



Original

Comparison of Sysmex UF-5000 bacterial count results and urine culture for urinary tract infection screening

†Seiji Nagasawa*¹, Shimpei Yoshioka*¹, Yohei Kaizuka*¹,
Kohei Kusakari*², Yoshikazu Togo*¹

†Correspondence: Department of Urology, Kawanishi City Medical Center 1-4-1 Hiuchi, Kawanishi, Hyogo 666-0017, Japan
Tel: +81-72-789-8199
E-mail: primalboys@yahoo.co.jp
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*¹Department of Urology, Kawanishi City Medical Center
*²Department of Pharmacy, Kawanishi City Medical Center

ABSTRACT

Background: Sysmex UF-5000 urine particle analyzer can simultaneously measure urinary organic constituents and provide bacterial information (BACT-info). Reported here are findings of a retrospective review of BACT-info bacterial flag information provided by Sysmex UF-5000 and urine culture findings, with focus on bacterial count.

Patients and methods: A total of 1011 patients were enrolled, including 465 males and 546 females. Sysmex UF-5000 shows bacterial count as BACT-info, and at the same time estimates bacterial count and classifies the findings into Gram-positive, Gram-negative, Gram-positive/negative, and Unclassified.

Results: The positive predictive value (PPV) of a BACT-info bacterial count ranging from 100-99,999/μL and urine cultures was 40.1% for all Gram-positive samples, and after dividing UF-5000 positive samples into groups A (100-999/μL), B (1000-9999/μL), and C (10,000-99,999/μL) was 34.4%, 46.2%, and 48.4%, respectively (P<0.05). For Gram-negative samples, the PPV was 86.0% overall, and 52.1%, 87.8%, and 95.5% (P<0.001) for Groups A, B, and C, respectively. In both Gram-positive and -negative samples, the PPV increased significantly with higher bacterial count.

Conclusions: A higher BACT-info bacterial count leads to a more accurate determination of bacteria, suggesting that BACT-info could lead to appropriate selection of antimicrobial agents in the treatment of urinary tract infections.

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Key Words

BACT-info, UF-5000, bacterial count, urinary tract infection, urine culture

I. Introduction.....

A urinary tract infection is one of the most frequent types of infections encountered and mainly caused by enteric bacteria. The effects range from mild cystitis to severe pyelonephritis, with prompt diagnosis and treatment required, as both community and nosocomial infections are possible. The guidelines in Japan for treatment of infectious diseases state that it is important to first determine the morphology of the causative organism

using urinary sediment and flow cytometry examinations before starting treatment for a urinary tract infection¹⁾, though antibacterial agents are often prescribed in clinical practice as empirical treatment for suspected cases.

While Gram staining of a urine sample for bacteriological testing is rapid, a disadvantage is differences among technologists, making it difficult to obtain immediate and accurate results for all specimens in the course of busy daily work. In addition, several days are required for urine culture results to be determined, thus a test able to

quickly reveal causative organisms is required for appropriate timely antimicrobial therapy.

Sysmex UF-5000 (Sysmex Corporation, Kobe, Japan) urine particle analyzer can simultaneously measure urinary plasmablasts and provide bacterial information (BACT-info) based on the principle of flow cytometry, as the dot distribution pattern of the scattergram displayed during quantitative measurement of bacteria can be analyzed by the device to estimate Gram stainability²⁾. The present study was conducted to retrospectively examine BACT-info flag results provided by UF-5000 and urine culture findings, with focus on bacterial count. To the best of our knowledge, this is the first reported comparison of urine culture and bacterial count obtained with UF-5000 for urinary tract infection cases.

II. Materials and methods

2.1. Urine samples

A total of 1,011 patients treated at our hospital for a suspected urinary tract infection between September 2022 and June 2024 with a bacterial count of 100-99,999/ μL , whose results included BACT-info obtained with UF-5000 and also urine culture findings, were enrolled in this study (Table 1). A bacterial count of 100/ μL is equivalent to $1 \times 10^5/\text{mL}$ of bacteria in a urine culture. A diagnosis of urinary tract infection cannot be made when the bacterial count is less than 100/ μL , while in cases with a

count of 100,000/ μL or more, urine turbidity is too great for accurate determination by UF-5000.

2.2. UF-5000 analysis

Urine specimens are usually measured with UF-5000 within one hour, or four hours at the latest, to ensure accuracy. In addition to bacterial count, a dot distribution pattern of the scattergram is analyzed to determine Gram-positive, Gram-negative, Gram-positive/negative, and Unclassified³⁾.

2.3. Microbiological analysis

Urine cultures were performed with blood agar and bromothymol blue lactose agar for up to two days. Identification of developing bacteria was performed using a Pos Combo Panel.

