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ORIGINAL ARTICLE

Efficacy of Automated Urinalysis in Detecting Low-Level Bacteriuria and Discriminating Bacterial Gram Status

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SUMMARY

Background: **Rapid and accurate diagnosis of urinary tract infections (UTIs) is essential to guide empirical therapy and curb antimicrobial resistance. However, conventional urine culture is too slow, hindering timely diagnosis of UTI. UF-5000, an automated flow cytometry urinalysis system equipped with the BACT-Info Gram-prediction feature, shows potential to expedite microbial screening. However, its performance under low bacterial loads remains unclear.**

Methods: **We retrospectively analyzed 1,529 clinical urine specimens using urinalysis and urine culture. Any bacterial growth in urine culture was considered a culture-positive result. Receiver operating characteristic (ROC) analysis of UF-5000 bacterial and white blood cell counts was performed to determine the optimal cutoffs. The agreement between the BACT-Info flag feature and urine culture results was assessed using Cohen's κ value.**

Results: **Urine cultures identified bacteria in 700/1,529 specimens (45.8%), with 585 (38.3%) showing ≥ 10^5 colony-forming units/mL. ROC analysis established a bacterial count cutoff of 195.2/μL, yielding a sensitivity of 0.851, specificity of 0.885, and area under the ROC curve of 0.940 (95% confidence interval, 0.928 - 0.951). It outperformed the cutoff value based on white blood cell count. At equivalent amounts of bacterial culture, UF-5000 bacterial counts were significantly higher for Gram-negative than for Gram-positive isolates (Welch's *t*-test: $p < 0.001$). Overall concordance between BACT-Info and urine culture results was substantial for Gram-negative flags (κ, 0.76; accuracy, 0.904) and moderate for Gram-positive flags (κ, 0.51; accuracy, 0.799). For Gram-negative bacteria, the sensitivity, specificity, positive predictive value, and negative predictive value were 0.739, 0.974, 0.923, and 0.898, respectively. However, 17.2% of the specimens containing only Gram-negative bacteria were flagged as "Gram Positive?". This indicates the potential for improvement.**

Conclusions: **The UF-5000 system provides a rapid, low-labor, and cost-effective method for UTI screening, even at low levels of bacteriuria. However, it is intended to complement, not replace, conventional urine culture, which remains indispensable for definitive species identification and antimicrobial susceptibility testing. Its primary value lies in accelerating the diagnostic workflow and reducing unnecessary cultures when used in conjunction with urine culture.**

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INTRODUCTION

Urinary tract infections (UTIs) are among the most common infectious diseases, affecting millions of individuals worldwide and imposing a socioeconomic burden of $3.5 billion annually in the United States [1,2]. Rapid and accurate diagnosis is essential for timely antibiotic therapy and prevention of complications such as pyelonephritis and urosepsis. Although relying on clinical symptoms for UTI diagnosis facilitates immediate empirical therapy, it leads to antimicrobial resistance owing to high false-positive rates [3]. Therefore, urine cultures are indispensable for the accurate diagnosis and treatment of UTIs. However, its turnaround time renders rapid treatment impractical. Dipstick testing is the fastest available diagnostic test for UTIs, but its accuracy is insufficient [3,4]. Recently, automated urinalysis has improved the diagnostic accuracy [5-7].

The Sysmex UF-5000 is an automated flow cytometry-based urinalysis system exhibiting high concordance with conventional quantitative microscopy [8]. Notably, it includes the BACT-Info feature to predict the Gram-staining characteristics (Gram-positive, Gram-negative, or both) of bacteria in the specimens. Specifically, BACT-Info indicates bacterial forward scatter (B_FSC) and lateral fluorescence intensity (B_FLH). B_FSC, which is influenced by cell wall composition, is high in Gram-positive bacteria, whereas B_FLH, which is indicative of the degree of pigment penetration, is generally high in Gram-negative bacteria.

In clinical practice, the UF-5000 system is effective in diagnosing UTIs and detecting Gram-negative bacteria, reducing the need for unnecessary cultures [9,10]. Many studies reporting its usefulness have defined the culture positivity cutoff at $\geq 10^5$ colony-forming units (CFU)/mL [10-13]. This cutoff value has traditionally served as the primary criterion for UTI diagnosis. However, strict adherence to the conventional cutoff value for screening may cause clinically significant UTIs to be missed, as even low levels ($< 10^5$ CFU/mL) of bacterial growth indicate UTIs [14,15]. Consequently, validating the UF-5000 system based solely on this conventional cutoff may be insufficient to establish its reliability as a comprehensive screening tool.

