# EVALUATION OF THE SYSMEX UF-1000i URINE ANALYZER

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## INTRODUCTION

The new automated clinical laboratory method, which is initially validated by the manufacturer, the end-user laboratory should be verified. (CLSI /NCCLS: EP15-A2) Verification should focus on the laboratory's particular patient population. This is essential for providing a safe and useful process to clinicians and patients. For this reason we confirmed that specified requirements were fulfilled.

## OBJECTIVE

The aim of this study was to compare the results of UF 1000i analyzer for red blood cells (RBC), white blood cells (WBC), epithelial cells (EPI), small round cells (SRC) and casts (PC) against manual microscopy of uncentrifuged urine specimens using Fuchs-Rosenthal cell counting chamber.

## METHODS AND MATERIALS

Analyzer: Sysmex 1000i is a fully automated third generation urine sediment flow cytometer. Based on diode laser technology using polymethine dyes specifically staining nucleic acids of urine particles and bacteria. It measures WBC, RBC, bacteria, epithel cells, cast, crystals, yeasts and spermatozoa.
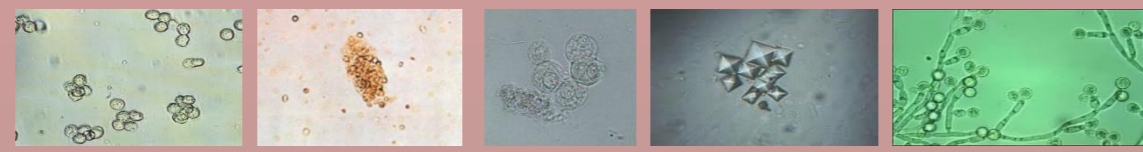
Urine specimens: A total of 500 mid stream urine samples were studied from outpatients during a period of three months. Carry-over, precision, Passing & Bablok regression line, Receiver Operating Curves (ROC) and diagnostic accuracy were tested according to well-established protocols.

## RESULTS

### PRECISION

### WITHIN-RUN PRECISION: (REPEATIBILITY RESULTS) N=20

Twenty consecutive replicates of low and high urine samples were tested on the UF 1000i in the manual mode. The mean, standard deviation and coefficient of variation were determined and compared to performance claims on the manufacturer.

| Low value | RBC | WBC | EC | CAST | BACT |
|---|---|---|---|---|---|
| Mean | 8,27 | 8,70 | 2,60 | 0,29 | 34,80 |
| SD | 0,79 | 0,70 | 0,64 | 0,15 | 4,30 |
| CV % | 8,80 | 8,60 | 24,30 | 62,00 | 12 |
| Acceptable | Yes | Yes | Yes | No | Yes |
| High value | RBC | WBC | EC | CAST | BACT |
| Mean | 49,50 | 229,10 | 81,40 | 5,68 | 667,1 |
| SD | 3,19 | 4,20 | 5,25 | 0,97 | 29,30 |
| CV % | 6,40 | 1,80 | 3,90 | 17,00 | 4,40 |
| Acceptable | Yes | Yes | Yes | Yes | yes |

### BETWEEN-RUN PRECISION:(REPRODUCIBILITY STUDY)N=30

data was collected for the control material (LOT: YS 1019, for RBC, WBC, EC, CAST and Bacteria.

| Low control | RBC | WBC | EC | CAST | BACT |
|---|---|---|---|---|---|
| Mean | 40,70 | 39,90 | 10,70 | 4,70 | 169,70 |
| SD | 2,35 | 2,16 | 1,44 | 0,68 | 14,18 |
| CV% | 5,80 | 5,40 | 13,50 | 14,50 | 8,40 |
| Acceptable | Yes | Yes | Yes | Yes | yes |
| High control | RBC | WBC | EC | CAST | BACT |
| Mean | 194,10 | 780,20 | 72,90 | 17,35 | 704,3 |
| SD | 6,04 | 15,39 | 7,28 | 1,83 | 27,65 |
| CV% | 3,10 | 2,00 | 10,00 | 10,60 | 3,90 |
| Acceptable | Yes | Yes | Yes | Yes | yes |

The within-run and between-run precision on the five enumerated parameters were acceptable.

