Clin. Lab. 2026;72:XXX-XXX

ORIGINAL ARTICLE

Performance Evaluation of HB&L Uroquattro System for Urinary Tract Infection Rapid Screening

Changyu Xia, Bohan Na, Lei Huang

Department of Clinical Laboratory, Peking University First Hospital, Beijing, China

SUMMARY

Background: **Precise and rapid pathogen identification is key in urinary tract infection (UTI) treatment. A negative rapid urine culture screening result provides critical information for clinical decision-making. Though the urine culture is the "gold standard" for UTI diagnosis, it usually takes about 48 hours to determine that bacteria aren't present in the culture. The HB&L uroquattro system (Aifax, Italy), formerly URO-QUICK, which can rule out the negative samples within 4 hours, should be evaluated for routine diagnostics. To this aim, this study evaluated the diagnostic accuracy of the HB&L uroquattro system by comparing with the gold standard conventional culture method and exploring the application value in clinical setting.**

Methods: **A total of 300 midstream urine samples were both cultured by routine method and HB&L uroquattro system in this study. Diagnostic performance in terms of sensitivity, specificity, positive and negative likelihood ratios, positive and negative predictive values were calculated. To evaluate the relationship between turbidity and report time, the urine samples were measured as McFarland turbidity (following the method of reference [13]) before being loaded on the machine. The instrument provided HB&L turbidity when sample was reported as positive.**

Results: **In total, 218 (73%) urine samples showed identical results by both methods, only 13 (6%) samples were misclassified as sterile by HB&L uroquattro system. At 10^2 CFU/mL, HB&L has the highest sensitivity with 91.67% (95% CI: 86.27% - 95.07%). At 10^5 CFU/mL, HB&L has the highest specificity with 97.22% (95% CI: 93.08% - 98.91%). McFarland turbidity showed a stronger correlation with report time.**

Conclusions: **The HB&L uroquattro system can give reliable urine microbiological results within 4 hours in appropriate clinic settings.**

(Clin. Lab. 2026;72:xx-xx. DOI: 10.7754/Clin.Lab.2025.250604)

Correspondence:
Lei Huang
Department of Clinical Laboratory
Peking University First Hospital
Beijing, 100034
China
Phone: +86-10-83572107
Email: leihuang2031@bjmu.edu.cn

Manuscript accepted July 14, 2025

KEYWORDS

HB&L uroquattro system, urinary tract infection, rapid screening, accuracy assessment

INTRODUCTION

Urinary tract infection (UTI) is one of the most prevalent diseases, encompassing common community or hospital acquired infections of people in all age groups [1-3]. Women in the age group of 15 - 44 are more prone to this infection [4]. Approximately 40% - 60% of women and 12% of men experience symptomatic UTI at some points in their lives [5,6].

Precise and rapid pathogen identification is key in UTI

treatment. The urine culture is the "gold standard" for UTI diagnosis. It usually takes about a day for bacteria from a urine sample to grow to sufficient quantities that they can be detected and identified using standard clinical microbiology lab techniques, and consequently it also takes at least this long to determine the negative culture results. Moreover, the percentage of positivity in urine samples varies from 20% to 30% in different settings and the rest of the samples were found to be sterile [7]. A negative rapid urine culture screening result provides critical information for clinical decision-making, ensures rational medication use, and offers essential protection for high-risk groups [8-10]. For patients with urological disorders such as kidney stones or benign prostatic hyperplasia, rapid urine culture helps rule out bacterial infections, ensuring safe and effective subsequent treatments. Pregnant women are prone to asymptomatic bacteriuria, which can progress to cystitis or pyelonephritis if undetected. Regular urine culture screening is vital for early detection and management, safeguarding maternal and fetal health. Elderly individuals and diabetic patients are immunocompromised, leading to a higher risk of UTIs. Rapid screening aids in early diagnosis and prevention of complications. In emergency settings, quickly determining the presence or absence of a UTI guides appropriate antibiotic use, preventing unnecessary broad-spectrum antibiotic prescriptions and reducing antibiotic resistance. Infants and young children often cannot articulate their discomfort effectively. Rapid urine culture helps clinicians promptly identify potential severe infections, enabling timely treatment. In summary, this test is indispensable in evaluating suspected UTI symptoms in all relevant patient populations.

