Performance Evaluation of the Semi-Automated Urine Chemistry Analyzer UC-1000

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In clinical testing, urine dipstick tests are widely performed as a first line screening test at laboratory facilities that use various devices. In this study, we conducted a basic evaluation of the Semi-Automated Urine Chemistry Analyzer UC-1000 (hereinafter referred to as the UC-1000 [Sysmex Corporation]) with the existing urine chemistry analyzers UC-3500 (Sysmex Corporation) and Clinitek Status Plus (Siemens Healthcare Diagnostics). The UC-1000 is a compact, lightweight and portable urine chemistry analyzer with a high throughput which has the capacity to simultaneously measure up to 12 urine qualitative parameters. The UC-1000 results indicated a good correlation with the two other urine chemistry analyzers tested. Therefore, the UC-1000 may help improve the efficiency of daily operations performed at a wide variety of clinical sites.

Key Words Semi-Automated Urine Chemistry Analyzer UC-1000, Fully Automated Urine Chemistry Analyzer UC-3500, Clinitek Status Plus

INTRODUCTION

In a urine dipstick test, diagnostic information can be obtained simply by dipping test strips into urine samples and obtaining colorimetric results ¹). For this reason, this type of analysis is widely performed as clinical laboratory screening tests for the diagnosis of kidney and urinary system diseases. Two highly regarded references citing the use of urine dipstick testing include the "Guideline for the Management of Hematuria 2013" ²) and the "Evidence-based Clinical Practice Guideline for CKD (2013)" ³). Today facilities use various urinalysis devices to quickly provide highly accurate analytical data ⁴). In this report we highlight the results obtained from the clinical performance evaluation of the Semi-Automated Urine Chemistry Analyzer UC-1000 (hereinafter referred to as the UC-1000 [Sysmex Corporation]).

The cut-off table used for the assessment of results from the UC-1000 is specific to markets outside of the United States. Therefore, results may differ when the devise is used in the United States.

BASIC CHARACTERISTICS OF THE ANALYZER

The UC-1000 is compact, lightweight, and portable. This high-throughput equipment can process up to 480 samples per hour. Its user-friendly design offers convenient operability, including easy test strip placement and simple maintenance. The UC-1000 is equipped with a light receiver and incorporated color CMOS sensor. The CMOS sensor allows for qualitative and semi-quantitative measurement using test strip images, allowing for the identification of foreign objects and abnormal colors on the test strip pads even after measurement. The analyzer can distinguish the colors of hemoglobin and red blood cells on an occult blood test pad and correct a false-positive reaction of bilirubin⁵⁾ caused by interfering drugs and chemicals. Additionally, the device supports test strips for the measurement of an albumin/creatinine ratio. This added functionality allows users to perform a wider range of screening tests, including urinary albumin, a high-risk parameter for patients with chronic kidney disease and hypertension. On par with the commercially available Fully Automated

Urine Chemistry Analyzer UC-3500 (hereinafter referred to as the UC-3500 [Sysmex Corporation]), the UC-1000 can be connected to the Urinalysis Work Area Information Management System (U-WAM; Sysmex Corporation), which makes this a convenient choice for use in smaller hospitals and clinics and as a backup instrument in larger testing centers.

MATERIALS AND METHODS

1) Samples

Salvaged urine specimens submitted to the Medical Laboratory Center of the Kanazawa Medical University Hospital during October 25, 2016 and February 1, 2017, were used for testing. This study was approved by the Ethics Committee of the Kanazawa Medical University Hospital.

2) Device, reagents, and parameters

(1) Device and reagents

Device: Semi-Automated Urine Chemistry Analyzer UC-1000

Test strip: UROPAPER III 'Eiken' 12 (Eiken Chemical)* [For comparison]

(2) Measured parameters

For the evaluation of protein, glucose, occult blood,

leukocyte, pH, bilirubin, urobilinogen, ketone, nitrite, specific gravity, creatinine, albumin, and A/C ratio, the rate of concordance with the device subjected to correlation comparison was calculated.

