

Authors

Sylvain Rama [1], Mathew Kyriakides [1], Henry Newman [1], Kabir Bonney-Bhandal [1], James Preece [1], Jean-Baptiste Vendeville [1], Neciah Dorh [1], and Josephine Dorh [1]

[1] FluoretiQ Limited, Unit DX, St Philips Central, Albert Road, Bristol BS2 0XJ

Title

Rapid 15-minute test to identify the 3 most common gram-negative uropathogens in Urinary Tract Infections

Introduction

6.2 million cases of Urinary Tract Infection (UTI) are reported in England and Wales every year and have the second highest antibiotic prescription rate. The absence of fast and sensitive diagnostics tests has increased empirical antibiotic use has contributed to the rise of antibiotic-resistant infections.

To address this challenge, we have developed NANOPLEX: a rapid 15-minute test that uses glycan-functionalised-latex nanoparticles, microscopy and image-analysis software to identify and enumerate samples with bacteria.

In this work, we show that NANOPLEX can correctly identify the 3 most common uropathogens using lab reference strains, clinical isolates and clinical urine samples.

Materials and Methods:

The NANOPLEX assay was performed as per Vendeville et al 2021. ACS Biomater 2022; 8, 1:242-252.

Clinical isolates of *E. coli*, *K. pneumoniae*, and *P. mirabilis* were obtained from an NHS clinical microbiology lab waste stream. N=30 isolates (per species) were tested via single-blind study protocols at concentrations between 10^3 – 10^8 CFU/mL and compared to microbial culture to define performance metrics (sensitivity, specificity, PPV, NPV and accuracy) of each probe.

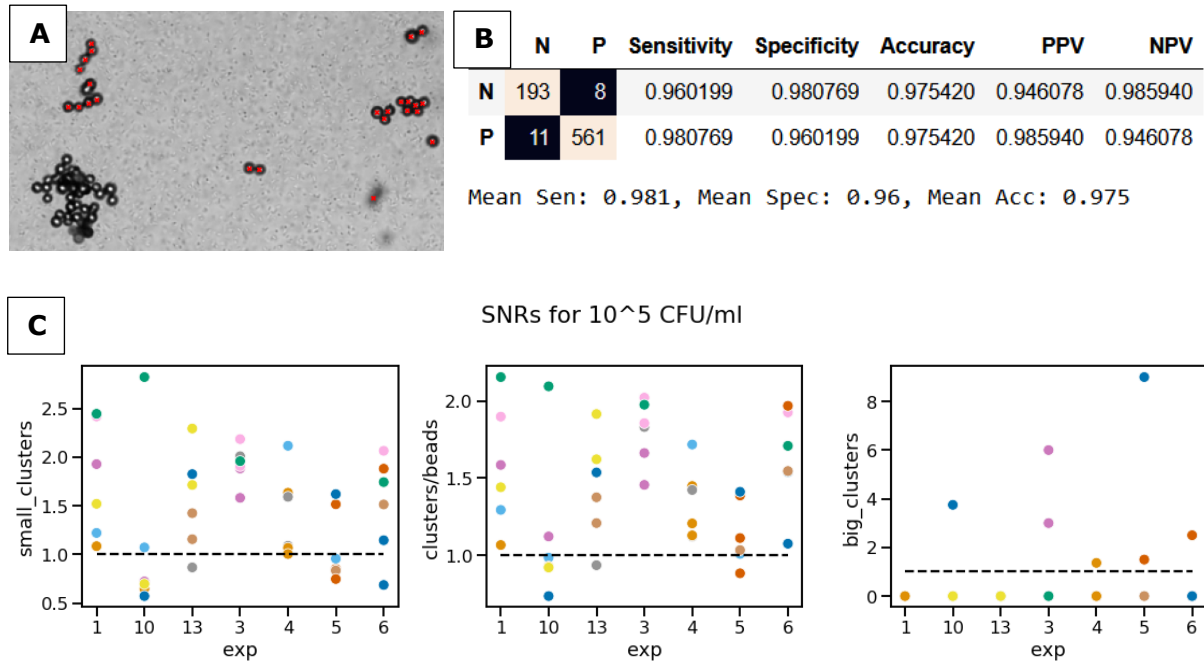
Results

A total of 90 isolates were tested against their target probes and demonstrated >90% accuracy (Sens 88-90%, Spec 94-98%, PPV 93-98%, 88-90% NPV, Accuracy 91-94%) for all probe-bacteria combinations at clinically significant concentrations (10^5 CFU/ml).

Discussion

NANOPLEX™ was able to successfully detect the top 3 common gram-negative pathogens in UTI at clinically relevant concentrations. A compact hardware and single-use cartridge system is under development to enable urologists to conduct rapid and accurate UTI testing in point-of-care environments. Larger clinical studies are planned to clinically validate these results.

Figures



A: Example of brightfield microscopy image processed by NANOPLEX

B: Summary of performance metrics for E. coli samples

C: Example of weighted classification scores for E. coli samples

References

1. Global Burden of Antimicrobial Resistance in 2019: a systematic analysis. Murray et al. 2022. The Lancet. [https://doi.org/10.1016/S0140-6736\(21\)02724-0](https://doi.org/10.1016/S0140-6736(21)02724-0)
2. Fast Identification and quantification of uropathogenic E.c coli through cluster analysis. Vendeville et al 2019. ACS Biomaterials. DOI: <https://doi.org/10.1021/acsbmaterials.1c00732>