Interim Results from the Analytical Validation of Rapid Direct from Urine and Urine Isolate Microcapillary Antimicrobial Susceptibility Testing (AST)

Sarah Helen Needs[1,2], Julie Hart[1,2], Hoyin Lam[3], Oliver Hancox[1,2], Stephen Kidd[3], Alexander Edwards[4,1]

[1]Astratus Limited, Reading, United Kingdom.
[2]University of Reading, Reading, United Kingdom.
[3]Hampshire Hospitals NHS Foundation Trust, Basingstoke, United Kingdom.
[4]University of Southampton, Southampton, United Kingdom

Abstract

Background

Standard manual culture AST methods are laborious with slow turnaround (2-7days+). Automated rapid AST diagnostic products have emerged but remain expensive. Faster, higher throughput, easy to use, accurate and affordable AST is still needed for both human and veterinary clinical medicine as part of a One Health approach. Astratus Limited was spun out of University of Reading (November 2024) to deliver a novel testing platform to meet this need. We present here interim findings from our clinical study evaluating the analytical performance of microcapillary AST with >450 urine samples from patients with suspected Urinary Tract Infection (UTI).

Methods
Analytical validation was conducted on urine samples and isolates from patients with suspected Urinary Tract Infection (UTI). Samples were spot plated onto Chromoagar UTI brilliance to obtain a presumptive ID and total viable count. Reference methods were conducted alongside; for diagnostic remnants, disc diffusion (EUCAST v12.0), for fresh samples broth microdilution according to ISO 20776-1:2019 and ISO 20776-2:2019 for results comparison.

Results
Interim analysis showed 96% sensitivity (95% CI: 87-99%) and 99% specificity (95% CI: 97-100%) for detecting microbial growth in urine for samples $>10^5$CFU/mL. Of 367 samples, 129 were considered positive $>10^5$ CFU/mL and 238 negative $<10^5$ CFU/mL by bacterial plate counts. Moreover, samples with growth of single Enterobacterales showed categorical agreement of ampicillin 90%; amoxycillin 95%; nitrofurantoin 100%; trimethoprim 95%; ciprofloxacin 100%, cefalexin 95% for microcapillary AST direct from urine compared to disc diffusion.

Conclusions
The unique patented properties of our microcapillary technology enables rapid, accurate AST at low cost. The scalable instrument configuration provides high throughput capability to improve productivity, digitise results, and optimise antimicrobial use. Additionally, our rapid AST platform could be used by researchers and companies

developing new antimicrobials or novel therapies, including phage therapies, and investigating biofilms.

Figure 1. Interim workflow for microcapillary AST.