Evaluation of the Fully Automated Integrated Urine Analyzer UX-2000

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UX-2000 is the instrument which is integrated the system of test strip analysis and urine particle analysis. On this instrument, the results of test strip analysis and urine particle analysis can be displayed on one screen. The integration of both analysis enable operator to manage the results easily by using the crosscheck between related parameters such as BLD and RBC, LEU and WBC, NIT and BACT. Therefore, reliability of measurement results can be improved.

In this study, we evaluated basic performance of UX-2000 such as within-run reproducibility, carryover testing, and correlation with UF-1000i, and with Clinitek ATLAS. The results of within-run reproducibility and carryover testing were excellent. And there was no problem about correlation with UF-1000i, and with Clinitek ATLAS. Thus, it seems UX-2000 is useful to routine assay of urine to promote efficient and speedy.

Key Words Fully Automated Integrated Urine Analyzer, UX-2000, Test Strip Analysis, Urine Particle Analysis

INTRODUCTION

There have been considerable advances in automation of urine sediment analysis in recent years because of the development of urine particle analyzers[1-3]. The environment in which urine analysis is undertaken has also changed in major ways, as shown by the recommendation of the UTI Study Group to report white blood cells in urine in quantitative terms [4], and the publication of "Guidelines for Diagnosis of Hematuria" [5]. The recently developed UX-2000 is an analyzer that can perform both test strip analysis (CHM) and urine particle analysis (FCM). In addition to improved user friendliness of the analysis operation, the results of the analyses can be understood comprehensively as they are now managed in an integrated manner [6-8].
We report here the results of a study wherein we evaluated the basic performance of UX-2000.

ANALYZER USED

The performance of the Sysmex fully automated integrated urine analyzer UX-2000 (UX-2000 ; Sysmex Corporation) was evaluated. A Siemens Health Care Diagnostics Clinitek Atlas (Atlas) was used for comparing the results of test strip analysis, and a Sysmex fully automated urine particle analyzer UF-1000*i* (UF-1000*i* ; Sysmex Corporation) was used for comparing the results of urine particle analysis.

SPECIMENS

Urine specimens (n=850) of patients of our hospital were analyzed.

METHODS

1. Within-run reproducibility

The within-run reproducibility for different parameters analyzed by CHM, and RBC, WBC, EC (Epitheial Cells), CAST and BACT measured by FCM was evaluated.
Two patient urine specimens of different concentration were analyzed 10 times consecutively and the within-run reproducibility was evaluated by calculating the coefficient of variation (CV%).

2. Carryover test

Carryover was examined for RBC, WBC and BACT measured by FCM.

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Three high concentration patient urine specimens were measured each followed by consecutive measurements on physiological saline to evaluate carryover.

3. Comparison with currently used methods

For the CHM parameters, 609 patient urine specimens that were tested by Atlas were also analyzed by UX-2000 and the agreement between the two methods in protein, urine glucose, occult blood, leukocyte esterase, pH, creatinine and P/C ratio was evaluated.
For FCM parameters, 685 patient urine specimens were measured by both UF-1000*i* and UX-2000, and the agreement ratios between the two methods for RBC, WBC, EC, CAST and BACT were calculated.

4. Comparison of semi-quantitative values measured by UX-2000 and quantitative values of specimens positive for protein and glucose

81 specimens positive for protein and 44 positive for glucose were analyzed by CHM of UX-2000 (semi-quantitative) and also by biochemical methods (quantitative) and the results of the two methods compared.

5. Comparison of details of "REVIEW" display in UX-2000 and UF-1000*i*

Samples that displayed "REVIEW" in UF-1000*i* but not in UX-2000 were examined in detail for test strip analysis logic and results of microscopic analysis of urine sediments.

RESULTS

1. Within-run reproducibility (*Table 1*)

The within-run reproducibility of the CHM measurements was good and without any problems (data not shown). In FCM, the CV of EC measurements of Sample 1 was high at 22.5% and the CV of CAST of Sample 1 was also high at 45.0%. The CV of EC of Sample 2 was, however, 11.6%. Thus the result was satisfactory for the high concentration specimen. The CV was 3.7% and 2.2% for RBC, 2.8% and 3.2% for WBC, and 10.5% and 10.6% for BACT, for the two samples, which were all good results.