Therefore, this study aimed to evaluate the diagnostic performance of the UF-5000 system for UTI detection, particularly at low bacterial loads. Thus, any level of bacterial growth was considered to be culture-positive. Our findings highlight the utility of automated urinalysis for the prompt detection of culture positivity, even at low levels of bacteriuria. Furthermore, differences in bacterial counts among species potentially enhanced the predictive accuracy of BACT-Info.

MATERIALS AND METHODS

Data collection

This retrospective study was conducted at the Rinku General Medical Center, southern Osaka, Japan, using urinalysis and urine culture data collected between July 2020 and June 2021. The initial dataset comprised 2,222 urine samples that underwent simultaneous sediment tests using the UF-5000 system (Sysmex, Kobe, Japan) and culture tests. After excluding 626 duplicate cases and 67 specimens with missing data, the final dataset comprised 1,529 specimens. Among these, specimens of male patients included 336 inpatients and 517 outpatients, whereas specimens of female patients included 292 inpatients and 384 outpatients. All specimens, including 860 midstream and 669 catheterized urine samples, were collected during routine clinical testing. The study population comprised individuals aged 0–100 years, with median ages of 75.0 and 76.0 years for men and women, respectively. This study was approved by the Rinku General Medical Center Ethics Committee (approval number: 2021-019), which waived the requirement for informed consent to use the diagnostic test results. This study was conducted in accordance with the Declaration of Helsinki.

Urine culture

Each urine sample (2–3 μL) was plated on glass slides (Matsunami Glass, Kishiwada, Japan), fixed with flame, and Gram-stained using a staining kit (Muto Pure Chemicals, Tokyo, Japan). Bacteria were semi-quantitatively assessed using plate culture. Briefly, 1 μL of urine was inoculated and spread onto Trypticase Soy Agar II with 5% sheep blood (Becton Dickinson [BD], Franklin Lakes, NJ, USA). To optimize bacterial isolation, the specimens were inoculated onto MacConkey II agar (BD) for Gram-negative rods, Phenylethyl Alcohol agar with 5% sheep blood (BD) for Gram-positive bacteria, and Chocolate agar with PolyViteX (bioMérieux, Marcy l'Etoile, France) primarily for *Neisseria gonorrhoeae*. The plates were incubated aerobically at 35°C for up to 48 hours, with incubation in 5% CO_2 when necessary. Bacterial colonies were semi-quantified by counting and reporting the counts as 10^3, 10^4, 10^5, 10^6, or 10^7 CFU/mL. All bacterial detections were considered culture-positive, regardless of the amount of growth. Bacterial identification was performed using WalkAway 96 Plus (Beckman Coulter, Brea, CA, USA) and Rapid ID 32 STREP (bioMérieux). Anaerobic cultures were incubated at 35°C for at least 72 hours on Brucella HK agar medium (Kyokuto Pharmaceutical Industrial, Tokyo, Japan) using AnaeroPac System (Mitsubishi Gas Chemical, Tokyo, Japan). Anaerobic isolates were identified using API 20 A (bioMérieux). Yeast-like organisms (YLOs) were detected after incubation for 48 hours at 35°C on CHROMagar Candida (Kanto Chemical, Tokyo, Japan). The specimens were stored at 4°C for up to 48 hours before bacterial culture.

Urinalysis using the UF-5000 system

Urinalysis was performed immediately upon sample submission using the UF-5000 system following the manufacturer's instructions. BACT-Info flagged specimens with bacterial counts ≥ 100/μL as "Gram Positive?" (Pos?) or "Gram Negative?" (Neg?). When both Gram-positive and -negative bacteria were predicted, the label "Gram Pos/Neg?" (Pos/Neg?) was applied, whereas specimens with uncertain Gram status were categorized as "Unclassified." Owing to system problems, 66 specimens with bacterial counts ≥ 100/μL had no BACT-Info results and were excluded from the analysis. BACT-Info did not work for specimens with bacterial counts < 100/μL (No flag). For 89 specimens exceeding the upper measurement limit of bacterial count, values of 100,000/μL were assigned for the analysis. Among these, five had Gram-positive bacteria, 45 had Gram-negative bacteria, and 39 had both.

