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Performance evaluation of UF-4000 body fluid mode for automated body fluid cell counting

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ABSTRACT

Background: Cytological analysis of body fluids (BF) provides important information for diagnosis in various medical conditions. We evaluated the analytical performance of the UF-4000 BF mode for ascitic, cerebrospinal, pleural, synovial and continuous ambulatory peritoneal dialysis fluids compared to light microscopy counting (LM).

Materials and methods: 223 consecutive BF were analyzed by UF-4000 and results were compared using Pearson's correlation, Bland-Altman analysis, and contingency tests at relevant cut-off values. This study also included the evaluation of precision, linearity, and carryover.

Results: For white and red blood cells (WBC, RBC) counts in all BF, correlation was excellent with Pearson's coefficients $R^2 > 0,98$. Bland-Altman analysis didn't reveal significant differences with limited bias for WBC ranging from -10 to -1 WBC/ μ L and bias ranging from -43 to -6 / μ L for RBC. At specific cut-off values for WBC, Se and Spe were 100% except for ascites (Spe = 98%) due to two false positive. Precision evaluated at three concentration levels was good for each parameter (WBC < 10%). Linearity was excellent for WBC ($R^2 > 0,99$) and carryover negligible (<0,004%).

Conclusion: UF-4000 BF mode is a good alternative to manual LM for BF cell counting. This automated method gives rapid and accurate results which is important for therapeutic decisions.

1. Introduction

Body fluids (BF) present in cavities or hollow organs can be of physiological or pathological origin. Their cytological analysis provides important information for medical diagnosis of infections and other inflammatory diseases or malignancies [1]. It consists of counting white and red blood cells (WBC and RBC respectively) and performing a differential WBC count.

The gold standard for cell count in BF is light microscopy using hemocytometer counting chamber and cytospin smears stained by May-Grunwald-Giemsa (MGG) for differential WBC count [2]. These methods are time consuming, labor-intensive, subjected to intra and inter-operator variability and require highly qualified professionals for differential count [3].

The most common BF analyzed are ascitic, cerebrospinal (CSF),

pleural or synovial fluid and continuous ambulatory peritoneal dialysis (CAPD). Threshold values of WBC specific to each of these fluids allow diagnostic orientation [1]. RBC count is difficult to interpret because there are no cut-off values reported in the literature. However, this count can be helpful to diagnose blood contamination due to a traumatic puncture of CSF or an hemothorax for instance [4,5].

In the last decade, automated methods have been developed on blood or urine analyzers to improve accuracy and workflow of BF cellular analysis [3,6]. UF-4000 (Sysmex Co., Kobe, Japan) is an automated urine particle analyzer with a body fluid mode using flow cytometry (FCM). Cells are classified according to their size, internal complexity and nucleic acid content. Results are expressed as number of RBC and WBC per microliter associated with a differential WBC count. Total nucleated cells, epithelial cells and bacterial counts are also available. The aspirated sample is mixed with diluent and staining

Abbreviations: BF, Body Fluid; CAPD, Continuous Ambulatory Peritoneal Dialysis; COFRAC, Comité Français d'Accréditation; CSF, Cerebrospinal Fluid; CV, Coefficient of Variation; DS, Deviation Standard; FCM, Flow Cytometry; LoQ, Limit of Quantification; MGG, May-Grunwald-Giemsa; MN, Mononuclear cells; PM, Polymorphonuclear cells; PMN, Polymorphonuclear Neutrophil cells; RBC, Red Blood Cell; WBC, White Blood Cell.

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solution and analyzed by FCM in two distinct channels: SF channel for elements without nucleic acids and CR channel for nucleated cells (WBC and epithelial cells). The BF mode requires 600 μL of BF sample for 450 μL aspirated. The system can analyze 15 samples per hour (20 for the UF-5000 model) and doesn't need any manual sample pre-treatment except for articular fluid [7]. This BF mode is expected to improve precision, accuracy and reduce inter and intra-operator variability. Although marketed for a decade, few studies on the performance of this mode have been published to date. One study was dedicated to the analysis of CSF samples by UF-5000 [8] and a second one has compared the performance of 4 analyzers (including UF-5000) for cell counting of different BF [9].

