



Improved Sensitivity for Detection of Urinary Tract Infections Using Novel Light Scattering Methodology

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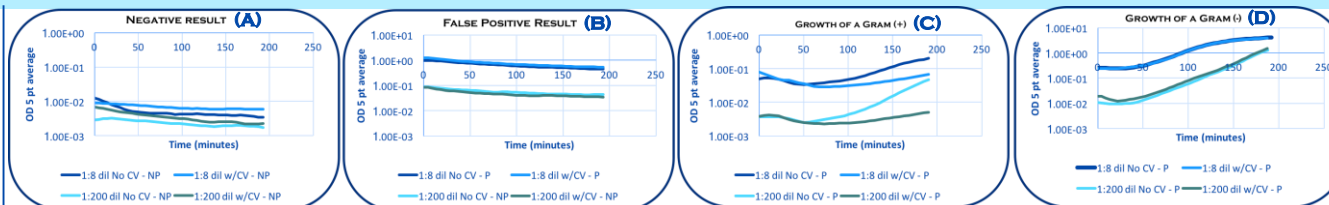
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BACKGROUND

- Urinary tract infection (UTI) is common, and urine culture is one of the highest volume tests performed in clinical microbiology laboratories
- THERE IS OVERUTILIZATION OF URINE CULTURE DUE TO SUBOPTIMAL SCREENING TECHNOLOGY:**
 - Monopolizes laboratory resources
 - As patients await results, there is unnecessary exposure to antibiotics
 - Promotes bacterial antimicrobial resistance
 - Increases risk for *Clostridium difficile* infection
 - Adverse side effects of antibiotic medication
- A common approach is to screen samples using urinalysis (UA) to determine those that should proceed to culture
- THE OBJECTIVE OF THIS STUDY IS TO COMPARE A NOVEL UTI DETECTION METHOD (BacterioScan 216Dx UTI System) TO URINALYSIS FOR SCREENING URINE SAMPLES FOR REFLEX TO CULTURE**
- Secondary objectives:**
 - Evaluate effectiveness of crystal violet to select for Gram negative organisms
 - Determine if a higher dilution decreases the false positive rate without notably sacrificing sensitivity

METHODS

- Urine samples (n=194) were evaluated by UA, culture and BacterioScan 216Dx UTI System to detect the presence/absence of UTI pathogens
- 2 urine dilutions (1: 8 and 1: 200) were prepared in Tryptic Soy Broth (TSB) with and without 2 ug/mL of crystal violet followed by 190 minutes of optical assessment
- UTI detection was defined as growth in culture of one or two uropathogens at densities of $\geq 10,000$ CFU/mL
- Reflex parameters for culture were compared to results from 216Dx to evaluate sensitivity and specificity

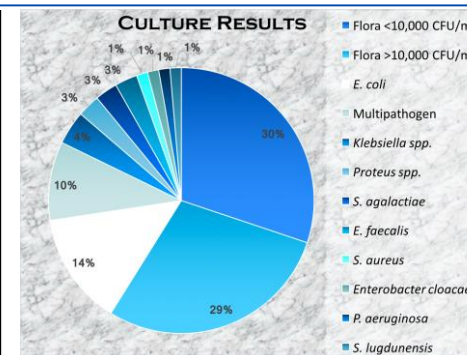
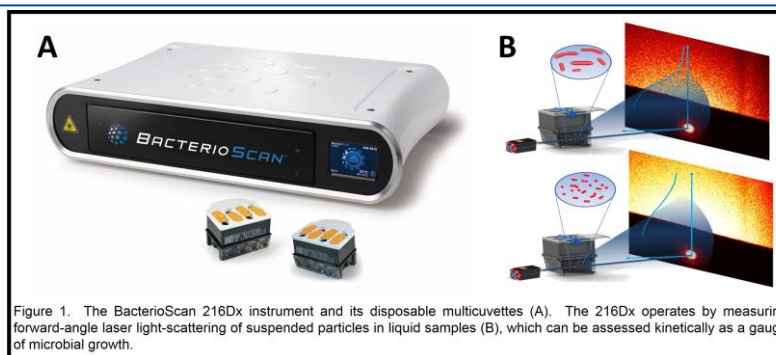


Graphs A-D: The BacterioScan 216Dx performs kinetic optical measurements over a three-hour period to detect changes in signal as a surrogate for microbial growth. The classification algorithm looks for indications of signal increase over the second half of the instrument run, as seen in (C) & (D). It also monitors the overall turbidity of the sample and classifies highly turbid samples as positive even if no detectable positive growth is observed (B), to eliminate the potential of positive samples being masked in a high optical background and reported as false negatives.

	1:8 No CV	1:8 w/CV	1:200 No CV	1:200 w/CV	UA
True Positives	30	23	27	19	26
True Negatives	134	141	148	163	118
False Positives	30	29	16	7	46
False Negative	0	1	2	4	4
Sum	194	194	193	193	194
Sensitivity	100.00%	95.83%	93.10%	82.61%	86.67%
Specificity	81.71%	82.94%	90.24%	95.88%	71.95%
PPV	50.00%	44.23%	62.79%	73.08%	36.11%
NPV	100.00%	99.30%	98.67%	97.60%	96.72%
Accuracy	84.54%	84.54%	90.67%	94.30%	74.23%
Incidence	15.46%	12.37%	15.03%	11.92%	15.46%
% Unnecessary Culture Identified	69.07%	72.68%	76.68%	84.46%	60.82%

**ZERO FALSE
NEGATIVES** with
BacterioScan Screen

69% reduction in
unnecessary culture;
**9% IMPROVEMENT
OVER UA SCREENING**



KEY OBSERVATIONS

- BacterioScan method is more sensitive and specific for the identification of uropathogens than UA
- Screening patients for UTI requires a **HIGH SENSITIVITY** so a UTI is not missed and treatment is not delayed
- Screening with BacterioScan did not miss a UTI in our study (**ZERO FALSE NEGATIVES**)
- Screening with UA missed 4 individuals confirmed to have UTI by culture (4 False Negatives)
- BACTERIOSCAN IDENTIFIED A GREATER NUMBER OF URINES TRULY NEGATIVE FOR PRESENCE OF UROPATHOGENS (69.07% VS 60.82%)**
- Screening with BacterioScan would further reduce unnecessary culture by 9% over UA.
- Crystal violet could select for Gram negative isolates, but lead to an increase in the false negative rate.
- Increasing the inoculation dilution factor decreased the false positive rate by approximately half but decreased the sensitivity (1:8 No CV vs 1:200 No CV)

CONCLUSION

In this study, the BacterioScan System proved to be **A MORE EFFECTIVE METHOD OF SCREENING FOR URINARY TRACT INFECTIONS** than traditional urinalysis.