Comparison of BACT-Info and culture

Specimens flagged as Gram-positive (Pos? or Pos/Neg?) or Gram-negative (Neg? or Pos/Neg?) were evaluated for agreement with the culture results. For example, specimens flagged as Gram-positive were considered true-positives if Gram-positive bacteria were observed and false positives if no bacterial growth or only Gram-negative bacteria were observed. Similarly, specimens showing Gram-positive bacteria on cultures with other flags ("Neg?," "Unclassified," or "No flag") were considered false negatives, whereas those with no growth or Gram-negative bacteria were considered true negatives. Additionally, Gram-staining results were compared with the culture results. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and agreement rate were calculated based on the set definitions.

Statistical analyses

BACT-Info and Gram-staining results were evaluated for agreement with the results of urine culture (reference method) using Cohen's κ coefficient to optimize sensitivity and specificity [16]. Welch's *t*-test was used to compare the bacterial counts of different culture groups, with p-values < 0.05 considered to be statistically significant. The cutoff value for culture positivity was determined via receiver operating characteristic (ROC) analysis of the bacterial and white blood cell (WBC) counts obtained from the UF-5000 system based on the Youden index [17]. All statistical analyses were performed using the EZR software [18].

RESULTS

Characteristics of urine specimens evaluated via culture and the UF-5000 system

Analysis of 1,529 urine specimens via culture tests revealed bacteria in 700 (45.8%) patients, with colony counts ≥ 10^5 CFU/mL in 585 (38.3%; Tables 1 and 2). Gram-staining findings largely concurred with the culture results (κ, 0.77; 95% confidence interval [CI], 0.74–0.80). Of the 700 culture-positive specimens, 450 exhibited monomicrobial growth and 250 exhibited polymicrobial growth. Among the monomicrobial isolates, *Escherichia coli* was detected in 158 specimens (35.1%), *Enterococcus faecalis* in 40 (8.9%), *Staphylococcus aureus* in 31 (6.9%), and *Klebsiella pneumoniae* in 31 (6.9%), collectively accounting for the majority of monomicrobial growth. Gram-positive bacteria were detected in 244 specimens, Gram-negative bacteria in 290, and both types in 166 (Table 2). Notably, the proportion of Gram-negative bacteria increased with increasing bacterial growth (Table 2).

Urine culture identified YLOs in 43 specimens, including 13 midstream and 28 catheterized urine samples. When evaluated against these culture results, Gram-staining correctly identified 31 of these specimens, with a sensitivity of 0.721. Importantly, the method yielded perfect specificity and PPV (both 1.000) owing to the absence of any false-positives, contributing to a high overall accuracy of 0.992.

Next, a comparative analysis of bacterial counts was performed for specimens containing both Gram-positive and -negative bacteria (Figure 1). In specimens with bacterial counts > 10^4 CFU/mL, urinalysis revealed high bacterial counts in specimens containing Gram-negative bacteria (Figure 1A). This trend was further confirmed in monomicrobial specimens with counts ≥ 10^7 CFU/mL (Figure 1B).

ROC analysis using UF-5000 parameters

To detect culture-positive specimens, ROC analysis was performed using the bacterial and WBC counts obtained with the UF-5000 system (Figure 2). The cutoff value was determined by maximizing the Youden index. The bacterial count cutoff was 195.2/μL (sensitivity, 0.851; specificity, 0.885; Youden index, 0.736), and the WBC count cutoff was 53.1/μL (sensitivity, 0.810; specificity, 0.865; Youden index, 0.675). The area under the ROC curve values for bacterial and WBC counts were 0.940 (95% CI, 0.928–0.951) and 0.898 (95% CI, 0.882–0.914), respectively. Consistent with previous reports [6,9], bacterial counts were superior to WBC counts for screening bacterial growth. For detecting culture-positive YLOs, ROC analysis of the UF-5000 yeast-like cell (YLC) count established a cutoff of 34.2/μL (Youden index, 0.576). This cutoff provided a sensitivity of 0.930, specificity of 0.646, low PPV of 0.071, and high NPV of 0.997, classifying 566 specimens as positive and 963 as negative.