The HB&L Uroquattro (Aifax, Italy) formerly UROQUICK rapid culture system, has been reported to provide pathogen identification and quantitative results in a shorter time, aiding in early clinical diagnosis [11,12]. It monitors the growth phases of bacteria from the inoculum step into specific culture broths providing real time growth curves and quantitative bacterial count results in colony forming unit (CFU)/mL. It rules out the negative samples within 4 hours, hence helping clinicians to rule out the possibility of UTI and shift their attention to find an alternative etiology. To this aim, this study evaluated the diagnostic accuracy of the HB&L uroquattro system by comparing with the gold standard conventional culture method and explored the application value in a clinical setting.

MATERIALS AND METHODS

This prospective observational study included a total of 300 midstream urine samples, collected in sterile containers and received at the clinical microbiology laboratory of Peking University First Hospital as part of routine diagnostic procedures. The samples were obtained from both outpatients and inpatients presenting with symptoms suggestive of urinary tract infections (UTIs) during the period from July to August in 2024. All samples were processed within 2 hours of collection for routine urine analysis and culture. This study was approved by the ethics committee of Peking University First Hospital with reference number No. 2023-293.

Urine culture

Semi-quantitative urine cultures were conducted on all samples using standard methods with Blood agar and MacConkey agar. Prior to inoculation, urine samples were gently mixed to ensure uniformity. A calibrated 10 µL loop was used to inoculate the agar plates, with a single vertical streak followed by horizontal streaking to evenly distribute the sample. The plates were incubated aerobically at 35 - 37℃ for 24 hours, and checked every 18 - 24 hours for colonies. After incubation, the colonies were counted to determine the colony-forming units per milliliter (CFU/mL) as bacterial counts.

HB&L uroquattro system (Alifax, Polverara, PD, Italy)

The instructions provided in the reagent kit were strictly followed; 500 µL of midstream urine was added to 2 mL of liquid culture medium. After thoroughly mixing, the sample was incubated in the HB&L uroquattro system. Bacterial growth was monitored in real time using laser scattering technology to generate growth kinetic curves. When bacterial growth was detected in the culture vial (threshold set at 500 CFU/mL), the instrument provided measurements of HB&L turbidity, bacterial count and report time for the sample. The bacterial concentration in the original sample was then calculated using a nonlinear least-squares fitting algorithm based on the growth curve. Samples never reporting positive were recognized as negative beyond 4 hours.

To evaluate the relationship between original turbidity and report time, the urine samples were measured as McFarland turbidity by a McFarland Nephelometer before being loaded on the machine. The detailed method of measuring urine turbidity using McFarland standard could be found in the study by Angaali N et al. [13], in which the turbidity of urine was adjusted to 0.5 McFarland for the next bacterial identification. The McFarland standards were prepared according to Ballabio et al. [14].

Statistical methods

Diagnostic performance in terms of sensitivity, specificity, positive and negative likelihood ratios, positive and negative predictive values were calculated using MedCalc version 12.1.4 (MedCalc Software bvba, Mariakerke, Belgium).

The primary aim was to evaluate how McFarland turbidity and HB&L turbidity relate to the report time. Pearson's correlation and linear regression analysis were calculated between the quantitative variables (McFarland turbidity, HB&L turbidity) and report time. Pearson's correlation coefficient measures the linear re-

lationship between two variables, ranging from -1 to 1. A value close to 1 indicates a strong positive correlation, close to -1 indicates a strong negative correlation, and close to 0 indicates no linear correlation.