2.4. Statistical analysis

Statistical analyses were performed using StatMate, ver. 4.01 (ATMS Co., Ltd., Tokyo, Japan). Comparisons between groups and associations among categorical variables were analyzed using a chi-square test, with a P value <0.05 considered to indicate significance.

2.5. Ethical approval

This study received approval from the ethics committee of Kawanishi City Medical Center (approval number: 24009) and was conducted in compliance with their ethical guidelines for human medical research.

III. RESULTS.....

Results of 1,011 patients, 465 (46.0%) males and 546 (54.0%) females with an average age of 76.4 (range 0-101) years, were examined. Of the 1,011 urine cultures of cases, cultures were detected in the urine in 797 cases and not in 214 cases. In 797 urine cultures, 921 bacteria species were detected, some of which contained more than one species, 346 were Gram-positive and 575 were Gram-negative. The Gram-positive cases showed *Enterococcus* spp. in 128 (13.9%), *Streptococcus* spp. in 103 (11.2%), *Staphylococcus* spp. in 84 (9.1%), *Corynebacterium* spp. in 27 (2.9%), and others in 4 (0.4%),

Table 1 Characteristics of the study population

n	1011	
Age, mean (range)	76.4 (0-101)	
Sex, n(%)	Male	465 (46.0)
	Female	546 (54.0)
Bacterial count (/ μL), n(%)	A : 100-999	345 (34.1)
	B : 1000-9999	296 (29.3)
	C : 10000-99999	370 (36.6)

Table 2 Microorganisms identified in the urine samples yielding significant bacterial growth on agar plates

Gram-positive (n=346)	n (%)	Gram-negative (n=575)	n (%)
<i>Enterococcus</i> spp.	128 (13.9)	<i>Escherichia coli</i>	353 (38.3)
<i>Streptococcus</i> spp.	103 (11.2)	<i>Klebsiella</i> spp.	95 (10.3)
<i>Staphylococcus</i> spp.	84 (9.1)	<i>Pseudomonas aeruginosa</i>	39 (4.2)
<i>Corynebacterium</i> spp.	27 (2.9)	<i>Citrobacter</i> spp.	28 (3.0)
others	4 (0.4)	<i>Proteus</i> spp.	22 (2.4)
		<i>Enterobacter</i> spp.	17 (1.8)
		<i>Serratia</i> spp.	3 (0.3)
		others	18 (2.0)

while Gram-negative cases showed Escherichia coli in 353 (38.3%), Klebsiella spp. in 95 (10.3%), Pseudomonas aeruginosa in 39 (4.2%), Citrobacter spp. in 28 (3.0%), Proteus spp. in 22 (2.4%), Enterobacter spp. in 17 (1.8%), Serratia spp. in 3 (0.3%), and others in 18 (2.2%) (Table 2).

As mentioned above, a bacterial count of 100/μL is equivalent to 1 × 10⁵/mL of bacteria in a urine culture, the amount of bacteria is equivalent to a urinary tract infection. Therefore, the patients were classified into three groups based on bacterial count, as follows: group A, 100-999 (n=345); group B, 1000-9999 (n=296); and group C, 10000-99999 (n=370), with the positive predictive value (PPV) shown by BACT-info flag and urine culture findings compared. The PPV obtained with urine cultures for

Gram-positive patients in groups A, B, and C was 34.4%, 46.2%, and 48.4%, respectively, (P<0.05), while that with urine cultures in Gram-negative groups A, B, and C was 52.1%, 87.8%, and 95.5%, respectively (P<0.001). In BACT-info flag findings, PPV for both Gram-positive and -negative samples showed a significant increase in association with higher bacterial count. On the other hand, the PPV for all Gram-positive and -negative urine cultures was 22.6% overall, while that for Gram-positive groups A, B, and C was 25.0%, 19.4%, and 23.3%, respectively, indicating a low PPV regardless of bacterial count. These results may have been due to the low number of cases, though the results for both Gram-positive and -negative patients were considered to be unreliable (Table 3A-D).

Table 3 A-D Discrimination of BACT-Info flags by UF-5000 compared to urine culture results by bacterial count

3A. bacterial count 100 – 99999/μL							
100 – 99999/μL		Bacterial species				Total	PPV
		Pos	Neg	Pos/Neg	No growth		
UF-5000 BACT-info	Pos flag	190	91	52	132	465	40.10%
	Neg flag	6	239	12	21	278	86.00%
	Pos/Neg flag	23	102	42	19	186	22.60%
	Unclassified	18	18	4	42	82	
	Total	237	450	110	214	1011	
	CR	80.20%	53.10%	38.20%			