Table 1 *Within-run reproducibility*

RBC

	Sample 1	Sample 2
1	707.6	2562.7
2	692.2	2567.8
3	708.4	2430.8
4	743.1	2431.7
5	740.7	2451.9
6	767.2	2439.6
7	760.5	2457.4
8	753.3	2463.8
9	769.7	2436.1
10	755.2	2424.3
Average	739.8	2466.6
SD	27.47	53.47
CV	3.7%	2.2%

WBC

	Sample 1	Sample 2
1	326.1	296.0
2	310.3	301.3
3	304.3	280.2
4	312.4	275.3
5	303.4	281.2
6	301.7	272.2
7	299.3	277.4
8	294.9	285.2
9	302.8	283.4
10	307.1	281.4
Average	306.2	283.4
SD	8.63	9.00
CV	2.8%	3.2%

EC

	Sample 1	Sample 2
1	2.8	24.8
2	2.6	20.9
3	4.4	21.6
4	4.5	20.3
5	4.2	23.2
6	2.4	17.1
7	4.0	17.3
8	3.0	21.6
9	3.3	19.3
10	3.2	20.1
Average	3.4	20.6
SD	0.77	2.40
CV	22.5%	11.6%

CAST

	Sample 1	Sample 2
1	0.53	0.80
2		1.33
3	0.66	0.80
4	1.06	1.06
5	0.40	1.20
6	0.26	0.66
7	0.80	0.93
8	0.66	1.20
9	0.26	0.93
10	0.53	1.33
Average	0.57	1.02
SD	0.26	0.24
CV	45.0%	23.0%

BACT

	Sample 1	Sample 2
1	135.9	14394.4
2	132.7	12494.2
3	133.7	13664.5
4	135.9	14094.4
5	104.5	12357.1
6	106.6	12203.8
7	115.0	11976.5
8	143.2	12859.9
9	130.7	11081.8
10	127.5	10109.2
Average	126.6	12523.6
SD	13.24	1321.63
CV	10.5%	10.6%

2. Carryover

The results of testing samples A, B and C for carryover are shown in Table 2. No carryover was detected with the sample having RBC 2,470.2/μL, WBC 1,834/μL, and BACT 1,000,000/mL.

3. Comparison with currently used assays

*1) Correlation between results of UX-2000 and Atlas (**Table 3**)*

Agreement within one grade was 97.9% for protein, 99.5% for glucose, 98.0% for occult blood, 97.2% for leukocyte esterase, 91.8% for pH, 95.6% for creatinine, and 97.7% for P/C ratio.

Among the 13 cases that showed discrepancy in protein data, 5 that were (–) by the Atlas and (1+) by the UX-2000 were seen to have 20, 29, 35, 40, and 45 mg/dL protein when analyzed quantitatively. In the 2 cases (one of them was measured 2 times and both data were reflected in the table, eventually there were 3 descrepancies) that were (–) by the Atlas and (2+) by the UX-2000, the quantitative values of protein were 87 and 116 mg/dL. On the other hand, 2 specimens were (–) by the UX-2000 but (1+) by the Atlas, and 3 were (–) by the UX-2000 and (3+) by the Atlas. However, a quantitative protein assay was not done for specimens that gave (3+) result Atlas, the cause of the discrepancy could not be ascertained. Among the 12 specimens that showed discrepancy in occult blood results, 6 were (–) by the Atlas and (1+) by the UX-2000, and 5 of them had RBC count of 1 - 4/HPF and 1 had 5 - 9/HPF. The 1 specimen that was (–) by the Atlas but (2+) by the UX-2000 had RBC count 30 - 49/HPF. On the other hand, of the 2 specimens that were (–) by the UX-2000 and (1+) by the Atlas, one had RBC count <1/HPF and the other 1 - 4/HPF. One specimen that was (±) by the UX-2000 and (2+) by the Atlas had RBC count 1 - 4/HPF. The 2 specimens that were (–) by the UX-2000 and (3+) by the Atlas had RBC count 1 - 4/HPF and 5 - 9/HPF.