RESULTS

Comparison of bacterial counting between HB&L and conventional culture

Among the total 300 urine samples processed, 130 were from the inpatient department and 170 from the outpatient department. Of these samples, on conventional culture, 156 (52%) were scored as positive cultures based on urinary bacteria counts and clinical conditions. A total of 144 (48%) cultures were negative after 24 hours of incubation, of which 12 (4%) showed gross contamination (3 types of organisms $\geq 10^5$ CFU/mL without any dominant organism). However, in HB&L, 139 (46%) urine samples were negative, but among them, 13 (6%) were misidentified because they had significant growth in conventional culture. In total, 143 (48%) samples were both positive and 126 (42%) of samples were negative by both methods as shown in Table 1. As for urinary bacteria counting, 218 (73%) urine samples had identical results by both HB&L uroquattro system and conventional culture.

Diagnostic performance of HB&L uroquattro system in comparison to conventional culture

To define the diagnostic performance of the HB&L for urine samples, all categories were included in the final calculations (Table 2). Diagnostic performance was calculated at four different bacterial counts i.e., 10^2, 10^3, 10^4 and 10^5 CFU/mL. At 100 CFU/mL, HB&L has the highest negative predictive value i.e., 90.78% (with 95% CI of 84.86% - 94.53%) and sensitivity i.e. 91.67% (with 95% CI of 86.27% - 95.07%). At 10^5 CFU/mL, HB&L has the highest positive predictive value i.e., 96.90% (with 95% CI of 92.30% - 98.79% and specificity i.e., 97.22% (with 95% CI of 93.08% - 98.91%).

Comparison of HB&L uroquattro system and conventional culture based on bacterial identification

Both on conventional culture and HB&L, pure growth of single organism was obtained in 128 (42.7%) urine samples, while 3 (1.0%) and 12 (4.0%) samples exhibited growth of two and three organisms, respectively. The most frequently isolated organisms were *Escherichia coli* (39/143, 27.3%) followed by *Candida albicans* (14/143, 9.8%), *Klebsiella pneumoniae* (13/143, 9.1%), *Proteus mirabilis* (11/143, 7.7%), *Pseudomonas aeruginosa* (8/143, 5.6%), *Enterococcus faecalis* (7/143, 4.9%), *Candida tropicalis* (6/143, 4.2%), *Enterococcus faecalim* (5/143, 3.5%), *Candida glabrata* (5/143, 3.5%), *Enterobacter cloacae complex* (4/143, 2.8%) and others.

However, 13 isolates were obtained from conventional culture, but were reported negative by HB&L, which included *Candida albicans* (5/13, 38.5%), *Candida glabrata* (3/13, 23.1%), *Enterococcus faecalim* (2/13, 15.4%) and *Pseudomonas aeruginosa* (1/13, 7.7%).

Correlation between HB&L turbidity or McFarland turbidity and report time

A moderate negative correlation was observed between HB&L turbidity and report time ($r = -0.436$, $p = 6.67 \times 10^{-5}$), indicating an inverse relationship. Regression analysis revealed that for each unit increase in HB&L turbidity, report time decreased by approximately 15.1 units (intercept = 107.68). A stronger negative correlation was found between McFarland turbidity and report time ($r = -0.648$, $p = 1.40 \times 10^{-10}$), suggesting a more pronounced inverse relationship compared to HB&L turbidity. For each unit increase in McFarland turbidity, report time decreased by about 4.29 units (intercept = 115.53). Both HB&L turbidity and McFarland turbidity exhibited significant negative correlations with report time, implying that higher turbidity measures are associated with reduced report time. Notably, the relationship with McFarland turbidity was stronger, although the regression coefficients indicated that HB&L turbidity had a larger absolute effect on report time.

DISCUSSION

Conventional urine culture, the gold standard for diagnosing UTIs, typically requires 2 - 3 days to yield results, often necessitating empirical antibiotic therapy while awaiting final culture readings. To address this delay, an automated, rapid urine testing method is urgently needed to reduce costs associated with sterile urine samples and provide negative results within 4 hours. However, only a limited number of studies have compared the performance of an automated system with a conventional culture [15-18].

