Evaluation of the Sysmex PA-100 system for rapid antibiotic susceptibility testing in urinary samples from borate tubes

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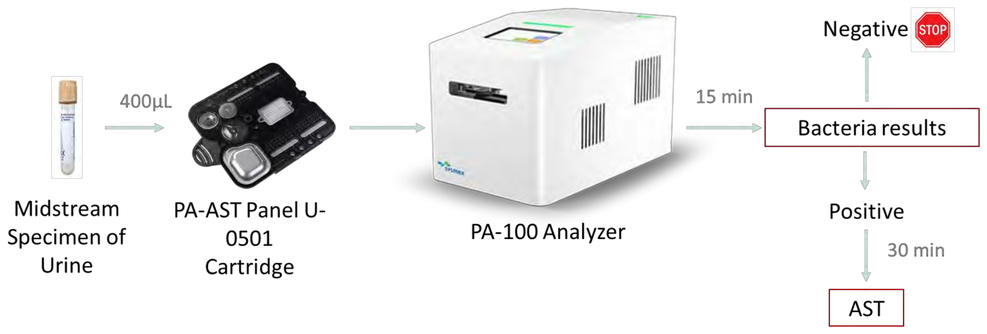
03c. Susceptibility testing methods (incl assay validation, phenotypic assays and comparative studies, excl TB)

P1502

Background and objective

Urinary tract infections (UTIs) are common bacterial infections often requiring empirically antimicrobial therapies. Increasing antibiotic resistance highlights the need for rapid antibiotic susceptibility tests (AST). This “off label” study firstly evaluates the Sysmex PA-100 system (PA100), a nanofluidic-based automated system for rapid AST directly from urine collected in borate tubes (BT), focusing on its medical value on pediatric and male populations.

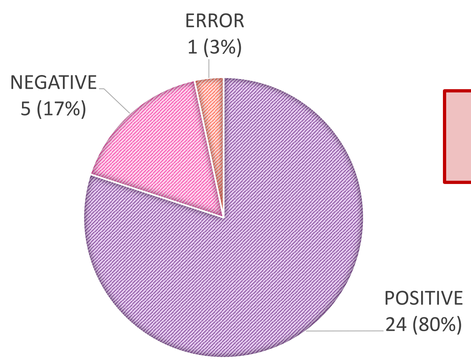
Methodology



30 urines with suspected UTI were prospectively collected in BT. An automatic screening to select eligible samples was performed with UF4000 instrument (Sysmex, Kobe, Japan) for leukocyturia and the positivity of Gram-negative bacilli indicator. Whereas not approved on BT, PA100 was used to detect bacteriuria and perform directly AST. Results were compared to conventional culture (REF) (ChromID CPSE, BIOMERIEUX, Marcy l’Etoile, France) performed on WASP/WASPLab instruments and AST results (VITEK2) combined to MIC strips (E-test) and disc diffusion tests performed according to CA-SFM/EUCAST 2023 rules.

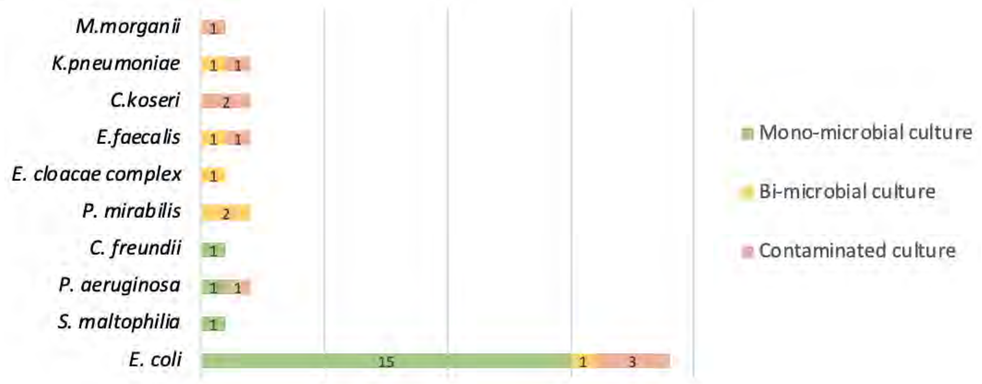
Main findings

1. Diagnostic accuracy of the PA-100 for bacteriuria detection



Sensitivity = 82,7%

Bacteriuria results obtained using the PA-100 analyzer.



Distribution of isolated species in culture for samples with positive bacteriuria detected by PA-100

2. Accuracy of the PA-100 for Antimicrobial Susceptibility Testing (AST)

Performance of the Sysmex PA-100 system for rapid antibiotic susceptibility testing (AST) on urine samples, compared with standard reference methods (VITEK®2, E-test, and disk diffusion).

Antibiotic	Number of results	CA n (%)	VME n (%)	ME n (%)	mE n (%)	Results excluded (E, NA, LG) n (%)
Amoxicillin/Clavulanate	12	**12 (100,0)**	0 (0)	0 (0)	0 (0)	12 (50.0)
Ciprofloxacin	20	**15 (95.0)**	0 (0)	0 (0)	1 (4,2)	4 (16.7)
Fosfomycin	11	**9 (81.8)**	0 (0)	2 (18.2)	0 (0)	13 (54.2)
Nitrofurantoin	20	**19 (95.0)**	1 (4,3)	0 (0)	0 (0)	4 (16.7)
Trimethoprim	23	**20 (87.0)**	0 (0)	2 (8.7)	1 (4.3)	1 (4.2)
Overall performance	24	**91.8%**	**0.9 %**	**5.4 %**	**1.7 %**	**28.3%**

The PA-100 analyzer reported nearly half of the amoxicillin/clavulanate results as errors or low bacterial growth (LG). For fosfomycin, these results affected 50% of the samples. Moreover, the majority of LG and error results for these two antibiotics were observed in samples stored at 4°(not approved by the manufacturer).

***CA** = Categorical Agreement; **VME** = Very Major Errors; **ME** = Major Errors**; mE** = Minor Errors **E** = technical errors; **LG** = low bacterial growth; **NA** = not applicable - Results classified as E, LG or NA were excluded from CA calculations.*

3. Potential impact and medical value of the PA-100 system

Regarding turnaround time (TAT), the PA100 **delivered results in 45 minutes**, compared to the REF, which typically required 24-48 hours. Based on antimicrobial therapies initiated **before** and **after** receiving PA100 AST results, **at least 20% of patients would have benefited from earlier appropriate therapies** compared to the REF workflow. With its shorter TAT, the PA100's medical value could enhance **early treatment in 50% of cases** by enabling appropriate and timely therapy, particularly **reducing the use of broad-spectrum antibiotics**.

Conclusions

The PA100 demonstrated **good accuracy** on BT compared to the REF.
The PA100 system shows **promise for the rapid diagnosis and management of UTIs**, particularly in emergency departments. Larger-scale studies are needed to validate these performance results, especially by further investigating the impact of pre-analytical conditions, optimizing workflows, and measuring real-life potential improvements in antibiotic stewardship and reductions in healthcare costs.

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