The 17 cases that showed discrepancy in the leukocyte esterase reaction were examined further. One which was (–) by the Atlas but (1+) by the UX-2000 had a WBC count of 5 - 9/HPF. The one case (duplicated measurement results were reflected in the table, eventually there were 2 descrepancies) that were (–) by the Atlas and (2+) by the UX-2000 had WBC count 30 - 49/HPF. The 2 cases (one of them was measured 2 times and both data were reflected to the table, eventually there were 3 descrepancies) that were (–) by the Atlas and (3+) by the UX-2000 had WBC count 30 - 49/HPF and >100/HPF. On the other hand, of the 7 cases that were (–) by the UX-2000 and (1+) by the Atlas, 3 had WBC count <1/HPF, another 3 had 1 - 4/HPF, and 1 had 5 - 9/HPF. Of the 3 specimens that were (±) by the UX-2000 and (2+) by the Atlas, 1 had WBC count 5 - 9/HPF and 2 had 10 - 19/HPF.

*2) Correlation between the results of UX-2000 and UF-1000i (**Table 4**)*

The agreement within one grade among a total of 685 specimens was good at 98.8% for RBC, 99.6% for WBC, 99.7% for EC, 96.9% for CAST, and 100.0% for BACT. Among the 575 specimens, which excluded those that displayed "REVIEW" in UF-1000*i*, the agreement was even better at 100.0% for RBC, 99.8% for WBC, 100.0% for EC, 99.7% for CAST, and 100.0% for BACT.

Table 2 *Carryover test*

		RBC	WBC	BACT
Sample A	1	2470.2	284.8	53.3
	2	2.6	0.0	0.0
	3	0.9	0.0	0.0
	4	0.3	0.0	0.0
Carry over (%)		0.105	0.000	0.000
Sample B	1	13.9	1834.0	1000000.0
	2	0.2	0.2	5.1
	3	0.3	0.0	2.0
	4	0.1	0.0	0.0
Carry over (%)		1.439	0.011	0.001
Sample C	1	589.2	333.3	39733.2
	2	0.3	0.0	2.0
	3	0.0	0.0	0.0
	4	0.5	0.0	0.0
Carry over (%)		0.051	0.000	0.005

Carry over (%) = Sample 2 / Sample 1 × 100

Table 3 *Correlation between UX-2000 and Atlas results*

Protein

UX-2000 **Agreement**: 97.9% N=609

UX-2000 \ Atlas	−	±	+	2+	3+
3+	0	0	0	0	5
2+	3	0	0	9	1
+	5	3	24	9	0
±	76	20	2	0	0
−	446	1	2	0	3

Occult blood

UX-2000 **Agreement**: 98.0% N=609

UX-2000 \ Atlas	−	±	+	2+	3+
3+	0	0	0	0	6
2+	1	0	0	28	11
+	6	6	32	17	0
±	33	29	16	1	0
−	408	11	2	0	2

Glucose

UX-2000 **Agreement**: 99.5% N=609

UX-2000 \ Atlas	−	±	+	2+	3+	4+
4+	0	0	0	0	0	14
3+	0	0	0	1	8	0
2+	0	0	3	6	0	0
+	2	0	15	0	0	0
±	15	0	3	0	0	0
−	541	0	1	0	0	0

Leukocyte esterase

UX-2000 **Agreement**: 97.2% N=609

UX-2000 \ Atlas	−	±	+	2+	3+
3+	3	0	0	1	12
2+	2	0	2	10	0
+	1	5	13	6	0
±	7	14	6	3	0
−	472	44	7	1	0

pH

UX-2000 **Agreement**: 91.8% N=609

UX-2000 \ Atlas	5.0	5.5	6.0	6.5	7.0	8.0
8.0	0	0	0	0	4	7
7.0	0	0	4	1	130	0
6.5	0	0	2	52	82	1
6.0	0	0	28	68	2	0
5.5	0	16	136	9	0	0
5.0	0	33	30	2	2	0

CRE

UX-2000 **Agreement**: 95.6% N=609

UX-2000 \ Atlas	10	50	100	200	300
300	0	0	0	0	2
200	0	6	11	18	6
100	6	24	84	29	4
50	84	199	74	7	3
10	51	0	1	0	0

P/C

UX-2000 **Agreement**: 97.7 % N=609

UX-2000 \ Atlas	N	150	300	500
200	5	3	9	30
100	103	68	20	4
N	332	30	2	3

Table 4 *Correlation between UX-2000 and UF-1000i results*

RBC — Agreement : 98.8% N=685

/μL	≧0	≧5.56	≧27.7	≧55.6	≧111.2	≧167	≧277	≧555 /μL
≧555	0	0	0	0	0	0	0	3
≧277	0	1	0	0	0	0	4	1
≧167	0	1	0	0	0	4	0	0
≧111.2	0	1	0	2	3	1	0	0
≧55.6	0	0	1	15	0	0	0	0
≧27.7	0	7	21	4	2	0	0	0
≧5.56	17	190	12	1	0	0	0	0
≧0	354	38	2	0	0	0	0	0