Comparison of urine culture and BACT-Info by UF-5000

The UF-5000 BACT-Info feature was evaluated against the urine culture results for its ability to discriminate between Gram-negative and -positive bacteria (Table 3). Specimens with bacterial counts below the ROC-derived cutoff of 195.2/μL were classified as "No flag."

Table 1. Comparison of urine culture and Gram-staining.

Gram-staining	Urine culture				
	ND	Pos	Neg	Pos/Neg	Total
ND	821	88	42	15	966
Pos	6	153	0	17	176
Neg	1	1	240	26	268
Pos/Neg	1	2	8	108	119
Total	829	244	290	166	1,529

ND: not detected, Pos: Gram-positive bacteria, Neg: Gram-negative bacteria, Pos/Neg: Gram-positive and -negative bacteria.

Table 2. Distribution of bacterial counts by the Gram status of isolates.

Gram status of isolates	Bacterial growth [CFU/mL]					
	10^3	10^4	10^5	10^6	10^7	Total
Gram-positive	21	47	61	57	58	244
Gram-negative	9	26	35	74	146	290
Gram-positive and -negative	4	8	17	46	91	166
Total	34	81	113	177	295	700

Table 3. Comparison of urine culture and BACT-Info results based on the established bacterial count cutoff.

BACT-Info	Urine culture				
	ND	Pos	Neg	Pos/Neg	Total
Pos?	73	151	50	35	309
Neg?	4	0	159	32	195
Pos/Neg?	10	14	55	91	170
Unclassified	8	1	7	1	17
No flag [a]	734	78	19	7	838
Total	829	244	290	166	1,529

[a] "No flag" indicates the specimens with bacterial counts below the cutoff value (195.2/μL).
ND: not detected, Pos: Gram-positive bacteria, Neg: Gram-negative bacteria, Pos/Neg: Gram-positive bacteria and -negative bacteria, Pos?: "Gram Positive?" flag, Neg?: "Gram Negative?" flag, Pos/Neg?: "Gram Pos/Neg?" flag.

Table 4. Performance evaluation of the UF-5000 system for Gram status discrimination using urine specimens.

BACT-Info	TP	TN	FP	FN	Sen	Spe	PPV	NPV	Accuracy
Pos? - flag including Pos/Neg?	291	931	188	119	0.710	0.832	0.608	0.887	0.799
Neg? - flag including Pos/Neg?	337	1,045	28	119	0.739	0.974	0.923	0.898	0.904

Pos?: "Gram Positive?" flag, Neg?: "Gram Negative?" flag, Pos/Neg?: "Gram Pos/Neg?" flag, TP: true positive, TN: true negative, FP: false positive, FN: false negative, Sen: sensitivity, Spe: specificity, PPV: positive predictive value, NPV: negative predictive value.

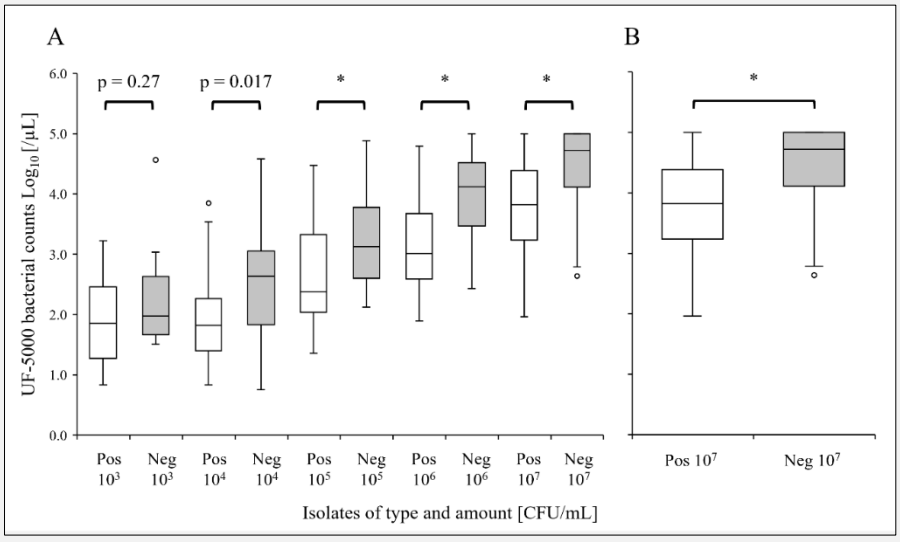

Figure 1. UF-5000 bacterial count distribution in specimens with Gram-positive and -negative isolates.