Only the Status Plus was used in the comparison of specific gravity. In the UC-3500, the specific gravity of urine was calculated based on the refractive index measured with a traditional refractometer. In comparison, when using the UC-1000 the concentration of cations in urine was measured by detecting colorimetric change of the test strip and converting this change into the specific gravity. Due to this difference in the measurement methods between the two models, it was not appropriate to evaluate the correlation between the results, and thus the comparison of this parameter between the two models is omitted from this report.

3) Examination method

Using patient urine samples (n = 762 [including 68 diluted samples]), we measured the above parameters by UC-1000, UC-3500, and the Status Plus and calculated the exact match concordance rate and the \pm 1 rank match concordance rate between the UC-1000 and the other two devices.

* Equivalent products are sold as "MEDITAPE UC-12S" from Sysmex Corporation.



Fig. 1 Appearance of UC-1000

Table 1 Devices and	test strips subjected	l to correlation comparison
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Device	Test strip
Fully Automated Urine Chemistry Analyzer UC-3500 (Sysmex Corporation)	MEDITAPE UC-11A (Sysmex Corporation)
Clinitek Status Plus (hereinafter referred to as the Status Plus [Siemens Healthcare Diagnostics])	Multistix 10SG CLINITEK Microalbumin 2 (Siemens Healthcare Diagnostics)

RESULTS

1) Protein (PRO)

The correlation between the UC-1000 and UC-3500 was represented by an exact match concordance rate of 87.0% and a \pm 1 rank match concordance rate of 99.7%. This indicates that the value obtained from the UC-1000 tended to be lower than that from the UC-3500 (*Table 2*). The correlation between the UC-1000 and Status Plus was represented by an exact match concordance rate of 76.6% and a \pm 1 rank match concordance rate of 99.7%. This indicates that the value obtained from the UC-1000 tended to be lower than that from the Status Plus (*Table 2*).

2) Glucose (GLU)

The correlation between the UC-1000 and UC-3500 was represented by an exact match concordance rate of 96.7% and a \pm 1 rank match concordance rate of 100% (*Table 3*).

The correlation between the UC-1000 and Status Plus was represented by an exact match concordance rate of 84.6% and a \pm 1 rank match concordance rate of 100%. This indicates that the value obtained from the UC-1000 tended to be higher than that from the Status Plus (*Table 3*).

Table 2

PRO			UC-3500									
FF	10	-	+-	1+	2+	3+	4+	Total				
	-	378	9	2	0	0	0	389				
	+-	53	106	17	0	0	0	176				
	1+	0	2	92	4	0	0	98				
UC-1000	2+	0	0	1	61	4	0	66				
	3+	0	0	0	2	19	5	26				
	4+	0	0	0	0	0	7	7				
	Total	431	117	112	67	23	12	762				
%Exact	Match =	87.0%										

%±1 Rank Match =99.7%

DE	PRO		CLINITEK Status+ [mg/dL]								
FRU		Negative	Trace	30	100	300	Total				
	-	384	4	1	0	0	389				
	+-	62	68	45	1	0	176				
	1+	0	0	55	43	0	98				
UC-1000	2+	0	0	0	44	22	66				
	3+	0	0	0	0	26	26				
	4+	0	0	0	0	7	7				
	Total	446	72	101	88	55	762				

%Exact Match = 76.6%
%±1 Rank Match = 99.7%

%±1 Rank Match = 99.7%

Table 3

					UC-3500			
GLU		-	+-	1+	2+	3+	4+	Total
	-	584	1	0	0	0	0	585
	+-	1	15	0	0	0	0	16
	1+	0	5	18	0	0	0	23
UC-1000	2+	0	0	8	24	5	0	37
	3+	0	0	0	1	17	1	19
	4+	0	0	0	0	3	79	82
	Total	585	21	26	25	25	80	762
%Exact	Match =	96.7%						