RBC — Agreement : 100.0% N=575

/μL	≧0	≧5.56	≧27.7	≧55.6	≧111.2	≧167	≧277	≧555 /μL
≧555	0	0	0	0	0	0	0	0
≧277	0	0	0	0	0	0	2	0
≧167	0	0	0	0	0	2	0	0
≧111.2	0	0	0	2	2	0	0	0
≧55.6	0	0	0	13	0	0	0	0
≧27.7	0	4	17	1	0	0	0	0
≧5.56	15	150	5	0	0	0	0	0
≧0	331	31	0	0	0	0	0	0

WBC — Agreement : 99.6% N=685

/μL	≧0	≧5.56	≧27.7	≧55.6	≧111.2	≧167	≧277	≧555 /μL
≧555	0	0	0	0	0	0	0	8
≧277	0	0	0	0	0	0	2	3
≧167	0	0	0	0	0	6	0	0
≧111.2	0	0	0	0	2	4	0	0
≧55.6	0	0	0	13	2	2	0	0
≧27.7	0	0	25	5	0	0	0	0
≧5.56	7	148	8	1	0	0	0	0
≧0	434	15	0	0	0	0	0	0

WBC — Agreement : 99.8% N=575

/μL	≧0	≧5.56	≧27.7	≧55.6	≧111.2	≧167	≧277	≧555 /μL
≧555	0	0	0	0	0	0	0	0
≧277	0	0	0	0	0	0	0	0
≧167	0	0	0	0	0	0	0	0
≧111.2	0	0	0	0	0	0	0	0
≧55.6	0	0	0	9	0	0	0	0
≧27.7	0	0	22	2	0	0	0	0
≧5.56	6	115	2	1	0	0	0	0
≧0	404	14	0	0	0	0	0	0

EC — Agreement : 99.7% N=685

/μL	≧0	≧5.56	≧27.7	≧55.6	≧111.2	≧167	≧277	≧555 /μL
≧555	0	0	0	0	0	0	0	0
≧277	0	0	0	0	0	0	0	0
≧167	0	0	0	0	0	0	0	0
≧111.2	0	0	0	0	1	1	0	0
≧55.6	0	0	0	1	0	0	0	0
≧27.7	1	0	8	1	0	0	0	0
≧5.56	5	73	6	1	0	0	0	0
≧0	543	44	0	0	0	0	0	0

EC — Agreement : 100.0% N=575

/μL	≧0	≧5.56	≧27.7	≧55.6	≧111.2	≧167	≧277	≧555 /μL
≧555	0	0	0	0	0	0	0	0
≧277	0	0	0	0	0	0	0	0
≧167	0	0	0	0	0	0	0	0
≧111.2	0	0	0	0	0	0	0	0
≧55.6	0	0	0	0	0	0	0	0
≧27.7	0	0	2	0	0	0	0	0
≧5.56	2	48	1	1	0	0	0	0
≧0	493	29	0	0	0	0	0	0

CAST — Agreement : 96.9% N=685

/μL	≧0	≧1	≧2	≧3	≧5	≧10	≧20	≧30 /μL
≧30	0	0	0	0	0	0	0	0
≧20	0	0	0	0	0	0	2	0
≧10	0	1	1	1	0	0	0	0
≧5	0	0	2	1	0	0	0	0
≧3	4	3	1	1	0	0	0	0
≧2	5	2	1	2	0	0	0	0
≧1	37	8	5	2	0	1	0	0
≧0	587	17	1	0	0	0	0	0

CAST — Agreement : 99.7% N=575

/μL	≧0	≧1	≧2	≧3	≧5	≧10	≧20	≧30 /μL
≧30	0	0	0	0	0	0	0	0
≧20	0	0	0	0	0	0	0	0
≧10	0	0	0	0	0	0	0	0
≧5	0	0	0	0	0	0	0	0
≧3	0	0	0	0	0	0	0	0
≧2	1	0	0	0	0	0	0	0
≧1	13	2	1	0	0	1	0	0
≧0	547	10	0	0	0	0	0	0

