TITLE: <Same day visual bacterial identification and semi-quantitative antibiotic sensitivity assay directly from clinical samples>

Authors: <u>Roshan Ratnakar Naik</u>¹, Lakshmi Swaroopa Naik¹, Pradnya Naik², Sachin Pawar³, Annie Rajan⁴, Maria Jose Wiseman Pinto², Rakshat Eknath Paryekar²

Affiliation of the Authors:

- 1. Diagopreutic Private Limited, Ponda-Goa, 403 401
- 2. Department of Microbiology, Goa Medical College, Bambolim, 403 202
- 3. Department of Data science and computer application, Manipal Institute of Technology, Manipal, Karnataka 576104
- 4. Department of Computer Science, Dhempe College of Arts and Science, Miramar, Panaji, Goa 403001

Introduction: <Urinary tract infections (UTIs) account for 150 million cases annually worldwide with a prevalence rate of 33.54% in India^{1,2}. Treatment without diagnosis is common during UTI treatment as reliable diagnosis takes 2-3 days and not getting the right treatment contributes towards antimicrobial resistance (AMR) and recurrent UTIs in 20-30% women. AMR continues to be a global public health challenge due to improper and excessive use of antibiotics in human health, animal welfare leading to severe antimicrobial resistant infections, disease complications and mortality. The current diagnosis of urinary tract infections (UTIs) involves a qualitative 2 minute dipstick analysis with a 25-75% sensitivity and 94-100% specificity but exact identification of microorganisms and the right antibiotics requires urine culture which takes 2-3 days, trained personnel and misses out nearly 48% UTI cases³. We tested the performance parameters of a novel urinary tract infection diagnosis kit (ESKAPE kit) in comparison to standard urine culture and sensitivity (UC/S) methods>

Material & Methods: <Standard urine culture and sensitivity methods along with ESKAPE test results with clinical urine specimen (n=218). The study was carried out at the department of microbiology, Goa medical college, bambolim with clinical urine specimen from both outpatient and inpatients.The data was analyzed using Microsoft Excel/GraphPad Prism software.>

Results: <The ESKAPE assay had a 95% sensitivity, 98% specificity, 98.1% positive predictive value, 95.5% negative predictive value and 96.8% accuracy in comparison to standard urine culture and sensitivity tests (UC/S). The tests were completed within 6 hours unlike 48 hours with the standard UC/S, required 3 steps from sample inoculation to final results and requires an incubator. According to the CLSI breakpoints, antimicrobial susceptibility testing (AST) with ESKAPE kit gave 96% correct category agreement, 0.85% very major errors, 0.15%

major errors, and 2.8% minor errors. The AST showed category agreement from 93-100% for *E. coli*, and 95-100% for *K. pneumoniae*. Sample result shown in Fig. A>



Figure A: 1. Disk diffusion assay, 2. ESKAPE test and 3. Color chart for result interpretation. Meropenem (MPM) was sensitive for patient 1 in both disk diffusion assay and ESKAPE kit(lower color change than control) while piperacillin-tazobactam (PTZ) was resistant in disk diffusion assay and ESKAPE kit (same color change as control). Patient 2, had both MPM and PTZ resistant in both methods.

Conclusion: <Same day bacteriuria detection and antibiotic sensitivity can help improve antibiotic stewardship, also make it accessible for primary and community health centers.>

References:

1Pardeshi, P. (2018). Prevalence of urinary tract infections and current scenario of antibiotic susceptibility pattern of bacteria causing UTI. Indian J Microbiol Res., 5(3), 334-338.

2Öztürk, R., & Murt, A. (2020). Epidemiology of urological infections: a global burden. World journal of urology, 38(11), 2669–2679.

3Harding, C *et al* (2022). Alternative to prophylactic antibiotics for the treatment of recurrent urinary tract infections in women: multicentre, open label, randomised, non-inferiority trial. BMJ (Clinical research ed.), 376, e068229.

4 Naik RR, Naik LS (2023). A kit for identifying bacteria and determining antibiotic sensitivity. The Patent Office Journal No. 39/2023 Dated 29/09/2023. Patent