%Exact Match =96.7

%±1 Rank Match = 100.0%

			CL	INITEK Sta	atus+ [mg/o	dL]	
GLU		Negative	100	250	500	1000	Total
	-	582	3	0	0	0	585
	+-	8	8	0	0	0	16
	1+	0	23	0	0	0	23
UC-1000	2+	0	18	14	5	0	37
	3+	0	0	4	15	0	19
	4+	0	0	0	79	3	82
	Total	590	52	18	99	3	762

Exact Match = 84.6%

%±1 Rank Match = 100.0%

3) Occult blood (BLD)

The correlation between the UC-1000 and UC-3500 was represented by an exact match concordance rate of 90.9% and a \pm 1 rank match concordance rate of 99.5% (*Table 4*).

The correlation between the UC-1000 and Status Plus was represented by an exact match concordance rate of 66.1% and a \pm 1 rank match concordance rate of 99.7%. This indicates that the value obtained from the UC-1000 tended to be lower than that from the Status Plus (*Table 4*).

4) Leukocyte (LEU)

The correlation between the UC-1000 and UC-3500 was represented by an exact match concordance rate of 78.0% and a \pm 1 rank match concordance rate of 97.6%. This indicates that the value obtained from the UC-1000 tended to be lower than that from the UC-3500 (*Table 5*). The correlation between the UC-1000 and Status Plus was represented by an exact match concordance rate of 78.9% and a \pm 1 rank match concordance rate of 97.7%. This indicates that the value obtained from the UC-1000 tended to be lower than that from the Status Plus (*Table 5*).

Table	4
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ы	D		UC-3500								
BLD		-	+-	1+	2+	3+	Total				
	-	537	20	2	0	0	559				
	+-	4	53	11	2	0	70				
UC-1000	1+	0	3	30	11	0	44				
00-1000	2+	0	0	5	28	11	44				
	3+	0	0	0	0	45	45				
	Total	541	76	48	41	56	762				
%Exact	Match =	90.9%									

%±1 Rank Match = 99.5%

BLD			CLINITEK Status+								
		Negative	Trace-lysed	Trace-intact	Small	Moderate	Large	Total			
	-	407	117	33	2	0	0	559			
	+-	0	18	2	50	0	0	70			
UC-1000	1+	0	0	0	13	31	0	44			
00-1000	2+	0	0	0	3	41	0	44			
	3+	0	0	0	0	22	23	45			
	Total	407	135	35	68	94	23	762			
%Exact	Match =	66.1%									

_____%±1 Rank Match = 99.7%

Table 5

	LEU		UC-3500							
LC			1+	2+	3+	Total				
	-	488	48	8	0	544				
	1+	28	14	34	1	77				
UC-1000	2+	9	2	36	36	83				
	3+	0	0	2	56	58				
	Total	525	64	80	93	762				

%Exact Match = 78.0%
%±1 Rank Match = 97.6%

_____%±1 Halik Watch =97.0%

	LEU		CLINITEK Status+							
	0	Negative	Trace	Small	Moderate	Large	Total			
	-	473	54	7	0	0	534			
	1+	30	26	19	0	0	75			
UC-1000	2+	10	7	44	18	4	83			
	3+	0	0	9	27	22	58			
	Total	513	87	79	45	26	750			

%Exact Match =78.9%

___%±1 Rank Match =97.7%

5) pH

The correlation between the UC-1000 and UC-3500 was represented by an exact match concordance rate of 84.1% and ± 1 rank match concordance rate of 100% (*Table 6*). The correlation between the UC-1000 and Status Plus was represented by an exact match concordance rate of 62.7% and a ± 1 rank match concordance rate of 99.7%. This indicates that the value obtained from the UC-1000 tended to be lower than that from the Status Plus (*Table 6*).

6) Bilirubin (BIL)

The correlation between the UC-1000 and UC-3500 was represented by an exact match concordance rate of 94.8% and a ± 1 rank match concordance rate of 99.1% (*Table* 7).