Boxplots show the log_{10}-transformed bacterial counts (/µL) measured using the UF-5000 system for urine specimens grouped by Gram status (white boxes, Gram-positive; gray boxes, Gram-negative). Statistical comparisons were performed using Welch's *t*-test at each growth level, with p-values ≥ 0.001 reported numerically and p-values < 0.001 denoted by an asterisk (*). A) Specimens with culture growth of 10^3, 10^4, 10^5, 10^6, or 10^7 colony-forming units (CFU)/mL compared Gram-positive and -negative isolates at each growth level. B) Specimens with monomicrobial culture growth ≥ 10^7 CFU/mL compared Gram-positive and -negative isolates. Pos Gram: positive bacteria, Neg Gram: negative bacteria.

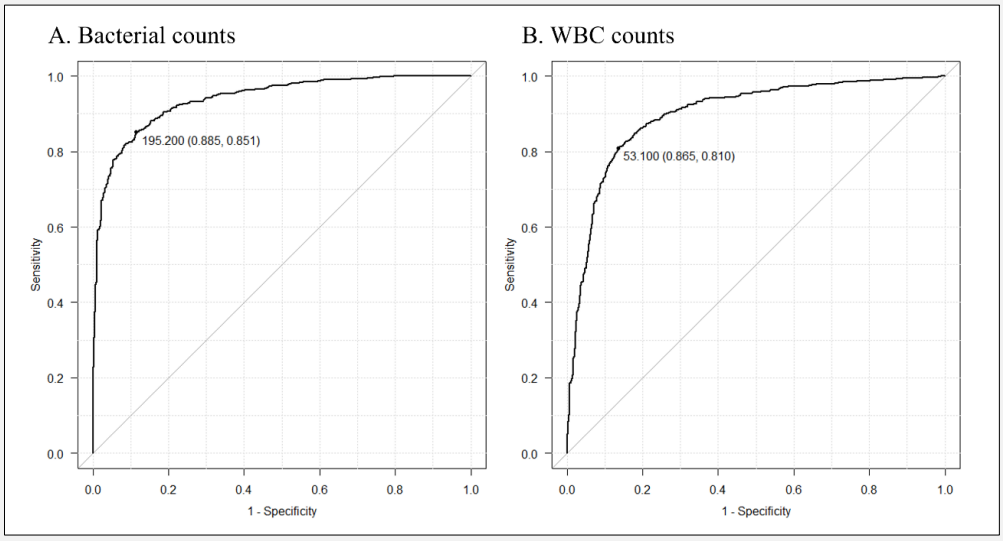

Figure 2. ROC analysis to discriminate culture-positive specimens using UF-5000 parameters.

Receiver operating characteristic (ROC) curves for A) bacterial counts and B) white blood cell (WBC) counts obtained using the UF-5000 system. The optimal cutoff value was 195.2/µL for bacterial counts (sensitivity, 0.851; specificity, 0.885; Youden index, 0.736) and 53.1/µL for WBC counts (sensitivity, 0.810; specificity, 0.865; Youden index, 0.675). The area under the ROC curves were 0.940 (95% CI, 0.928–0.951) for bacterial counts and 0.898 (95% CI, 0.882–0.914) for WBC counts.