3B. bacterial count 100 – 999/μL (Group A)							
100 – 999/μL		Bacterial species				Total	PPV
		Pos	Neg	Pos/Neg	No growth		
UF-5000 BACT-info	Pos flag	76	41	17	87	221	34.40%
	Neg flag	2	25	3	18	48	52.10%
	Pos/Neg flag	1	2	1	0	4	25.00%
	Unclassified	16	11	4	41	72	
	Total	95	79	25	146	345	
	CR	80.00%	31.60%	4.00%			

3C. bacterial count 1000 – 9999/μL (Group B)							
1000 – 9999/μL		Bacterial species				Total	PPV
		Pos	Neg	Pos/Neg	No growth		
UF-5000 BACT-info	Pos flag	84	30	26	42	182	46.20%
	Neg flag	1	65	6	2	74	87.80%
	Pos/Neg flag	9	13	7	7	36	19.40%
	Unclassified	2	2	0	0	4	
	Total	96	110	39	51	296	
	CR	87.50%	59.10%	18.00%			

3D. bacterial count 10000 – 99999/μL (Group C)							
10000 – 99999/μL		Bacterial species				Total	PPV
		Pos	Neg	Pos/Neg	No growth		
UF-5000 BACT-info	Pos flag	30	20	9	3	62	48.40%
	Neg flag	3	149	3	1	156	95.50%
	Pos/Neg flag	13	87	34	12	146	23.30%
	Unclassified	0	5	0	1	6	
	Total	46	261	46	17	370	
	CR	65.20%	57.10%	74.00%			

CR : Concordance rate
 PPV : Positive Predictive Value

As noted above, samples shown as Gram-negative by BACT-info had a PPV of 93.0% with a BACT quantitative count of 1,000/μL or higher considered to be reliable, while Gram-positive samples had a PPV of 48.4% even with a bacterial count of 10,000/μL or higher, indicating a low level of reliability (Figure). Finally, when all 1,011 cases were divided into males (n=465) and females (n=546), BACT-info flag and urine culture PPV results showed that 82.5% and 88.8%, respectively, were Gram-negative, not a significant difference (P=0.133), whereas 51.4% and 31.6%, respectively, were Gram-positive, a significant difference between genders (P<0.001) (Table 4A, B).

IV. Discussion.....

UF-5000 is an instrument that uses flow cytometry as its principle method to quantitatively determine numbers

of erythrocytes, leukocytes, epithelial cells, squamous cells, columns, and bacteria in non-centrifuged urine. The dot distribution of the BACT scattergram displayed when quantitatively determining bacteria is analyzed by an in-instrument algorithm to show Gram-positive and -negative bacteria based on differences in cell wall structure using forward scattered light and lateral fluorescence. With this instrument, it is possible to determine the presence of a mixture of Gram-positive and -negative bacteria in samples, as well as those with only Gram-positive or -negative strains. However, the low PPV limits application of UF-5000 for diagnosis urinary tract infection and determination of treatment⁴. Nevertheless, UF-5000 analyzer is considered to be a reliable diagnostic tool for UTI screening, as the displayed BACT-info flags allow for quick decision making regarding diagnosis by the clinician⁵.

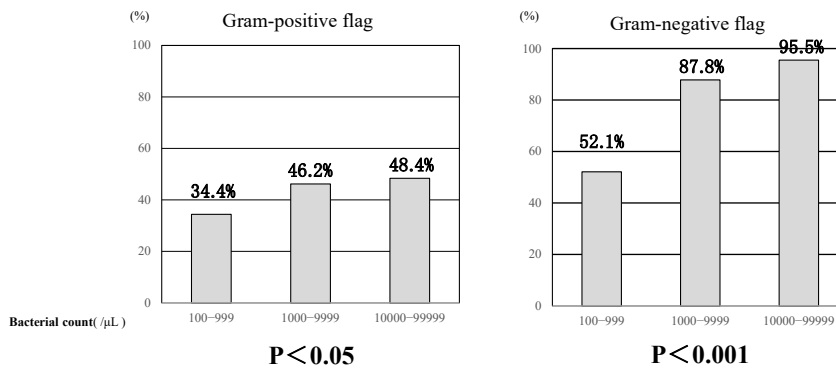


Figure 1 PPV of comparison of BACT-info flag by bacterial count

Table 4 A-B Discrimination of BACT-Info flags by UF-5000 compared to urine culture results by sex

4A. Male (n=465)

100 – 99999/μL		Bacterial species				Total	PPV
		Pos	Neg	Pos/Neg	No growth		
UF-5000 BACT-info	Pos flag	112	32	17	57	218	51.40%
	Neg flag	3	104	7	12	126	82.50%
	Pos/Neg flag	19	26	17	8	70	24.20%
	Unclassified	13	10	2	26	51	
	Total	147	172	43	103	465	
CR		76.20%	60.50%	39.50%			

