.

Turnaround time for the Molecular UTI test is 5 hours once in the laboratory.

CHALLENGES

Increasing multidrug resistance in uropathogens is leading to high recurrence rates of UTI’s and has become a global challenge for antibiotic treatment regimens.

It is extremely important to accurately identify the causative uropathogens for effective use of antibiotics.

WORK FLOW OF OPEN ARRAY VERSUS URINE CULTURE

MOLECULAR UTI TEST

TEST RESULTS IN 5 HOURS

CONVENTIONAL CULTURE

TEST RESULTS IN 48 HOURS

URINE SPECIMEN

Culture on selective media for identification of gram negative and gram-positive bacteria

Gram stain to confirm by morphology

Re-incubate for slow growers

DNA extraction using MagMAX

q PCR (Open Array)
**SPECIMEN COLLECTION**

Proper sample collection is critical for assuring the accuracy of the Molecular UTI test. Clean, uncontaminated specimens help to eliminate false positives and significantly boost the accuracy of results.

Wellness Laboratories believes that providing our medical professionals with the highest quality supplies, results in a better overall patient experience. We therefore offer medical practices, clinics and hospitals only the finest accessories, specimen collection kits and transporting supplies.

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**SPECIMEN CONTAINERS**

Wellness Laboratories provides sterile, 90 mL specimen containers with labels. The jars are of the highest quality, leak proof and are fully certified for use in hospital pneumatic systems and approved for airline transport.

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**CASTILE SOAP TOWELETTES**

Castile Soap Towelettes are pH-balanced and saturated with a 2% coconut oil-based soap solution. Castile soap is gentle and often used for general cleaning, as well as surgical preparation. These individually packaged single use 5"x7" towelettes are ideal for mid-stream clean catch urine specimen procedures as well as general cleaning and personal hygiene.
Capable of producing organism detection with sensitivity reports for UTIs within 24 hours.