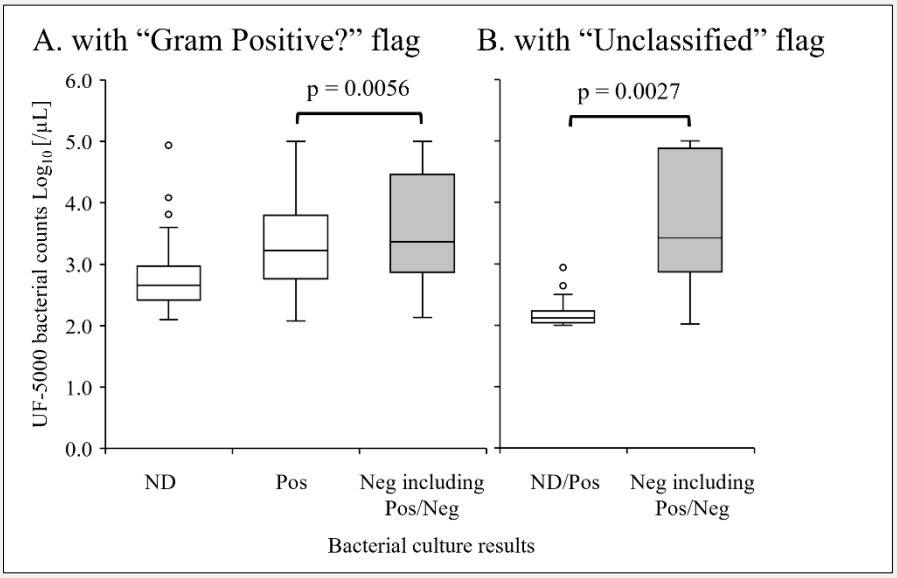

Figure 3. Distribution of bacterial counts in specimens with “Gram Positive?” and “Unclassified” flags.

Boxplots show the log_{10}-transformed bacterial counts determined using the UF-5000 system in urine specimens flagged as A) “Gram positive?” or B) “Unclassified.” Statistical comparisons were performed using Welch’s *t*-test. ND not detected, Pos Gram: positive bacteria, Neg Gram: negative bacteria, Pos/Neg Gram: positive and -negative bacteria, ND/Pos: not detected or Gram-positive bacteria.

Overall, 54.8% (838/1,529) of the specimens were classified as “No flag,” with only 3.1% (26/838) being false-negative for Gram-negative bacterial growth.

Table 4 shows the comparison results, focusing separately on Gram-positive and -negative flags. Gram-positive flags showed moderate agreement (accuracy, 0.799; κ, 0.51; 95% CI, 0.47–0.56), although their PPV was relatively low (0.608). Gram-negative flags showed substantial agreement (accuracy, 0.904; κ, 0.76; 95% CI, 0.72–0.79) and exhibited particularly high specificity (0.974) and PPV (0.923). However, in BACT-Info, compared to Gram-staining results, Gram-positive flags were frequently false-positive, whereas Gram-negative flags were frequently false-negative (Table 4).

Refinement of “Gram positive?” and “Unclassified” flags by bacterial counts

Bacterial counts were compared with the culture results to modify the “Gram-positive” and “Unclassified” flags (Figure 3). As the Gram-positive flag yielded a considerable number of false positives, bacterial counts of 151 specimens with Gram-positive bacteria were compared with those of 85 specimens with Gram-negative bacteria (including the co-growth of Gram-positive and -negative bacteria). Among specimens with Gram-positive flags, high bacterial counts indicated the presence of Gram-negative bacteria but were not consistently predictive (Figure 3A).

In the raw data, 69 specimens were flagged as “Unclassified”; however, applying the cutoff value reclassified 52 of them as “No flag” (Table 4). Among these, 67.3% (35/52) of the specimens were culture-negative, indicating that the bacterial counts effectively excluded them. Furthermore, among the remaining 17 specimens with bacterial counts above the cutoff value, those with high bacterial counts predicted Gram-negative bacterial growth (Figure 3B).

DISCUSSION

In this study, we evaluated the performance of the UF-5000 system in detecting bacteria, including those with low growth, and discriminating their Gram-staining characteristics. ROC analysis of bacterial counts exhibited a sensitivity of 0.851, specificity of 0.885, and area under the ROC curve of 0.940 (95% CI, 0.928–0.951) at a cutoff of 195.2/μL, indicating superior screening capability even at low bacterial loads. The cutoff values for bacterial detection should be adjusted for each population, as they vary according to culture positivity criteria and cohort characteristics [7,9,10,13,19].

While 10^5 CFU/mL has long been the traditional threshold for significant bacteriuria, its clinical applicability is limited, given that clinically significant UTIs are also diagnosed at lower bacterial counts [14,15]. Consequently, a revised threshold of 10^4 CFU/mL has been proposed in a recent consensus study [20]. This context underscores the importance of our study, which assessed performance at these lower concentrations, a focus largely absent from previous studies that adhered to the traditional cutoff.

