

FDA clears rapid UTI detection system

October 2018—BacterioScan received FDA 510(k) clearance for its 216Dx Urinary Tract Infection detection system for the detection of bacterial UTIs. The system uses an advanced laser sensor to rapidly detect infections, reducing lab turnaround time to three hours.

In clinical studies of more than 3,000 patients, the BacterioScan 216Dx was able to correctly identify patients with bacterial infections at a rate of 98.6 percent sensitivity and correctly identify patients without infection at a rate of 99.6 percent (negative predictive value).

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