The correlation between the UC-1000 and Status Plus was represented by an exact match concordance rate of 86.1% and a \pm 1 rank match concordance rate of 97.5%. This indicates that the value obtained from the UC-1000 tended to be lower than that from the Status Plus (*Table* 7).

Table 6

						UC-	3500				
pl		5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0	Total
	5.0	40	29	0	0	0	0	0	0	0	69
	5.5	0	130	25	0	0	0	0	0	0	155
	6.0	0	7	149	25	0	0	0	0	0	181
	6.5	0	0	4	109	11	0	0	0	0	124
UC-1000	7.0	0	0	0	0	92	4	0	0	0	96
00-1000	7.5	0	0	0	0	6	90	1	0	0	97
	8.0	0	0	0	0	0	3	20	3	0	26
	8.5	0	0	0	0	0	0	1	3	0	4
	9.0	0	0	0	0	0	0	0	2	7	9
	Total	40	166	178	134	109	97	22	8	7	761
%Exact	Match =	84.1%									

%±1 Rank Match = 100.0%

						CLINITE	K Status+				
pl	П	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0	Total
	5.0	25	44	0	0	0	0	0	0	0	69
	5.5	3	109	43	0	0	0	0	0	0	155
	6.0	0	3	117	59	2	0	0	0	0	181
	6.5	0	0	0	53	71	0	0	0	0	124
UC-1000	7.0	0	0	0	0	96	0	0	0	0	96
00-1000	7.5	0	0	0	0	30	68	0	0	0	98
	8.0	0	0	0	0	0	9	2	15	0	26
	8.5	0	0	0	0	0	0	0	4	0	4
	9.0	0	0	0	0	0	0	0	5	4	9
	Total	28	156	160	112	199	77	2	24	4	762

%Exact Match =62.7%

____%±1 Rank Match =99.7%

Table 7

Р	BIL			UC-3500						
В			1+	2+	3+	Total				
	-	698	17	2	1	718				
	1+	4	13	11	2	30				
UC-1000	2+	0	0	4	1	5				
	3+	2	0	0	7	9				
	Total	704	30	17	11	762				
%Exact	%Exact Match =94.8%									

%±1 Rank Match =99.1%

Б	BIL		CLI	NITEK Stat	us+	
DIL		Negative	Small	Moderate	Large	Total
	-	638	67	9	4	718
	1+	1	8	16	5	30
UC-1000	2+	0	0	3	2	5
	3+	1	0	1	7	9
	Total	640	75	29	18	762

Exact Match =86.1%

%±1 Rank Match =97.5%

7) Urobilinogen (URO)

The correlation between the UC-1000 and UC-3500 was represented by an exact match concordance rate of 93.6% and a \pm 1 rank match concordance rate of 100% (*Table 8*).

The correlation between the UC-1000 and Status Plus was represented by an exact match concordance rate of 91.2% and a ± 1 rank match concordance rate of 100% (*Table 8*).

8. Ketone (KET)

The correlation between the UC-1000 and UC-3500 was represented by an exact match concordance rate of 97.8% and a \pm 1 rank match concordance rate of 100% (*Table 9*).

The correlation between the UC-1000 and Status Plus was represented by an exact match concordance rate of 91.5% and a \pm 1 rank match concordance rate of 99.9% (*Table 9*).

Table	8
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	URO		UC-3500									
UNU		normal	1+	2+	3+	4+	Total					
	normal	639	11	0	0	0	650					
	1+	10	41	0	0	0	51					
UC-1000	2+	0	11	24	0	0	35					
00-1000	3+	0	0	14	8	0	22					
	4+	0	0	0	3	1	4					
	Total	649	63	38	11	1	762					

Exact Match = 93.6%

%±1 Rank Match = 100.0%

	URO		CLINITEK Status+ [mg/dL]								
UNU		0.2	1.0	2.0	4.0	8.0	Total				
	normal	611	39	0	0	0	650				
	1+	0	41	9	1	0	51				
UC-1000	2+	0	0	17	18	0	35				
00-1000	3+	0	0	0	10	12	22				
	4+	0	0	0	0	4	4				
	Total	611	80	26	29	16	762				