The aim of the present study was so to evaluate and validate the performance of UF-4000 body fluid mode for cellular analysis of ascitic, CSF, pleural, synovial and CAPD fluids under the routine operating conditions of a microbiology laboratory. This was performed according to the guide SH-GTA-04 published by the COFRAC (Comité Français d'Accréditation) [10] and to the standard NF EN ISO 15189 [11].

2. Materials and methods

2.1. Body fluid samples and study protocol

The study was performed on 223 consecutive BF prospectively collected over 4 months in the Rouen University Hospital: 101 ascitic, 54 CSF (10 obtained by lumbar puncture and 44 by ventricular drainage), 35 pleural, 35 synovial and 8 CAPD fluids. Excepted for CSF received in sterile tubes, body fluids were collected in anticoagulant tubes (EDTA and heparin for articular) to prevent cell clumping and to prolong cell stability.

Each sample was sequentially analyzed (within 2 h) by manual light microscopy and Sysmex UF-4000 (Sysmex Co., Kobe, Japan) in accordance with routine protocol.

Evaluated parameters were WBC, RBC and differential WBC counts. Considering the low number of samples for CSF and CAPD in this study, results were grouped for statistical analysis.

2.2. Manual light microscopy (LM)

WBC and RBC counting were performed in Kova® counting chamber (Glasstic® Slide 10, CML, Nemours, France) that contains a volume of 1 μL . One chamber is a grid composed of 9 large squares themselves subdivided into 9 small squares. The samples were analyzed according to supplier's recommendations. Briefly, for a low cellularity sample, the count was performed throughout the entire chamber. Conversely, for a high cellularity sample, the average of the counts made in 3 small squares was used and multiplied by 90.

Differential WBC count was performed by LM at $\times 1000$ magnification on cytospin smears stained by MGG.

2.3. UF-4000 body fluid mode

WBC and RBC were then counted using the UF-4000 BF mode. WBC were further differentially classified into polymorphonuclear cells (PM) and mononuclear cells (MN). PM included neutrophils (PMN) and eosinophils and MN contained lymphocytes and monocytes.

The RBC and WBC counts expressed by microliter as well as absolute counts and ratio (%) of MN and PM cells were compared to the manual method.

2.4. Imprecision

The precision within-run of UF-4000 body fluid mode was evaluated by measuring 10 replicates of each body fluid for 3 different levels of concentration: low, medium, high level, one of them around a clinical relevant cut-off value. Results obtained for each parameter (WBC, RBC,

PM, MN) were expressed as mean \pm deviation standard (DS) and coefficient of variation (CV%).

2.5. Between-day precision

Between-day precision was assessed by 3 daily analyses using two levels (low and high) of quality control (UF-Control, Sysmex Europe GmbH) throughout the entire study, corresponding to 95 measures. UF-Control is an artificial matrix commonly used for urine and body fluid modes. Results for both WBC and RBC were expressed as mean \pm DS and CV% that were compared to supplier's data and literature.

2.6. Linearity

Linearity was calculated only for WBC, after serial dilutions (from 1/2 to 1/400) of a high cell count sample of each body fluid with physiological serum. A graphic representation between measured and theoretical values was drawn and the Pearson's correlation coefficient (R^2), the slope and the intercept were calculated according to the CLSI document EP6-A [12].

2.7. Carryover

Carryover was assessed for each type of body fluid on 3 aliquots (A1, A2, A3) with a high WBC count ($>10\,000$ WBC/ μL) followed by 3 measures of a blank (physiological saline solution; B1, B2, B3). Carryover ratio was calculated using the formula $[(B1-B3)/(A3-B3)] \times 100$ [10]. Results were compared to acceptable supplier's data [13].

2.8. Uncertainty

Uncertainty was estimated using the CV% of within-run imprecision at different threshold values of WBC for each body fluid: 250 PMN/ μL for ascitic, 5 WBC/ μL for CSF and CAPD; 10,000 WBC/ μL for pleural and 50,000 WBC/ μL for articular fluid.