BACT — Agreement : 100.0% N=682

/μL	≧0	≧100	≧1000	≧10000 /μL
≧10000	0	0	5	12
≧1000	0	1	19	2
≧100	2	36	1	0
≧0	599	5	0	0

BACT — Agreement : 100.0% N=575

/μL	≧0	≧100	≧1000	≧10000 /μL
≧10000	0	0	0	3
≧1000	0	1	10	0
≧100	2	26	0	0
≧0	530	3	0	0

4. Comparison of semi-quantitative values measured by UX-2000 and quantitative values of specimens positive for protein and glucose (*Fig. 1* and *Fig. 2*)

The relationship between the semi-quantitative values determined by UX-2000 and the quantitative values measured by the biochemical method gave y=0.9938x+7.0263 and R^2=0.89 for protein, and y=1.0316x+0.8806 and R^2=0.95 for glucose. Thus, the correlation was more or less satisfactory for these 2 parameters.

5. Comparison of details of "REVIEW" display in UX-2000 and UF-1000*i* (*Table 5*)

Of the 50 samples that triggered the "REVIEW" display in UF-1000*i*, 7 did not cause the display when analyzed by UX-2000. These 7 specimens were examined in detail for the urine test strip analysis logic and microscopic analysis of urine sediments. Among these 7 cases, 4 displayed "REVIEW" because of Path. CAST in UF-1000*i*. Of these 4, 3 did not require microscopic observation. Microscopic observation was indicated by the urine test strip logic in the remaining 1 because of the presence of urinary protein (2+), and microscopy detected epithelial casts and oval fat bodies. For 1 specimen that triggered "REVIEW" because of Path. CAST and SRC (Small Round Cells), microscopy was indicated by the urine test strip logic because of (3+) level of occult blood, and microscopy could detect epithelial casts. "REVIEW" was displayed for 2 specimens due to X'TAL of which 1 revealed calcium oxalate crystals. Microscopy was indicated by both UX-2000 and UF-1000*i* for the remaining specimen by the test strip analysis logic as the sample had RBC count <5/HPF although it was (2+) for occult blood, and microscopy could detect both granular casts and epithelial casts.

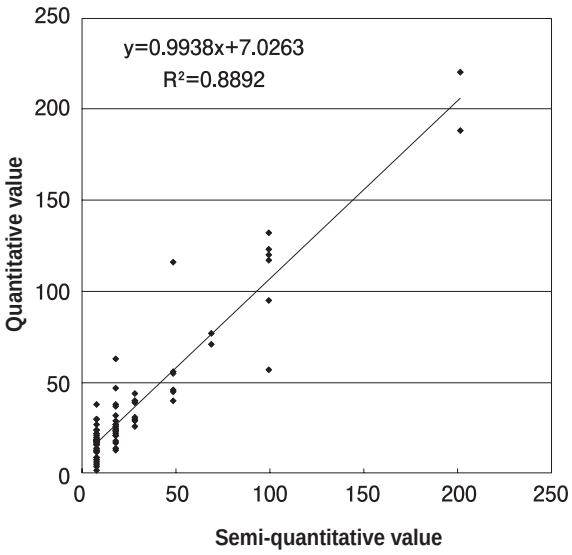

Fig. 1 *Relationship between semi-quantitative protein levels determined by UX-2000 and its quantitative levels (n=81)*

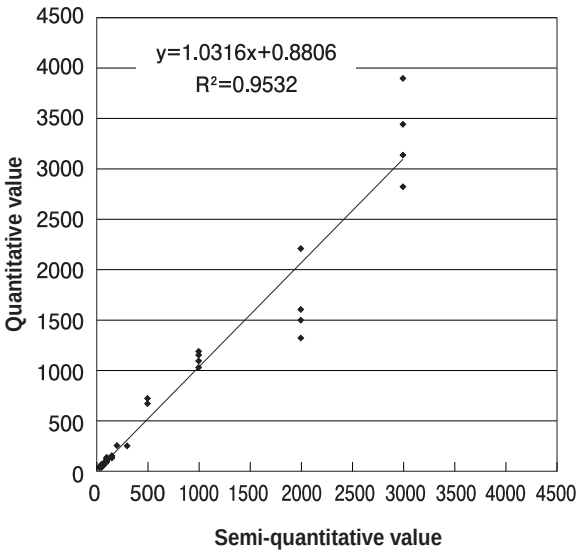

Fig. 2 *Relationship between semi-quantitative glucose levels determined by UX-2000 and its quantitative levels (n=44)*