%Exact Match =91.2%
%±1 Rank Match =100.0%

Table 9

K	т			UC-3500						
	KET		1+	2+	3+	Total				
	-	673	3	0	0	676				
	1+	4	35	1	0	40				
UC-1000	2+	0	7	24	2	33				
	3+	0	0	0	13	13				
	Total	677	45	25	15	762				
Exact	%Exact Match = 97.8%									

%±1 Rank Match = 100.0%

_____%±1 Rank Match = 100.0%

	KET		CLINITEK Status+ [mg/dL]								
NE I		Negative	Trace	15	40	80	160	Total			
	-	624	43	8	1	0	0	676			
	1+	0	4	34	2	0	0	40			
UC-1000	2+	0	0	8	23	2	0	33			
	3+	0	0	0	1	5	7	13			
	Total	624	47	50	27	7	7	762			

%Exact Match =91.5%

%±1 Rank Match =99.9%

9) Nitrite (NIT)

The correlation between the UC-1000 and UC-3500 was represented by an exact match concordance rate of 95.8% and a \pm 1 rank match concordance rate of 100% (*Table 10*).

The correlation between the UC-1000 and Status Plus was represented by an exact match concordance rate of 96.7% and a ± 1 rank match concordance rate of 100% (*Table 10*).

10) Specific gravity (S.G.)

The correlation between the UC-1000 and Status Plus was represented by an exact match concordance rate of 33.1% and a \pm 1 rank match concordance rate of 80.4%. this indicates that the value obtained from the UC-1000 tended to be lower than that from the Status Plus (*Table 11*).

Table 10

N	г	UC-3500						
IN	NIT		+	Total				
	-	659	3	662				
UC-1000	+	29	71	100				
	Total	688	74	762				
%Exact Match =95.8%								
	nk Motob	100.00/						

%±1 Rank Match = 100.0%

N	г	CLI	NITEK Stat	US+					
IN	11	Negative Positive		Total					
	-	658	4	662					
UC-1000	+	21	79	100					
	Total	679	83	762					
%Exact Match =96.7%									
%±1 Ra	ank Match =	100.0%							

Table 11

6.0	S.G.		CLINITEK Status+										
5.0	а.	1.005	1.010	1.015	1.020	1.025	1.030	Total					
	1.000	1	1	0	0	0	0	2					
	1.005	33	46	20	2	0	0	101					
	1.010	8	65	125	38	14	1	251					
UC-1000	1.015	0	9	42	62	22	3	138					
00-1000	1.020	0	4	15	77	35	8	139					
	1.025	0	0	9	19	17	4	49					
	1.030	0	0	1	26	38	17	82					
	Total	42	125	212	224	126	33	762					

SExact Match = 33.1%

___%±1 Rank Match =80.4%

11) Creatinine (CRE)

The correlation between the UC-1000 and UC-3500 was represented by an exact match concordance rate of 56.2% and a \pm 1 rank match concordance rate of 99.9%. This indicates that the value obtained from the UC-1000 tended to be higher than that from the UC-3500 (*Table 12*).

The correlation between the UC-1000 and Status Plus was represented by an exact match concordance rate of 61.8% and a ± 1 rank match concordance rate of 97.1% (*Table 12*).

12) Albumin (ALB)

The correlation between the UC-1000 and UC-3500 was represented by an exact match concordance rate of 84.1% and a \pm 1 rank match concordance rate of 99.2% (*Table 13*).

The correlation between the UC-1000 and Status Plus was represented by an exact match concordance rate of 87.7% and a \pm 1 rank match concordance rate of 99.9% (*Table 13*).

