

# URINARY TECHNOLOGIES CORP.

Faster, better Urinary Tract Infection (UTI) testing for Pediatric patients, Enabling their Doctors to prescribe the *right* antibiotic the *first* time



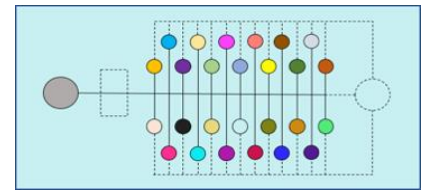
## THE PROBLEM

Urinary tract infections (UTIs) are the second most common bacterial infection, affecting about 20 million people in the U.S. and over 200 million people world-wide each year. UTIs are one of the most common bacterial infections of childhood, account for nearly 50,000 hospital admissions per year in the United States and over \$520 million of aggregated hospital.

Unfortunately, 1950s-era technology using a Petri dish culture test is the current standard to diagnose UTIs. This test takes 2 to 3 days, including an antibiotic susceptibility test (AST) that is required – in part – because antibiotic abuse has made over half of UTIs being resistant to the most common antibiotics. Worse yet, especially with pediatric patients where urine collection can be problematic: urine samples are often contaminated, requiring re-sampling and re-starting the clock. As a result, most patients are *never* tested for a suspected UTI and instead are given a ‘best guess’ prescription for antibiotics, half of which will not be effective and further contribute to the problem of antibiotic resistance.

## OUR APPROACH

Urinary Technologies Corp. (UTC) is developing a probe-based test to diagnose the specific bacteria causing an infection as we *simultaneously* identify which antibiotics will be most effective at killing those bacteria, all in *less than 2 hours*.



Parallel Antibody Cartridge

UTC accomplishes this by using *proven* probe technologies in our patented and patent pending assays. This approach will enable us to run multiple bacterial assays and the AST in parallel using low-cost disposable cartridges, yielding both a confirmed diagnosis for the 9 bacterial species which cause over 99% of US UTIs and an AST in less than 2 hours. Such tests are *more accurate* and *much faster* than traditional Petri dish cultures.

Furthermore, UTC’s rapid assays are inherently insensitive to contamination. The impact of this for children is significant: urine collection can take place using nappy pads or urine bags rather than invasive and painful methods such as catheter insertion or SPA (needle insertion into the child’s bladder). Accurate results will be available much faster, allowing doctors to prescribe the *right* antibiotic the *first* time.

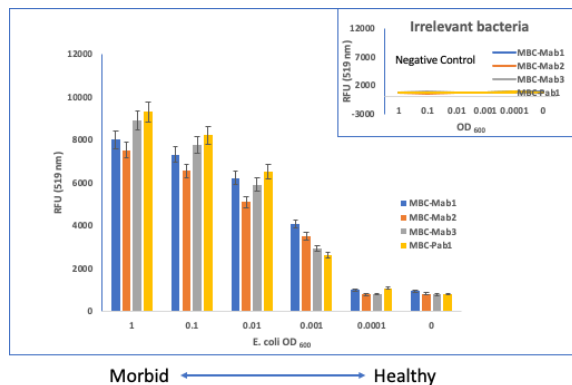
UTC’s benchtop instrument (reader) will fully automate analysis and reporting of the test. A lab technician with minimal training will place a disposable cartridge and a sample in the instrument, push a button and the instrument does the rest.

Including adults, the addressable market for this product is \$1-3 billion. If funded by January 2022, UTC expects 510(k) regulatory clearance and market launch by early 2024.

## DEVELOPMENT STATUS

UTC has demonstrated proof-of-concept using off-the-shelf probes and bacterial samples. Specifically, we used two strains of *E. coli* and four species of unrelated bacteria which are commonly found in UTIs. We attached fluorescent dyes to four different probes specific to *E. coli*. As shown in the chart, without washing or lysing, UTC is able to measure the presence of *E. coli* from morbid infection levels down to healthy levels, while ignoring the unrelated bacteria (chart insert).

UTC has designed disposable cartridges for the test and initial prototypes have been produced. Each cartridge will enable both species diagnosis using probes and an AST using antibiotics to be done on the same substrate. UTC will develop, optimize and patent novel antibodies that are highly sensitive and specific for each of the 9 bacterial species which cause over 99% of US UTIs. UTC will begin discussions with potential instrument producers shortly after completion of financing.



## TEAM

UTC has assembled a highly experienced and proven team to commercialize this product:

- A.R. Weiler, AB, [in](#) CEO, healthcare technology & data start-ups, including multiple company exits
- Chuck Dennis, JD, [in](#) VP & General Counsel, medtech business development/R&D, patent attorney
- Mike Finch, PhD, [in](#) Board Chair, public health and start-up promotion
- Susan Alpert, MD, PhD, [in](#) former FDA Director & Medtronic Senior VP Regulatory, infectious disease pediatrician
- Cari Dutcher, PhD, [in](#) Associate Professor, UMN, test cartridge expert
- Greg Gillispie, PhD, [in](#) President, Fluorescence Innovations, fluorescence expert
- Tom Gunderson, MS, [in](#) former Piper Jaffray analyst, initial public offering (IPO) expert
- Jon Hawkinson, PhD, [in](#) Director, UMN High Throughput Screen & Assay Development, assay expert

## FUNDING REQUEST

UTC is seeking \$1.25 million in convertible debt, which will be used primarily for the following activities:

- Enable research and development to build out a fully functional and tested prototype
- Broaden and strengthen our intellectual property position
- Identify and secure outsourced developers and manufacturers
- Pursue business development including reimbursement and distribution partnerships

UTC anticipates requiring an additional \$4-6 million to finalize UTI product development, establish suppliers, and obtain a 510(k) clearance.

For more information, please contact Chuck Dennis at [Charles.L.Dennis@urinarytechnologies.com](mailto:Charles.L.Dennis@urinarytechnologies.com)