Table 5 *Examination of cases that triggered "REVIEW" display by UF-1000i but not by UX-2000*

No.	REVIEW display	Test strip logic	Urine sediment microscopy
1	Path. Cast	TP (2+) P/C ratio 500	EC 5/WF OFB 1/LPF
2	Path. Cast		No abnormality detected
3	Path. Cast, SRC	Occult blood (3+)	EC 3/WF
4	Path. Cast		No abnormality detected
5	Path. Cast		No abnormality detected
6	X'TAL	Occult blood (2+)	GC 1/WF EC 1/WF Ca oxalate
7	X'TAL		Ca oxalate

DISCUSSION

The biggest advantage of the UX-2000 is that one analyzer can carry out both CHM and FCM and the results of both these analyses can be viewed on the same screen. Such integration makes it possible to check the results on the same screen, which makes data management easier. Besides this, cross checking can be set between related parameters such as occult blood and RBC, leukocyte esterase and WBC, nitrite and BACT, etc. The use of this function can contribute to better reliability of analysis results. The within-run reproducibility was good, there was no carryover, and we found no problem with analyzer performance. In the correlation of the UX-2000 results with the results given by the Atlas, a currently used CHM analyzer, the agreement within one grade was good. Among samples that showed discrepancy in measured results for protein, 5 that were false positive compared to the results given by the Atlas were indeed found to be positive when verified by quantitative protein assay. The specimens that showed discrepancy in occult blood and white blood cells were also found to have no major problem with the results of the UX-2000 when compared respectively with the RBC and WBC counts. The correlation between UX-2000 and UF-1000*i* results in the FCM parameters was good, the results being even more satisfactory when specimens that displayed "REVIEW" in UF-1000*i* were excluded. Of the 50 specimens than displayed "REVIEW" in UF-1000*i* analysis, 7 did not display "REVIEW" in UX-2000. However, as a detailed examination of the test strip analysis logic and the results of urine sediment microscopy of these specimens did not show any problem, we might say that "REVIEW" was displayed appropriately by UX-2000.
UX-2000 is an instrument with good accuracy, and the assay results can be cross-checked in various combinations. Therefore, it can provide highly reliable test results at the point of care.

CONCLUSION

The UX-2000 is a single integrated unit that provides both CHM and FCM analysis. This makes data management easier and highly reliable test reports can be expected. If this analyzer is deployed in a suitable manner in clinical laboratories, it would make a significant contribution to making routine testing efficient and speedy.
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References

1) *Higashino Y. A Device for General Test: Fully automated urine particle analyzer UF-1000i. Medical Technology. 2006; 34 (13): 1510. (Japanese).*
2) *Tanaka Y, Inoue J. An outline of the fully automated urine particle analyzer UF-1000i and the measuring technique. Japanese Journal of Clinical Laboratory Automation. 2006; 31(4): 653. (Japanese).*
3) *Miwa N et al. The Basic Performance of the Fully Automated Urine Particle Analyzer UF-1000i — Focusing on the case that should be noted —. Igaku Kensa. 2009; 58(1): 115-118. (Japanese).*
4) *UTI Subcommittee of the Clinical Evaluation Guidelines Committee, Japanese Society of Chemotherapy. Japanese Guideline for clinical research of antimicrobial agents on urogenital infections — First edition. Japanese Journal of Chemotherapy. 2009; 57(6): 511-525. (Japanese).*
5) *Working Group for the Creation of Hematuria Guidelines. Guidelines for diagnosis of hematuria. Japanese Journal of Nephrology. 2006; 48 (Suppl.): 1-34. (Japanese).*
6) *Kobayashi H, Tanaka C. Overview of a fully automated integrated urine analyzer UX-2000. Sysmex J. 2011; 34 (Suppl. 1): 70-75. (Japanese).*
7) *Ichiyanagi Y et al. Basic evaluation of the fully automated integrated urine analyzer UX-2000. Igaku Kensa. 2011; 60(4): 502. (Japanese).*
8) *Yuno T et al. Positioning of urine dip stick, urine sediment and urine component data as laboratory test information — New potential offered by an integrated urine analyzer —. Igaku Kensa. 2011; 60(4): 504. (Japanese).*