Table 12

0				UC-3500) [mg/dL]		
CRE		10	50	100	200	300	Total
	10	140	2	0	0	0	142
	50	119	170	0	0	0	289
UC-1000	100	0	153	104	0	0	257
[mg/dL]	200	0	1	53	13	0	67
	300	0	0	0	6	1	7
	Total	259	326	157	19	1	762
%Exact	Match =	56.2%					

%±1 Rank Match = 99.9%

CRE		CLINITEK Status+ [mg/dL]						
UNE		10	50	100	200	300	Total	
	10	110	23	3	4	2	142	
	50	58	191	31	9	0	289	
UC-1000	100	1	70	126	58	2	257	
[mg/dL]	200	0	1	8	39	19	67	
	300	0	0	0	2	5	7	
	Total	169	285	168	112	28	762	
%Exact Match = 61.8%								

%±1 Rank Match = 97.1%

/0±1 Halik Match = 97.1 /6

Table 13

ALB		UC-3500 [mg/L]							
		10	30	80	150	over	Total		
	10	330	11	2	1	0	344		
UC-1000 [mg/L]	30	53	104	13	1	0	171		
	80	0	4	53	13	2	72		
	150	0	0	8	41	12	61		
	over	0	0	0	1	113	114		
	Total	383	119	76	57	127	762		

Exact Match = 84.1%

%±1 Rank Match = 99.2%

ALB		CLINITEK Status+ [mg/L]						
		10	30	80	150	Total		
	10	322	21	1	0	344		
UC-1000 [mg/L]	30	20	119	32	0	171		
	80	0	2	63	7	72		
	150	0	0	11	50	61		
	over	0	0	0	114	114		
	Total	342	142	107	171	762		
%Exact Match =87.7%								

%±1 Rank Match =99.9%

– 8 –

13) A/C ratio

The correlation between the UC-1000 and UC-3500 was represented by an exact match concordance rate of 71.6% and a \pm 1 rank match concordance rate of 94.3% (*Table 14*).

The correlation between the UC-1000 and Status Plus was represented by an exact match concordance rate of

70.7% and a \pm 1 rank match concordance rate of 95.4% (*Table 14*).

For A/C ratio, the number of samples used in the comparison was smaller than that used in the comparison of other parameters because the measurement results were treated as errors in cases in which there was a clear discrepancy between the albumin pad and the protein pad.

Table	14
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	111 1			UC-3500							
	dilute	normal	1+	>=1+	2+	Total					
dilute	120	0	0	0	0	120					
ormal	90	132	32	0	0	254					
1+	6	42	153	0	33	234					
>=1+	0	0	0	2	9	11					
2+	2	0	2	0	138	142					
Total	218	174	187	2	180	761					
	ormal 1+ >=1+ 2+ Γotal	90 1+ 6 >=1+ 0 2+ 2 Fotal 218	90 132 1+ 6 42 >=1+ 0 0 2+ 2 0 Total 218 174	90 132 32 1+ 6 42 153 >=1+ 0 0 0 2+ 2 0 2 Total 218 174 187	90 132 32 0 1+ 6 42 153 0 >=1+ 0 0 0 2 2+ 2 0 2 0 Total 218 174 187 2	90 132 32 0 0 1+ 6 42 153 0 33 >=1+ 0 0 0 2 9 2+ 2 0 2 0 138 Total 218 174 187 2 180					

%±1 Rank Match = 94.3%

	0	CLINITEK Status+ [mg/gCr]					
A/C		30	30-300	300	Total		
	dilute	96	24	0	120		
	normal	182	71	1	254		
UC-1000	1+	67	138	29	234		
00-1000	>=1+	0	9	2	11		
	2+	5	24	113	142		
	Total	350	266	145	761		

%Exact Match = 70.7%
%±1 Rank Match = 95.4%

DISCUSSION

We evaluated the clinical performance of the Semi-Automated Urine Chemistry Analyzer UC-1000. Despite its compact size and lighter weight, the UC-1000 also has a high throughput and the capacity to measure 12 parameters at once, which is on par with the Fully Automated Urine Chemistry Analyzer UC-3500. The UC-1000 allows the user to visually evaluate color intensity using test strip images. This visual confirmation allows for the detection of false-positive results from interfering drugs, identification of errors due to strip misalignment, and discovery of foreign materials within the testing unit. This additional functionality improves result reliability.