2.9. Method comparison, bias estimation and diagnostic agreement between UF-4000 body fluid mode and LM

Method comparison was performed for WBC and RBC count for each body fluid. However, comparison of WBC differential counts was only done for ascitic fluid because the major criteria defining ascitic infection is the cut-off value of 250 PMN and not the WBC count [1].

Comparison was performed by several statistics methods. First, agreement was assessed with Pearson's correlation. For the Bland-Altman plot analysis, differences were plotted against the mean of the two methods results. Finally, agreement for diagnostic orientation was evaluated at specific threshold values of 250 PMN/ μL for ascitic, 5 WBC/ μL for CSF/CAPD, 1000 WBC/ μL for pleural and 2000 WBC/ μL for articular fluids (Table 1). The statistics parameters of sensibility (Se) and specificity (Spe) were calculated.

3. Results

3.1. Imprecision

The within-run imprecision results of UF-4000 body fluid mode are presented in Table 2. For WBC, CV% were comprised between 8.8% and 2.3%, with mean WBC/ μL sample values ranging from 7 to 65,444. For PMN, CV% varied from 22.6% to 2.3% (4 to 60,954 PMN/ μL), and for RBC it ranged from 29.4% to 3.2% (7 to 13,138 RBC/ μL). All these CV% were acceptable compared to supplier's data [13].

3.2. Between-run precision,

The between-run precision expressed by CV% was found to be 6.9%

Table 1
Threshold values of WBC for body fluid and diagnostic orientation adapted from Flemming et al [1].

Body fluid	Cut-off value (cells/ μ L)	Diagnostic orientation
Ascitic fluid	PMN > 250	Spontaneous bacterial peritonitis*
CSF	WBC < 5	Physiological value*
	WBC > 250 (PMN > 50%)	Bacterial meningitidis
	WBC = 10–100 (Ly > 50%)	Viral meningitidis
Pleural fluid	WBC = 50–500 (Ly > 50%)	Tuberculous meningitidis
	WBC < 1000	Transudate*
	WBC > 1000	Exudate*
Synovial fluid	WBC > 10,000 (PMN > 50%)	Bacterial infection
	WBC < 2000	Mechanical arthropathy*
	WBC = 2000–50,000 (PMN > 50%)	Inflammatory arthropathy*
CAPD fluid	WBC > 50,000 (PMN > 90%)	Septic arthritis
	WBC > 100 (PMN > 50%)	Bacterial infection

PMN: Polymorphonuclear neutrophils leukocyte, Ly: Lymphocyte; * diagnostic agreement at this threshold value evaluated in this study.

Table 2
Within-run imprecision of UF-4000 body fluid mode.

Body fluid	Within-run imprecision (mean \pm DS cells/ μ L; CV%)		
	Low level	Medium level	High level
<i>Ascitic fluid</i>			
WBC	45.0 \pm 2.3; 5.1%	273.3 \pm 11.0; 4.1%	1264.7 \pm 44.6; 3.5%
PMN	33.3 \pm 5.3; 15.4%	250.8 \pm 10.6; 4.2%	1229.8 \pm 42.7; 3.5%
MN	22.1 \pm 1.9; 8.4%	197.4 \pm 15.5; 7.9%	1004.3 \pm 56.8; 5.6%
RBC	43.5 \pm 3.4; 7.9%	266.0 \pm 4.9; 1.8%	1677.5 \pm 24.3; 1.5%
<i>CSF, CAPD fluid</i>			
WBC	7.2 \pm 0.6; 8.8%	267.3 \pm 14.6; 5.5%	960.6 \pm 36.9; 3.9%
PMN	3.9 \pm 0.8; 22.6%	213.6 \pm 9.5; 4.4%	785.1 \pm 35.5; 4.5%
MN	3.3 \pm 0.9; 28.6%	175.5 \pm 12.6; 7.2%	876.1 \pm 60.2; 6.8%
RBC	42.6 \pm 2.3; 5.5%	1698.5 \pm 120.9; 7.1%	13,138 \pm 426.2; 3.2%
<i>Pleural fluid</i>			
WBC	368.5 \pm 20.5; 5.5%	1629.5 \pm 60.8; 3.7%	13,302.2 \pm 338.3; 2.5%
PMN	353.5 \pm 20.1; 5.7%	647.4 \pm 23.1; 3.6%	11,522.2 \pm 310.8; 2.7%
MN	154.9 \pm 14.8; 9.6%	982.1 \pm 41.4; 4.2%	12,936.7 \pm 347.1; 2.7%
RBC	261.4 \pm 21.4; 8.2%	1709.7 \pm 58.6; 3.4%	12,919.1 \pm 753.6; 5.8%
<i>Articular fluid</i>			
WBC	177.7 \pm 10.7; 6.0%	2568.1 \pm 71.7; 2.8%	65,444.4 \pm 1528.8; 2.3%
PMN	52.4 \pm 6.7; 12.7%	2366.0 \pm 69.1; 2.9%	60,954.2 \pm 1411.7; 2.3%
MN	125.3 \pm 12.6; 10.1%	2200.2 \pm 117.1; 5.3%	4490.2 \pm 287.6; 6.4%
RBC	7.4 \pm 2.2; 29.4%	628.9 \pm 50.9; 8.1%	1819.2 \pm 243.9; 13.4%

