

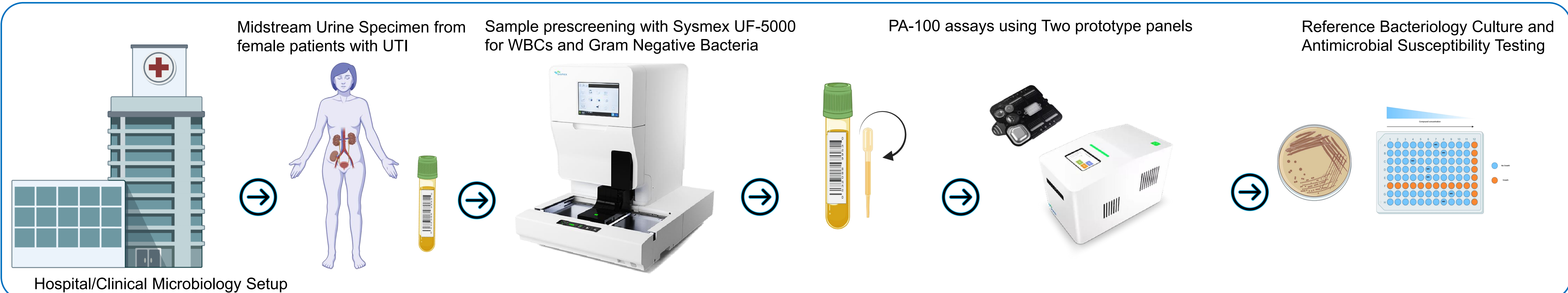
Evaluation of a Point-of-Care Ultra-Rapid Direct AST System for Diagnosing UTIs in a Tertiary Care Setting

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SUMMARY

Sysmex PA-100 AST system is a point-of-care platform for rapid detection of bacteriuria and phenotypic antimicrobial susceptibility testing (AST) directly from urine, delivering actionable results within 45 minutes. We evaluated the diagnostic accuracy of PA-100 AST system with two prototype panels at a tertiary care hospital using clinical urine samples (up to 2 hours old, beyond recommended 30 minutes for this system) from patients suspected with urinary tract infections (UTI). Overall, prototype panel U-0502 demonstrated 92.1% accuracy, 95.0% sensitivity, and 76.9% specificity for bacteriuria detection, while U-0503 achieved 93.7% accuracy, 96.0% sensitivity, and 82.5% specificity. Across antimicrobial susceptibility testing, U-0502 showed categorical agreements ranging 84–94% and 82–97% for U-0503 across their respective antibiotics in the panel.

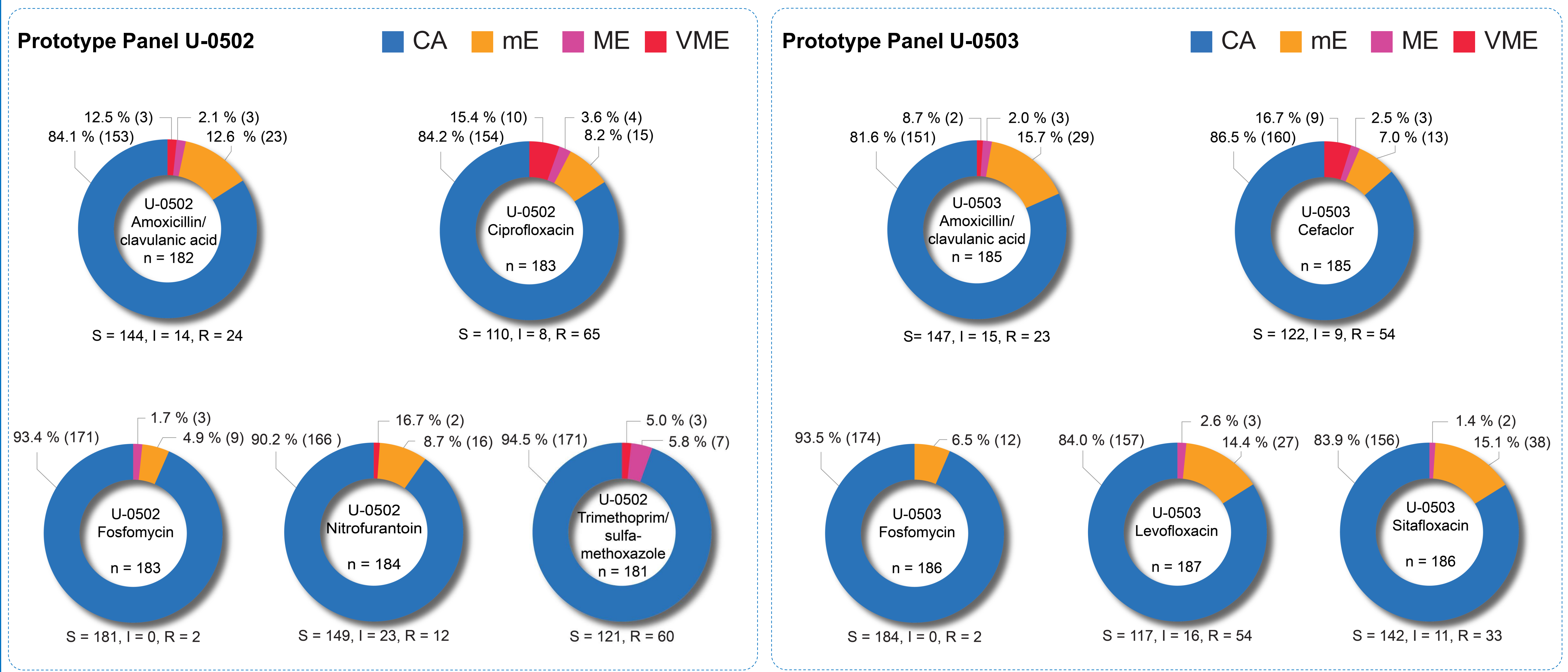
STUDY SETUP



RESULTS

A total of 239 non-repetitive midstream urine specimens from females (≥ 18 years) with suspected UTI were analyzed on the PA-100 using PA-AST prototype panels (U-0502, U-0503) and processed by quantitative urine culture for bacteriuria (cutoff: ≥ 50000 CFU/mL) and reference AST methods (broth microdilution and agar dilution). Since the main goal was to assess AST performance, urine specimens were pre-screened with the Sysmex UF-5000 (Gram-negative bacteria $>500/\mu\text{L}$) and white blood cells ($>10/\mu\text{L}$). This data was also used for the calibration of new prototypes. U-0502 detected bacteriuria with 95.0% sensitivity (95% CI: 91.1–97.3%), and 76.9% specificity (95% CI: 61.7–87.4%), whereas U-0503 showed 96.0% sensitivity (95% CI: 92.3–97.9%), and 82.5% specificity (95% CI: 68.1–91.3%). The results below summarize the AST performance of the PA-100 AST system with positive samples.

AST Performance across prototype panels



CONCLUSION

The study showed that the Sysmex PA-100 AST system provided reliable AST outcomes, demonstrating potential for faster targeted therapy and enhanced antimicrobial stewardship. Results indicated clinical utility even with samples up to 120 minutes old, exceeding the standard 30-minute recommendation for fresh urine. When combined with prescreening, the system showed potential for tertiary care settings involving older or complex samples from complicated UTIs.