The results of the UC-1000 demonstrated good correlation with those of the existing urine chemistry analyzers the UC-3500 and the Status Plus, indicating a satisfactory performance of the new device. However, there were discrepancies in the results of several

parameters between the UC-1000 and the existing analyzers.

In two cases of occult blood, the UC-1000 demonstrated false negative results. In these cases the UC-1000 indicated negative results while the UC-3500 indicated positive results, while the images of the test strips revealed that the red blood cell reaction was weakly positive and the reflectivity value of the UC-1000 was close to positive. Based on these findings, we assume that measurement variations caused this discrepancy.

In two cases of bilirubin, the UC-1000 demonstrated false positive results. In these cases the UC-1000 results were strongly positive and the UC-3500 results were negative, and it was determined that the corrective function for determining a false-positive bilirubin reaction had worked as intended only on the UC-3500. A false-positive bilirubin reaction is observed in cases of a coupling reaction between the diazonium salt in the bilirubin pad and a phenolic metabolite discharged into urine after dosing of drugs such as etodolac. The developed color ranges from pink to reddish-brown, which is different from the color observed in a normal reaction with bilirubin⁶⁾. The false-positive bilirubin can be corrected with software using certain criteria, so that a negative reaction can be obtained in cases in which abnormal color development is observed in the bilirubin pad. Although the UC-1000 has the same function, it did not work as intended in this case. In three cases in which the UC-1000 results were negative and the UC-3500 results were strongly positive, all urine samples showed a strongly positive urobilinogen reaction and the color of the samples was yellow or orange. This discrepancy was partly because the results were not corrected according to the sample colors, i.e., the false-positive results of the UC-1000 seemingly occurred because the color on the test strip pads was produced by concentrated substances in the urine.

In nine cases of discordant leukocyte results, in which the UC-1000 results were strongly positive and the UC-3500 results were negative, many of the samples showed a positive bilirubin or urobilinogen reaction and the urine was noticeably colored. This discrepancy likely occurred because the UC-1000 has no function to correct for urine color. In eight cases in which the UC-1000 results were negative and the UC-3500 results were positive, the results of the two devices revealed that the used samples contained a large amount of glucose or protein. We assume that these substances affected the results. In the urine dipstick test, it is known that the reactivity of leukocyte test pad to baruria, such as high protein urine or high glucose urine, is usually low compared to the reactivity to normal urine, leading to a false-negative result⁷⁾.

In three cases in which the albumin level was negative in the UC-1000 (10 mg/L) and positive in the UC-3500 (80 mg/L or higher), the color of all used samples was orange or red. Although albumin pads turn green in a positive reaction, analyzers without a function for urine color correction may produce unreliable results such as a red color, which is a complementary color to green.

In contrast to the test strips used in the UC-3500, the test strips used in the UC-1000 do not have a blank pad and thus cannot correct for sample color. The parameters measured by the UC-1000 and the existing analyzers had a good overall correlation. However, the discrepancies in some results between the UC-1000 and UC-3500 indicate that further studies are desirable to improve the test strips and devices.

Despite its compact size, the parameters measured on the UC-1000 are identical to those measured in the Fully Automated Urine Chemistry Analyzer UC-3500, and the former can process samples with a throughput of 480 samples per hour. Therefore, we believe that the UC-1000 will improve the efficiency of daily operations at various clinical sites, including in community hospitals and clinics and as a backup instrument in larger healthcare facilities.

CONCLUSION

We compared the UC-1000 with the existing analyzers the Sysmex UC-3500 and the Siemens Clinitek Status Plus. Despite its compact size, the UC-1000 measured as many parameters as the Fully Automated Urine Chemistry Analyzer UC-3500, and the measurement results of the UC-1000 indicated a good correlation with those of the UC-3500 and the Status Plus. Therefore, we believe that the UC-1000 may be useful in a wide variety of clinical sites.

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