for WBC and 6.4% for RBC at low level, and 3% and 4.4% at high level for WBC and RBC respectively. These results were also acceptable compared to supplier’s data (<10% for WBC and < 30% for RBC) [13].

3.3. Linearity

Linearity was conducted with a wide range of WBC values for each fluid. Linear regression showed good correlation between measured and calculated results (Table 3), with slopes comprised between 0.99 and 1.03 and with all regression coefficients (R²) > 0.99.

3.4. Carryover

The carryover was negligible, being < 0.004% for WBC for each BF

Table 3
Linearity results of WBC count for each body fluid of UF-4000 body fluid mode.

Body fluid	Range (cells/ μ L)	Equation	Coefficient regression (R ²)
Ascitic fluid	10 – 4300	y = 1.01x + 11.56	0.9986
CSF, CAPD fluid	50 – 3000	y = 1.02x – 7.00	0.9997
Pleural fluid	50 – 11,200	y = 0.99x – 43.15	0.9991
Articular fluid	60 – 7000	y = 1.03x – 66.35	0.9993

(0.0037% for ascitic, 0.0035% for CSF and CAPD, 0.001% for pleural and 0.003% for articular fluids). These results were acceptable according to the supplier’s data (<0.05%).

3.5. Uncertainty

Uncertainties estimated at specific cut-off values of WBC for each BF (PMN for ascitic fluid) are presented in Table 4. There were all lower than 10% of the cut-off value, except for CSF (20%).

3.6. Method comparison, bias estimation and diagnostic agreement between UF-4000 body fluid mode and LM

The comparison of the WBC and RBC counts between the 2 methods showed good results (Table 5). First, Pearson’s correlation coefficients calculated were excellent for each parameter and each body fluid (R² > 0.98). The Bland-Altman bias were < 10 cells/ μ L for absolute count of WBC and PMN for all types of fluids, except for articular fluid (-62 cells/ μ L). About the population studied, it should be noted that in the 62 CSF/CAPD fluids included, 33 (53%) showed a low WBC count (ranging from 0 to 20 WBC/ μ L), and 20 of them harbored a count under the decision threshold of 5 WBC/ μ L.

Agreement evaluated at specific threshold diagnostic values (Table 1) showed satisfactory results of Se and Spe. They were 100% at 5 WBC/ μ L for CSF and CAPD, 1000 WBC/ μ L for pleural and 2000 WBC/ μ L for articular fluids. Regarding the cut-off value of 250 PMN/ μ L in ascitic fluid, Se was 100% and Spe 98% due to 2 false positive results with UF-4000.

4. Discussion

We evaluated the analytical performance of the UF-4000 BF mode for cellular analysis of ascitic, CSF, pleural, synovial and CAPD fluids under routine operating conditions of a microbiology laboratory. The overall impression of UF-4000 is very positive. The analytical performance is satisfactory for all parameters of the different fluids evaluated and in agreement with those declared by the manufacturer or published in previous studies [8,9,13].