4B. Female (n=546)

100 – 99999/μL		Bacterial species				Total	PPV
		Pos	Neg	Pos/Neg	No growth		
UF-5000 BACT-info	Pos flag	78	59	35	75	247	31.60%
	Neg flag	3	135	5	9	152	88.80%
	Pos/Neg flag	4	76	25	11	116	21.60%
	Unclassified	5	8	2	16	31	
	Total	90	278	67	111	546	
CR		86.70%	48.60%	37.30%			

CR : Concordance rate
 PPV : Positive Predictive Value

In a previous study of UF- 5000 results obtained with 94 samples, PPV was 90% in cases determined to be Gram-negative and 54% in those determined as Gram-positive²⁾, while another study of 179 samples reported PPV of 93% for Gram-negative and 75.0% for Gram-positive cases⁶⁾. The main causative organisms of UTI are *Escherichia coli* and other Gram-negative organisms, thus a PPV greater than 90% for the Gram-negative flag suggests that UF-5000 device may be helpful for selection of an appropriate antimicrobial agent. UF-5000 sensitivity and specificity were shown to be 80.0% and 88.2%, respectively, for Gram-negative, and 70.0% and 86.5%, respectively, for Gram-positive cases⁷⁾. Additionally, another study reported that UF-5000 showed good sensitivity and specificity for Gram-negative samples as compared to its predecessor the UF-1000i, with improved detection sensitivity for Gram-positive samples as well⁸⁾.

It is important to note that the PPV for Gram-positive flagged and urine cultures was lower as compared to that for the Gram-negative cultures. A possible explanation is that Gram-positive strains are less likely to be stained than Gram-negative strains because they are more often found to be clumped, resulting in a grape-like, lenticular, or fenestrate-like morphology. Furthermore, UF-5000 also counts debris in the urine specimen and analysis of the scattergram in cases with debris shows a morphology similar to that of a Gram-positive sample, resulting in possible false-positive findings for Gram-negative specimens. One of the debris components in urine specimens is squamous cells, which in females are more likely to have a vulvar or vaginal origin even in the absence of urinary tract system abnormalities. When a urine specimen is microscopically examined in the laboratory, contamination is considered to be positive when five or more epithelial cells are present in one field of view, while contamination by vaginal secretion, epithelial cells, or indigenous skin bacteria is reported to be found in 25% or more cases⁹⁾. According to the European Urinalysis guidelines, the presence of squamous cells from the vulva or urethra in urine obtained outside of the fertile period is a problem with specimen collection that must be considered¹⁰⁾. As for UF-5000, the presence of squamous cell contamination in female urine samples was reported to be the reason for the low PPV of Gram-positive and Gram-positive/negative samples noted by the BACT-info flag¹¹⁾⁻¹⁴⁾. Gilboe et al. examined urine specimens for contamination and noted that most had only small amounts of squamous cells, while a few contained large amounts, though they did not consider squamous cells to be a parameter useful for predicting contamination¹⁵⁾. In the present study, we

also examined PPV in female urine samples that contained 5 or more squamous cells per field of view, but this did not significantly affect the results, and the degree of contamination was difficult to determine based on squamous cells alone.

The present results indicate that the bacterial flag becomes more accurate as the bacterial count in BACT-info increases. In addition, PPV was lower in the Gram-positive than -negative samples, and Gram-positive samples from females had a significantly lower PPV as compared to those from males, suggesting that contamination by debris such as squamous cells may affect the BACT-info flag.

This study has some limitations, including its retrospective nature and analysis of results obtained from a single center aggregate. Nevertheless, it is considered that the findings obtained are valuable for demonstrating the efficacy of the UF-5000 particle analyzer.

In conclusion, it is suggested that a higher bacterial count in BACT-info findings provided by UF-5000 can help with more accurate determination of bacteria present in the patient. It should be kept in mind that the PPV for a Gram-positive flagged sample in BACT-info results can be as low as 48.4%, even when the bacterial count is 10,000/ μ L or greater, while the PPV is potentially lower in females due to contamination. With a Gram-negative flag, a bacterial count of 1,000/ μ L or greater is considered to be reliable with a PPV of 90% or more, suggesting that BACT-info could lead to appropriate selection of antimicrobial agents in the treatment of urinary tract infections.

Additional studies are needed to establish the accuracy of these results, including prospective and multicenter studies.

Authors' contributions

Seiji Nagasawa: Data curation, investigation, writing

Shimpei Yoshioka: Data curation

Yohei Kaizuka: Data curation

Kohei Kusakari: Data curation

Yoshikazu Togo: Data curation, review, editing

All of the authors have read and approved the final version of the manuscript.

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Conflicts of interest

There are no conflicts of interest to declare.

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