BACTERIOSCAN RECEIVES FDA CLEARANCE
FOR RAPID INFECTION DETECTION SYSTEM

Automated diagnostic system cleared for detection of Urinary Tract Infections

Reduces lab time-to-results from two days to three hours

St. Louis, May 14, 2018 – BacterioScan, Inc. today announced that the U.S. Food and Drug Administration (FDA) has issued a 510(k) Premarket Notification clearance for its 216Dx Urinary Tract Infection (UTI) detection system. The BacterioScan 216Dx system is a rapid automated diagnostic system for the detection of bacterial UTIs, one of the most common types of infection.

Current UTI testing is a labor-intensive, manual culturing process that typically requires two days or more to yield a result. The BacterioScan 216Dx system utilizes an advanced laser sensor to rapidly detect infections, reducing lab turnaround time to just three hours, an improvement of up to 90%.

“Our rapid UTI detection system can quickly guide the most effective therapeutic responses to cure infected patients,” said Dana Marshall, BacterioScan’s President and Chief Executive Officer. “Faster detection of infection means better patient outcomes and diminishes over-prescription of antibiotics. Inappropriate and excessive antibiotic use promotes drug resistance, a serious and growing global health crisis.”

UTIs are among the most common infections, responsible for an estimated 10.8 million emergency department visits in the U.S. annually, and nearly 17% of those visits require hospitalization. UTI symptoms also result in upwards of 10.5 million physician office visits annually and the societal costs of these infections, including health care costs and time missed from work, are approximately $3.5 billion per year in the U.S. alone. Globally, over 150 million UTIs are estimated to occur annually.

In clinical studies of over three thousand patients, the BacterioScan 216Dx was able to correctly identify patients with bacterial infections at a rate of 98.6% (sensitivity) and correctly identify patients without infection at a rate of 99.6% (negative predictive value). This level of performance assures labs of reliable UTI detection, and matches or exceeds the current standard of care in U.S. hospitals.

“Today’s announcement is a significant milestone and the culmination of years of hard work by our team and clinical research partners,” noted Greg Hewett, Chairman of BacterioScan’s Board of Directors. “We are grateful for all their efforts and look forward to continuing to
develop our robust pipeline of additional applications, including antimicrobial susceptibility testing (AST) for UTIs, and infection detection and AST for other bodily fluids,” Hewett added.

BacterioScan has entered into a sales and distribution agreement for its 216Dx system with Fisher Healthcare, part of Thermo Fisher Scientific.

About BacterioScan:
BacterioScan is an in-vitro diagnostics (IVD) company dedicated to changing the way infectious disease is diagnosed and treated by providing rapid, reliable, automated, and accessible microbiology that ensures the successful use of antibiotics. BacterioScan, Inc. is a global, privately held corporation, with headquarters in St. Louis, Missouri. For more information about BacterioScan, visit www.bacterioscan.com, contact BacterioScan at info@BacterioScan.com, or call 844-222-7226 (844-BAC-SCAN).