In this study, we evaluated the HB&L uroquattro system for bacterial quantification and organism identification in comparison to conventional urine culture, demonstrating its diagnostic accuracy for UTIs. Our results revealed a strong concordance in bacterial counts between the HB&L uroquattro system and conventional urine culture. Specifically, 73% of urine samples yielded identical results, and 42% were identified as negative by both methods. This concordance exceeds that reported by Ilki et al., who observed agreement in 66% of samples, with 25.6% reported as negative by both methods [14], but it is slightly lower than the findings of Bhawna Sharma et al., who reported 78% concordance and 47% sterility [19]. Notably, while the HB&L uroquattro system identified 139 (46%) urine samples as negative, 13 (6%) of these were misclassified, as they exhibited significant growth in conventional culture. This discrepancy highlighted the need for further refinement of automated systems to minimize false negative results and enhance diagnostic reliability. False-positive results were observed in 18 isolates, necessitating con-

Table 1. Bacterial counting results comparison between HB&L uroquattro system and conventional culture.

HB&L (CFU/mL)		Conventional culture			
		Sterile (n = 144)	Positive		
			$< 10^3$ (n = 4)	10^3 - 10^4 (n = 64)	$\geq 10^5$ (n = 88)
Sterile (n = 139)		126	1	12	0
Positive	$< 10^3$ (n = 2)	2	0	0	0
	10^3 - 10^4 (n = 30)	12	0	11	7
	$\geq 10^5$ (n = 129)	4	0	44	81

Dark Grey cells represent concordance positive results; underlined line numbers represent identical bacterial counting results.

Table 2. Performance evaluation of HB&L uroquattro system at different cutoff values for bacteria after 4 hours.

HB&L uroquattro system cutoff	Sensitivity (95% CI)	Specificity (95% CI)	Positive predictive value (95% CI)	Negative predictive value (95% CI)
10^2	91.67% (86.27% - 95.07%)	88.89% (82.71% - 93.04%)	88.82% (83.02% - 92.81%)	90.78% (84.86% - 94.53%)
10^3	91.47% (86.07% - 94.57%)	87.50% (81.11% - 91.94%)	89.94% (84.28% - 93.71%)	90.65% (84.66% - 94.45%)
10^4	85.90% (79.57% - 90.50%)	91.67% (85.99% - 95.17%)	91.78% (86.18% - 95.24%)	85.71% (79.32% - 90.37%)
10^5	80.13% (73.18% - 85.63%)	97.22% (93.08% - 98.91%)	96.90% (92.30% - 98.79%)	81.87% (75.42% - 86.92%)

Table 3. Organism comparison between HB&L uroquattro system and conventional culture.

Organisms	Identical results (C+/HB&L+)	Different results (C+/HB&L-)
Escherichia Coli	39	0
Candida albicans	14	5
Klebsiella pneumoniae	13	0
Proteus mirabilis	11	0
Pseudomonas aeruginosa	8	1
Enterococcus faecalis	7	0
Candida tropicalis	6	0
Enterococcus faecalim	5	2
Candida glabrata	5	3
Enterobacter cloacae complex	4	0
Candida parapsilosis	3	0
Morganella morganii	3	1
Corynebacterium striatum	2	0
Enterobacter asburiae	1	0
Providencia rettgeri	1	0
Enterococcus raffinosus	1	0
Serratia marcescens	1	0
Enterobacter kobei	1	0
Pseudomonas putida	1	0
Staphylococcus epidermidis	1	0
Aeromonas Caviae	1	1

firmatory testing (e.g., Gram staining or microscopic examination) were necessary after positive reporting to improve diagnostic accuracy. Among the 13 isolates yielding false-negative results, *Candida albicans* and *C. glabrata* predominated. Pre-loading nephelometric turbidity measurements for these samples were negligible (~ 0). Following a 4-hour incubation, most exhibited turbidity values below 0.5, while five isolates demonstrated elevated turbidity (> 1.5). Notably, *Candida* species particularly *C. glabrata* exhibit slow growth kinetics, with microcolonies often requiring ≥ 48 hours for visual detection. Standard laboratory protocols typically discard routine urine culture plates after 48 hours, potentially leading to under detection of *C. glabrata* [20]. False-negative results were additionally observed in two *Enterococcus faecalis* isolates, along with single isolates of *Pseudomonas aeruginosa*, *Morganella morganii*, and *Aeromonas caviae*.