UF-4000 showed good within device precision, CV% being <10% for WBC and 15% for RBC excepted for synovial fluid at low concentration level (CV% at 29%). This could be due to the measured value below the limit of quantification (LoQ) of RBC (7 vs 15 RBC/ μ L) [13]. Between-day precision was also good with CV% lower than 7% for high and low levels of both WBC and RBC counts. The linearity was excellent whatever the body fluid evaluated and carryover was negligible, probably thanks to a rinse cycle between each sample. However, considering the low cut-off

Table 4
Uncertainty measurement of UF-4000 BF mode for WBC count at specific cut-off values.

Body fluids	Cutoff value (cells/ μ L)	Uncertainty (cells/ μ L)
Ascitic fluid	250 PMN	+/- 10 PMN
CSF, CAPD fluid	5 WBC	< +/- 1 WBC
Pleural fluid	10,000 WBC	+/- 250 WBC
Articular fluid	50,000 WBC	+/- 1500 WBC

Table 5

Linear regression and Bland-Altman bias for WBC, PMN, RBC counts of different BF determined using the UF-4000 BF mode versus LM.

	Range (cells/ μ L)	Linear regression	Bias (cells/ μ L)
<i>Ascitic fluid (n = 101)</i>			
WBC	26 – 1500	$y = 0.97x + 3.15$; $R^2 = 0.9957$	–4
PMN	0 – 1000	$y = 0.97x + 6.78$; $R^2 = 0.9816$	+4
RBC	2 – 8000	$y = 0.99x - 13.35$; $R^2 = 0.9833$	–17
<i>CSF, CAPD fluid (n = 62)</i>			
WBC	0 – 3000	$y = 1.01x - 2.53$; $R^2 = 0.9984$	–1
RBC	1 – 8000	$y = 0.96x - 12.58$; $R^2 = 0.9966$	–43
<i>Pleural fluid (n = 35)</i>			
WBC	61 – 14,000	$y = 1.01x - 23.84$; $R^2 = 0.9994$	–7
RBC	49 – 9000	$y = 0.99x + 10.11$; $R^2 = 0.9986$	–6
<i>Articular fluid (n = 35)</i>			
WBC	26 – 68,000	$y = 0.99x - 24.69$; $R^2 = 0.9985$	–62
RBC	8 – 8500	$y = 1.01x - 29.39$; $R^2 = 0.9977$	–19

value of 5 WBC/ μ L for CSF, we decided to add a rinse cycle following analysis of a sample with WBC count > 25,000/ μ L to avoid the risk of contamination of 1 leukocyte.

For CSF and CAPD fluids, the analytical performances observed in our study were in accordance with those reported in a preliminary evaluation of UF-5000 by Seghezzi *et al.* [8]. They reported a good level of agreement for WBC and RBC counts with the gold standard manual technique, and a slight positive bias of 10 WBC/ μ L which decreased to 2.45 WBC/ μ L at low level counts (<20/ μ L). In the study of Cho *et al.* performed on 88 CSF samples, a positive bias of 9 WBC/ μ L was reported but difficult to interpret without indication of the range of measurement levels [9]. On the contrary, we found a negative bias of 1 WBC/ μ L (WBC ranging from 0 to 3,000/ μ L) that was not clinically significant. Uncertainty of \pm 1 WBC/ μ L obtained at the threshold value of 5 WBC/ μ L can also explain the excellent diagnostic agreement observed, with no false classification among 33 samples with WBC count < 20/ μ L, and 20 of them with a WBC count < 5/ μ L. Diagnostic agreement was not improved when applying the instrument specific threshold of 6 WBC/ μ L proposed by Seghezzi *et al.* [8].