The CARRYOVER rates were 0,465 % for RBC, 0,117 % for WBC, 0,195 for EPI, 0,058 % for BACT.

### REPORTABLE RANGE (ANALYTICAL RANGE)

The manufacturer's published reportable range for WBC 1-5000/ul and for EC 1-200/ul., for bact 5-10000/ul. Our laboratory verified the range from 5- 3500/ul, for WBC, and from 0,9 -123//ul. for EC, from 14-3920/ul for Gram positive bacteria, and from 5,4-10303/ul for Gram negative bacteria.

## ACCURACY: (TRUENESS, METHOD COMPARISION)

THE DIAGNOSTIC PERFORMANCE of UF 1000i was evaluated by ROC (receiver operating characteristic) curve analysis.
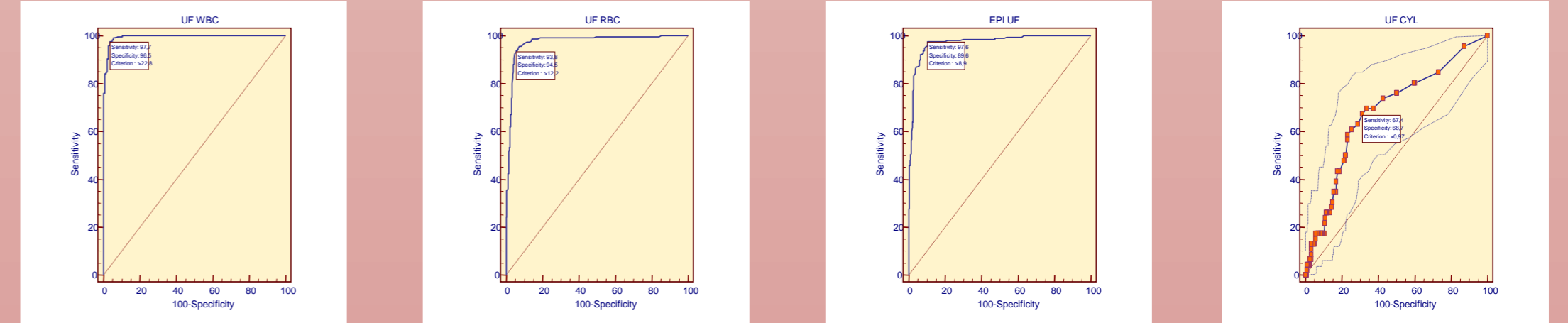


The position of the cutpoint will determine the number of true positive (TP), true negatives (TN), false positive (FP) and false negative (FN). We calculated the negative predictive value (NPV) in a 2x2 contingency table. NPV was 95,1 % for WBC, 96,8 % for RBC, 97,4 % for EC, 99,5 % for SRC and 94 % for cast respectively.

Sensitivity, specificity and their confidence intervals of UF 1000i against manual microscopy are listed below.

### RESULTS for ROC curve analysis

| Parameter | AUC | Sensitivity % | Specificity % | 95 % confid. | intervals | cutpoints |
|---|---|---|---|---|---|---|
| WBC | 0,995 | 97,7 | 96,5 | 0,983 | 0,999 | 22,80 cells |
| RBC | 0,973 | 93,8 | 94,5 | 0,955 | 0,985 | 12,20 cells |
| EPI | 0,972 | 97,6 | 89,6 | 0,954 | 0,985 | 8,90 cells |
| SRC | 0,929 | 80,0 | 98,2 | 0,902 | 0,950 | 10,00 cells |
| CAST | 0,684 | 67,4 | 68,7 | 0,639 | 0,727 | 0,97 cells |

The area under the ROC curve (AUC) is a measure to distinquish between UF 1000i and manual microscopy.

Manual cell counts were compared with cell counts of Sysmex UF 1000i. Results obtained using Passing-Bablok regression analysis , that allows estimation of analytical methods agreement .