The pre-culture turbidity, measured using a nephelometer prior to initiating rapid culture, was expressed as McFarland Turbidity. However, the turbidity changes during rapid culture were automatically recorded by the instrument, with each sample's initial turbidity serving as the baseline reference. The final turbidity value (Turbidity), recorded at the conclusion of the incubation period, demonstrated limited clinical significance. Besides bacteria, urine turbidity can also be affected by many factors, such as crystals and lipid particles. Our results showed the McFarland turbidity was correlated with the report time; however, more studies should be conducted for further validation.

The HB&L uroquattro system demonstrated optimal negative predictive value (NPV = 90.78%) and sensitivity (91.67%) at a threshold of 10^2 CFU/mL. At a higher threshold (10^5 CFU/mL), it achieved superior positive predictive value (PPV = 96.90%) and sensitivity (97.22%). For screening purposes (minimizing false negatives), cutoff of 10^2 CFU/mL is recommended, yielding a low false-negative rate (FNR = 8.3%). For confirmatory diagnosis (minimizing false positives): A cutoff of 10^5 CFU/mL is preferred, with a false-positive rate (FPR) of only 2.8%.

The HB&L uroquattro system has inherent limitations in detecting slow-growing microorganisms (e.g., fungi), as insufficient biomass accumulation within the 4-hour incubation may lead to false-negative results. Consequently, this method demonstrates optimal performance for rapidly growing uropathogens, while potentially underdetecting slow-growing pathogens. Additionally, positive results require confirmation through Gram staining and subculture to discriminate true infections from false positives caused by contamination or polymicrobial growth. Bacterial growth-positive samples can be standardized to a 0.5 McFarland suspension for direct use in identification and antimicrobial susceptibility testing. Notably, the HB&L Uroquattro system demonstrates promise in rapidly differentiating carbapenem-resistant Enterobacterales (CRE) from carbapenem-susceptible strains by enhancing bacterial growth kinetics [21]. Further exploration of its clinical utility in diagnosing antimicrobial-resistant isolates is warranted.

CONCLUSION

Notwithstanding these limitations, the HB&L uroquattro system remains a clinically valuable rapid diagnostic tool, exhibiting high NPV and utility in appropriate clinical settings.

Source of Funds:
This study was supported by National High Level Hospital Clinical Research Funding No. 2023IR46 (Interdepartmental Research Project of Peking University First Hospital) to Lei Huang.

Declaration of Interest:
The authors declare no competing financial interests.

References:

1. McIsaac WJ, Hunchak CL. Overestimation error and unnecessary antibiotic prescriptions for acute cystitis in adult women. Med Decis Making 2011 May-Jun;31(3):405-11. (PMID: 21191120)

2. Al Lawati H, Blair BM, Larnard J. Urinary Tract Infections: Core Curriculum 2024. Am J Kidney Dis 2024 Jan;83(1):90-100. (PMID: 37906240)

3. Foxman B. The epidemiology of urinary tract infection. Nat Rev Urol 2010 Dec;7(12):653-60. (PMID: 21139641)

4. Kant S, Misra P, Gupta S, et al. The Ballabgarh Health and Demographic Surveillance System (CRHSP-AIIMS). Int J Epidemiol 2013 Jun;42(3):758-68. (PMID: 23620380)

5. Vasudevan R. Urinary tract infection: an overview of the infection and the associated risks factors. J Microbiology Exp 2014 May;1(2):42-54. https://www.scirp.org/reference/referencespapers?referenceid=3914807

6. Medina M, Castillo-Pino E. An introduction to the epidemiology and burden of urinary tract infections. Ther Adv Urol 2019 May 2;11:1756287219832172. (PMID: 31105774)