When equivalent bacterial loads were detected by culture, the UF-5000 system revealed higher bacterial counts in the specimens containing Gram-negative bacteria than in the specimens containing Gram-positive bacteria (Figure 1). Similar findings have been reported in a previous study [9]. Bacterial aggregation (e.g., biofilm formation) in culture specimens leads to an underestimation of the actual bacterial growth [21]. Therefore, further studies should explore culture methods accounting for such bacterial aggregation. Moreover, careful evaluation is necessary, as destructive methods for aggregates affect the viable bacterial counts.

In this study, the discriminatory performance of BACT-Info varied based on the bacterial type. “Neg?” flags were not observed in 244 specimens with only Gram-positive bacteria growth, whereas 50 of 290 (17.2%) specimens with only Gram-negative bacteria growth were flagged as “Pos?” (Table 3). BACT-Info discrimination is driven by the slopes of B_FSC and B_FLH scattergrams. Aggregation elevated B_FSC values in Gram-negative bacteria, thereby altering the slope of the scattergram. This effect possibly contributed to the erroneous identification of Gram-negative bacteria. In contrast, a previous study on pediatric patients reported a low frequency of “Pos?” flags assigned to Gram-negative bacteria [19]. This may be because pediatric patients generally exhibit short bladder retention times, which are insufficient for biofilm formation. Future studies should validate the effects of bacterial aggregation on the UF-5000 system’s discrimination performance.

This study demonstrated that the UF-5000 is a viable option for UTI screening. The iQ200 analyzer (Iris Diagnostics, Chatsworth, CA, USA), an automated microscopy analyzer, is another common option for this purpose [7]. The primary distinction between these platforms lies in the bacterial information they provide: while the UF-5000 offers Gram status, the iQ200 provides bacterial morphology [22]. Crucially, neither system can fully replace definitive culture-based methods, although their utility in reducing unnecessary urine cultures can be maximized by establishing a cutoff value that yields a near-perfect NPV.

The rapid Gram status discrimination provided by the UF-5000's BACT-Info feature offers a key advantage in guiding more appropriate empirical therapy. For example, the rapid prediction of Gram-negative organisms by BACT-Info enables the targeted, direct detection of extended-spectrum beta-lactamase in urine specimens [23]. Additionally, combining the UF system with Matrix-Assisted Laser Desorption Ionization-Time of Flight Mass Spectrometry allows for rapid species identification, bypassing the need for lengthy culture incubation [24]. The strategic use of such rapid diagnostic information is a crucial component of effective antimicrobial stewardship. Crucially, this system should be viewed as a rapid screening tool for complementing, not supplanting, conventional urine cultures.

The UF-5000 YLC parameter was suitable for ruling out candiduria, demonstrating high sensitivity and NPV for YLO detection in urine. Conversely, its insufficient PPV underscores the superiority of Gram-staining for confirmation. The potential for red blood cells to interfere with the UF-5000's YLC count is a well-documented limitation, sometimes addressed in the literature by excluding flagged data [8,25]. In our analysis, all specimens that were positive for YLOs by Gram-staining also exhibited YLC counts above the established cutoff value. This suggests that harnessing the distinct characteristics of each method synergistically can maximize the overall screening capability.

This study has several limitations. First, because the dataset did not focus on a specific patient group, the established cutoff values were not directly applicable to all populations. Second, as this study focused on assessing the ability of the UF-5000 system to detect and predict low bacterial loads, its capability to differentiate between severe contamination and low bacterial growth remains unclear, warranting further investigation.

In conclusion, this study revealed that the UF-5000 system is a highly effective and cost-efficient platform for rapid UTI screening, particularly for detecting low bacterial loads. However, one must understand both its inherent limitations as a screening tool and its role as a supplement, not a substitute, for urine cultures. Urine cultures remain indispensable for optimizing therapy by identifying and testing the antimicrobial susceptibility of isolates. Therefore, the UF-5000, when used simultaneously with urine culture, will be a highly effective and cost-efficient platform for rapid UTI screening.

Declaration of Interest:
The authors received no specific funding for this study and declare no conflicts of interest.

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