

Amended Abstract

Background: Urinary tract infections (UTIs) are one of the most common infections, associated with 10.5 million outpatient visits annually. Fast and accurate identification (ID) of bacteria causing a UTI would allow for immediate targeted therapy, as opposed to conventional methods which take one to three days. The Accelerate Pheno[®] system (ACC, Accelerate Diagnostics Inc., Tucson, AZ, USA) provides microbial ID and susceptibility (AST) from positive blood cultures. Our objective was to determine ACC's potential to quickly ID bacterial pathogens directly from urine.

Materials/methods: Remnant urine samples with >100K colony forming units (CFU)/mL of gram-negative bacteria as determined by quantitative plating were obtained from the clinical lab. 1.5ml of urine was loaded onto the Accelerate PhenoPrep[™] module, then into the ACC for analysis using a custom designed assay which detects the presence of bacteria and employs an *Enterobacteriaceae* family specific FISH probe. The results were compared to standard of care ID results.

Results: There were 10 *E. coli* and 1 *C. koseri* among the eleven samples tested. Baseline concentration of samples immediately prior to testing ranged from 2.5 x 10⁶ to 1.08 x 10¹⁰ CFU/mL (average 4.19 x 10⁹). After specimen processing, average concentration was 2.14 x 10⁹ CFU/mL and average recovery was 42.83%. ACC detected bacteria and identified it as *Enterobacteriaceae* in 11/11 samples (100%). Average sample prep time was 55 min. Average time to *Enterobacteriaceae* ID was 8.6 hrs. Average total time to ID, including specimen processing, was 9.5 hrs.

Conclusions: ACC identified *Enterobacteriaceae* directly from remnant urine specimens in an average of 9.5 hours, approximately 24 to 48 hours faster than conventional methods. ACC was able to be adapted for use in urine samples.

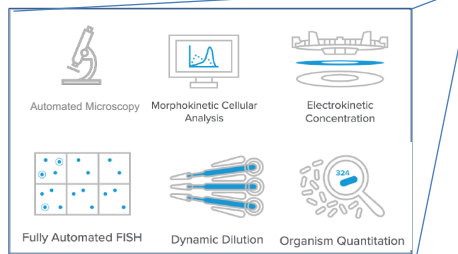
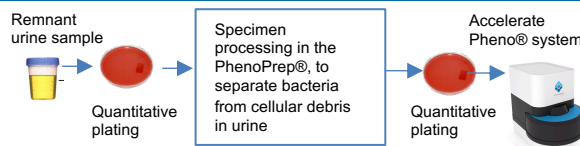
Background

We chose to focus on urine specimens because of the **clinical impact of Urinary Tract Infections (UTIs):**

- > 10.5 million outpatient visits for UTIs in the year 2000
- > A very common reason for outpatient antibiotic prescriptions
- > Cost 3.5 billion US dollars annually
- > Current methods take 1 to 3 days to provide a microbiologic diagnosis
- > The Accelerate Pheno[®] system (ACC, Accelerate Diagnostics Inc., Tucson, AZ, USA) can provide microbial ID and susceptibility (AST) from positive blood cultures.

Hypothesis: The ACC can quickly ID bacterial pathogens directly from urine

Methods



→ Report is generated to determine presence of bacteria and Enterobacteriaceae

Results

Microbiology of clinical samples tested



■ E.coli ■ C.Koseri

Baseline Concentration of Samples (mean CFU/ml)	Post specimen processing (mean CFU/ml)	Recovery (Mean Post specimen processing concentration/baseline concentration in CFU/ml)
4.19 x 10 ⁹	2.14 x 10 ⁹	42.83%.

Results

	Bacteria Detected?	Enterobacteriaceae Detected?	Concordance with clinical lab
Total n=11	11	11	100%
E.coli n=10	10	10	100%
C. koseri n=1	1	1	100%

Sample prep time (mean)	Time to Enterobacteriaceae ID (mean)	Total time to ID (mean)	Conventional Methods (mean)	Time saved (mean)
55 min	8.6 hrs	9.5 hrs	24-48 hrs	26.5 hrs

Limitations

- Remnant samples were used for testing
- Small sample size
- Was difficult to obtain other species due to abundance of *E. coli* in clinical samples available

Conclusions

- ACC identified *Enterobacteriaceae* directly from remnant urine specimens in an average of 9.5 hours, approximately 24 to 48 hours faster than conventional methods.
 - ACC was able to be adapted for use in urine samples.
 - Future directions include improving the assay to identify bacteria to the species level and adding AST testing.
- ★ **This shows promise in providing fast actionable UTI diagnosis, allowing for tailored antibiotic therapy.**

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