7. Mohan B, Gautam N, Sethuraman N, Kaur H, Taneja N. Evaluation of matrix assisted laser desorption ionisation-time of flight mass spectrometry in direct identification of bacteriuria from urine samples. J Med Microbiol 2020 Jul-Dec;38(3 & 4):293-8. (PMID: 33154238)

8. Storme O, Tirán Saucedo J, Garcia-Mora A, Dehesa-Dávila M, Naber KG. Risk factors and predisposing conditions for urinary tract infection. Ther Adv Urol 2019 May 2;11:17562872188143 82. (PMID: 31105772)

9. Wagenlehner FM, Naber KG. Hospital-acquired urinary tract infections. J Hosp Infect 2000 Nov;46(3):171-81. (PMID: 11073725)

10. Simões E Silva AC, Oliveira EA, Mak RH. Urinary tract infection in pediatrics: an overview. J Pediatr (Rio J) 2020 Mar-Apr;96 Suppl 1(Suppl 1):65-79. (PMID: 31783012)

11. Davenport M, Mach KE, Shortliffe LMD, Banaei N, Wang TH, Liao JC. New and developing diagnostic technologies for urinary tract infections. Nat Rev Urol 2017 May;14(5):296-310. (PMID: 28248946)

12. Oyaert M, Delanghe J. Progress in Automated Urinalysis. Ann Lab Med 2019 Jan;39(1):15-22. (PMID: 30215225)

13. Angaali N, Vemu L, Padmasri C, Mamidi N, Teja VD. Direct identification and susceptibility testing of Gram-negative bacilli from turbid urine samples using VITEK2. J Lab Physicians 2018 Jul-Sep;10(3):299-303. (PMID: 30078966)

14. Mahesh PP, Kolape J, Sultana H, Neelakanta G. McFarland Standards-Based Spectrophotometry Method for Calculating Approximate Multiplicity of Infection for an Obligate Intracellular Bacterium Anaplasma phagocytophilum. Microorganisms 2025 Mar 14;13(3):662. (PMID: 40142553)

15. Ballabio C, Venturi N, Sala R, Mocarelli P, Brambilla P. Evaluation of an automated method for urinoculture screening. Microbiol Med 2010;25:178-80. https://www.researchgate.net/publication/274149137_Evaluation_of_an_automated_method_for_urinocolture_screening

16. Ilki A, Bekdemir P, Ulger N, Soyletir G. Rapid reporting of urine culture results: impact of the uro-quick screening system. New Microbiol 2010 Apr;33(2):147-53. (PMID: 20518276)

17. Millan-Lou MI, Garcia-Lechuz JM, Ruiz-Andres MA, et al. Comparing two automated techniques for the primary Screening-out of urine culture. Front Med (Lausanne) 2018 Dec 14;5:353. (PMID: 30619863)

18. Gessoni G, Antico F, Solinas M, et al. Evaluation of Sysmex UF-1000i and Alifax Alfred and HB&L in rapid diagnosis of acute urinary tract infections in a hub and spoke setting. J Med Lab Diagnosis 2015 Jan;6:1-8. https://www.researchgate.net/publication/289686899_Evaluation_of_Sysmex_UF-1000i_and_Alifax_Alfred_and_HBL_in_rapid_diagnosis_of_acute_urinary_tract_infections_in_a_hub_and_spoke_setting

19. Sharma B, Mohan B, Sharma R, et al. Evaluation of an automated rapid urine culture method for urinary tract infection: Comparison with gold standard conventional culture method. Indian J Med Microbiol 2023 Mar-Apr;42:19-24. (PMID: 36967210)

20. Kauffman CA. Diagnosis and management of fungal urinary tract infection. Infect Dis Clin North Am 2014 Mar;28(1):61-74. (PMID: 24484575)

21. Wei M, Wang P, Wang S, Yang C, Gu L. HB&L system for rapid phenotypic detection of clinical carbapenem-resistant Enterobacterales isolates. J Glob Antimicrob Resist 2021 Sep;26:272-8. (PMID: 34284124)