PASSING –BABLOK REGRESSION LINE for WBC, RBC and EC cells.
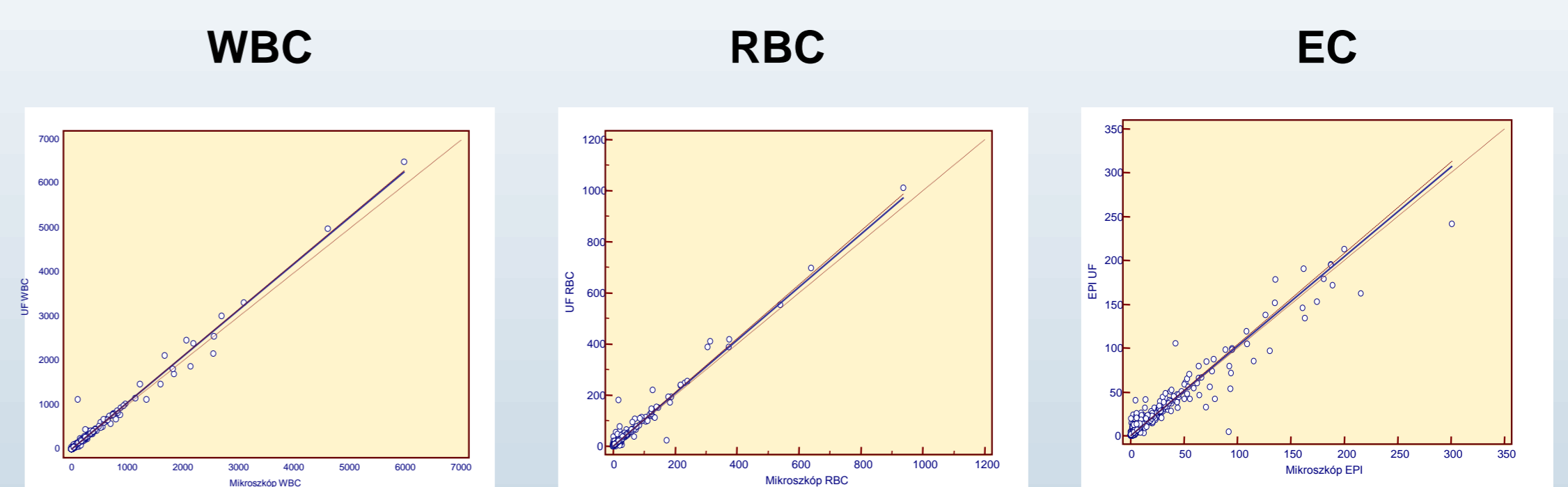
| WBC | RBC | EC |
|---|---|---|



The UF 1000i has good agreement with the reference methos for WBC, RBC and EC.
The results of regression equation and Pearson correlation are shown below. Pearson correlation coefficient measures the strenght of the association between the two method.

| Parameter | Regression | Pearson correlation |
|---|---|---|
| WBC | $y = -0,2990 + 1,0499x$ | 0,9918 |
| RBC | $y = -0,0321 + 1,0383x$ | 0,9840 |
| EPI | $y = 0,2285 + 1,0191x$ | 0,9641 |
| SRC | $y = -0,2161 + 1,6129x$ | 0,6306 |
| CAST | $y = -0,4300 + 3,7330x$ | 0,2526 |
| PAT.C. | $y = 0,0000 + 4,2666x$ | 0,2788 |

Results indicate, that the strength of association between the variables is very high for WBC, RBC and EC, for SRC is 0,6306, but for the cast it is very poor.

## CONCLUSIONS

Our results show that the new UF1000i has good imprecision performance with CV% for RBC, WBC, EPI, and BACT. We found satisfactory agreement between the UF 1000i and quantitative microscopy for WBC, RBC, EPI . SRC and casts were poorly differentiated by UF 1000i. SRC and cast cells reported by the UF 1000i, should be confirmed by manual microscopy. Screening for negative urine samples requires a high negative predictive value and high sensitivity. It improved the workflow in the laboratory, resulting in faster turnaround time of patient results.

In conclusion, the Sysmex UF 10000i urine sediment analysis system is a reliable tool in the clinical practice.