Excellent performance was also observed for RBC count of all samples and for a large range of values (RBC ranging from 0 to 8,000/ μ L) with linear regression slope of 0.96 and intercept of –12 corresponding to an estimated LoQ of 15 RBC/ μ L, in accordance with that reported by the manufacturer [13]. A negative bias of 43 RBC/ μ L was obtained, which decreased to –6 RBC/ μ L when calculated for an interval range of 0 to 1,000 RBC, that was slightly superior to that of –0.5 reported by Seghezzi *et al.* [8,14].

Despite good performances, the most relevant limitation of UF-4000 for CSF analysis is the volume of sample required (600 μ L) difficult to obtain except in case of CSF collected by ventricular drainage as for the 44 of 54 CSF analyzed in this study. Some authors propose to dilute CSF in order to overcome this problem but the LoQ increases with the dilution factor and accuracy is compromised [1].

For BF other than CSF, the comparison between WBC-UF count versus LM-count displayed a good agreement all along the range of measures evaluated. Bland Altman bias for each fluid were limited (all < –62/ μ L) with no impact on the respective clinical thresholds for these fluids. The Se and Spe were 100% at the respective cut-offs of 1,000 and 2,000 WBC/ μ L thus enabling the differentiation between transudate and exudate for pleural fluid and between mechanical or inflammatory

pathology for articular fluid [1]. Due to the low number of pathological pleural or articular fluids included, we cannot assess the diagnostic agreement at their respective infection thresholds of 10,000 and 50,000 WBC/ μ L.

Considering the differential WBC count, some limitations persist with UF-4000 body fluid mode: the first one is that UF-4000 does not provide separate counts for lymphocytes and monocytes, and for PMN and PNE. The second is that it doesn't recognize nor report other types of non-hematopoietic cells such as mesothelial cells, blasts or cells derived from solid tumors and atypical cells [3]. Differences between total nucleated cell and WBC counts can be used for indication of microscopic review as well as a high value of the percentage count of MN and abnormal scattergram distribution [1]. Boldu *et al.* showed a percentage of MN significantly higher in neoplastic samples than in non neoplastic, and recommended the use of this percentage as an indicator of malignancy [15]. Our study didn't include enough pathological ascitic fluids with non-hematopoietic cells to assess these propositions.

We only evaluated the diagnostic agreement of the differential WBC count for ascitic at the threshold value of 250 PMN/ μ L which is the best diagnostic criterion of spontaneous bacterial peritonitis [16]. At this cut-off, diagnostic agreement was good with Se of 100% and Spe > 97% due to two false positive samples. In the first case UF-4000 count was 256 PMN/ μ L versus 242 with LM for an evacuating puncture with no infection criteria. This discordance could be related to the technical uncertainty of \pm 10 PMN/ μ L at this cut-off value. On the second case UF-4000 and LM PMN counts were respectively 267 and 243/ μ L for an infected ascite with positive culture leading to an antibiotic treatment; UF-4000 WBC count was most probably the exact value.

These results suggest that UF-4000 BF mode with differential count could be useful for initial screening of ascites in case of urgent situations where infection needs to be ruled-out. However, complementary studies are required to evaluate the performance of UF-4000 BF mode for differential WBC count of other body fluids and to develop algorithms for decision-making criteria for the indication of microscopic review. The performance of bacterial count for diagnostic of infection need also to be evaluated as a cut-off value of 240 bacteria/ μ L was recently reported to predict culture positivity and could be useful to identify situations requiring direct complementary tests [17].

Finally, in the routine operating conditions of our laboratory, UF-4000 body fluid mode proved to be rapid (4 min between 2 samples), time saving and enhancing the laboratory workflow particularly when presence of skilled personnel cannot be ensured. It performed in a single run, accurate counts of WBC and RBC associated to a differential WBC count with an easy and informative visualization of instrumental data. More-over, sample pre-treatment was not necessary except a dilution for synovial fluid due to its viscosity.

5. Conclusion

In our microbiology laboratory, UF-4000 body fluid mode allow to replace LM counting for different BF, including CSF, but excluding samples with abnormal WBC counts or abnormal scattergram distributions for which manual differential cell counts is still be required. Further evaluation of differential WBC and bacterial counts are required to better appreciate their diagnostic performance in case of infection or presence of malignant cells.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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