

Performance Evaluation of the UC-1100 Semi-Automated Urine Chemistry Analyzer

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Objective: Urinalysis is one of the most common, inexpensive, and non-invasive tests used as a screening tool to detect metabolic disorders, renal dysfunction, and urinary tract infections (UTIs). With growing expectations for rapid, accurate, and user-friendly testing, newly developed semi-automated analyzers are expected to provide fast and reliable results. The aim of this study was to compare the performance of the UC-1100 Semi-Automated Urine Chemistry Analyzer (Sysmex Corporation, Kobe, Japan; hereinafter Sysmex, UC-1100) with the existing Sysmex urine chemistry analyzers: the Semi-Automated Urine Chemistry Analyzer UC-1000 and the Fully Automated Urine Chemistry Analyzer UC-3500.

Methods: One hundred and fifteen clinical urine samples were used in this study. The analysis was done based on results from urine chemistry analyzers using test strips that measure 12 parameters: urobilinogen, blood, protein, glucose, ketone, bilirubin, nitrite, specific gravity, leukocytes, pH, creatinine, and albumin. A rank value table was created for each measurement item and the rates of complete agreement and ± 1 rank agreement were then calculated.

Results: The UC-1100 results indicated a good correlation with the two other urine chemistry analyzers tested. Samples exhibiting discrepancies of $\geq$ two ranks constituted only a minor proportion of the total analyzed. Overall, UC-1100 exhibited reliable agreement with the reference instruments, with no significant issues observed.

Conclusions: Overall, UC-1100 shows satisfactory performance and offers a low-cost, easy-to-use, and reliable primary screening method for urinalysis, which may improve the efficiency of daily operations performed at a wide variety of clinical sites.

Keywords

UC-1100 Semi-Automated Urine Chemistry Analyzer, Semi-Automated Urine Chemistry Analyzer UC-1000, Fully Automated Urine Chemistry Analyzer UC-3500

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Notes: This article is based on current regulatory requirements in Japan. (as of Feb. 2026)

The specifications, performances, and functions described here may be different depending on the regions or the countries due to regulatory, legal and/or local guidelines. For more details, please contact your regional affiliates or distributors.

INTRODUCTION

Urinalysis is one of the most frequently requested laboratory tests and is commonly used to screen patients with metabolic disorders, renal dysfunction, urinary tract infections (UTIs), as well as being included in routine annual health checkups.¹⁾ Routine urinalysis testing is performed using a strip (dipstick), which provides results on an ordinal scale and allows diagnostic information to be obtained quickly and easily by immersing the strip into a urine sample.²⁾ The "Guidelines for the Management of Hematuria" and the "Evidence-based Clinical Practice Guidelines for CKD" are two highly regarded references that outline steps for urine dipstick testing. However, many facilities today utilize various urinalysis devices to rapidly provide highly accurate analytical data.³⁾

Manual urine dipstick testing is routinely utilized as a primary screening method in clinical laboratory practice. While manual dipstick testing is simple and cost-effective, it relies on visual interpretation and is therefore prone to human error and variability.⁴⁾ Newly developed urine chemistry analyzers may help to minimize these errors and enable digital documentation, thereby improving both accuracy and workflow.

Semi-automated urine chemistry analyzers are vital tools in modern laboratories, streamlining urinalysis by balancing manual and automated processes. Several semi-automated urine chemistry analyzers have been introduced for use in medical laboratories. In this study, we report the results obtained from the clinical performance evaluation of the UC-1100 Semi-Automated Urine Chemistry Analyzer (Sysmex Corporation, Kobe, Japan; hereinafter Sysmex, UC-1100) in comparison with the existing Sysmex urine chemistry analyzers: the Semi-Automated Urine Chemistry Analyzer UC-1000 (hereinafter UC-1000) and the Fully Automated Urine Chemistry Analyzer UC-3500 (hereinafter UC-3500).

BASIC ANALYZER CHARACTERISTICS

UC-1100 is compact, lightweight, and portable. This high-throughput analyzer can process up to 480 samples per hour. Its user-friendly design offers

convenient operability, including easy placement of test strips on the analyzer and simple maintenance. UC-1100 is equipped with a light receiver that incorporates a color complementary metal-oxide semiconductor (CMOS) sensor, which allows the user to evaluate the output of qualitative and semi-quantitative measurements. It also provides test strip images allowing the identification of foreign objects and abnormal colors on the test strip pads even after measurement. The analyzer can distinguish patterns of color development for hemoglobin and red blood cells on a blood test pad and correct a false-positive reaction of bilirubin caused by interfering drugs and chemicals. The device supports test strips for the measurement of protein/creatinine (P/C) and albumin/creatinine (A/C) ratios. This allows users to conduct a wide range of screening tests, which are vital diagnostic tools with established utility in identifying kidney diseases, monitoring disease progression and assessing therapeutic targets. Identifying a nephrotic-range urine P/C ratio during acute kidney injury (AKI) can frequently uncover previously unrecognized glomerular diseases,⁵⁾ and urinary albumin is a high-risk parameter for patients with chronic kidney disease (CKD) and hypertension.⁶⁾

Equivalent to the commercially available UC-3500, UC-1100 can be connected to the Urinalysis Work Area Information Management System (Sysmex; hereinafter U-WAM), which contributes to operational efficiency by enabling centralized management of test results.

MATERIALS AND METHODS

1. Samples

115 clinical urine samples were obtained from Kobe University Hospital between December 2024 and March 2025. This study was approved by the Ethics Committee of the Kobe University Hospital and Institutional Review Board of Sysmex Corporation.

2. Instruments, Reagents, and Parameters

2.1 Instruments and Reagents

Instrument: UC-1100 Semi-Automated Urine Chemistry Analyzer (**Fig. 1**)

Reagent: MEDITAPE™ UC-12S (Sysmex) test strip (**Fig. 2**)



Fig. 1 Image of UC-1100



Fig. 2 MEDITAPE UC-12S

The correlation and comparison between the instruments and test strips are shown in **Table 1**.

Test strips (MEDITAPE UC-11A (Sysmex), Lot number: AC3071; MEDITAPE UC-12S, Lot number: AC4004) which include reagent pads for ordinal scale reporting of urobilinogen, blood, protein, glucose, ketone, bilirubin, nitrite, specific gravity (S.G.) (UC-12S), leukocytes, pH, creatinine, and albumin (**Table 2**).

2.2 Measured Parameters

For the evaluation of urobilinogen, blood, protein, glucose, ketone, bilirubin, nitrite, S.G., leukocytes, pH, creatinine, albumin, P/C ratio and A/C ratio, the rate of concordance with the instrument subjected to correlation comparison was calculated.

Note: There are methodological differences in the measurement of S.G. between UC-1100 and UC-3500. UC-3500 determines urine S.G. by measuring the refractive index using a refractometer, providing quantitative results. In contrast, UC-1100 and UC-1000 determine S.G. by measuring the concentration of cations in urine, which is detected through color changes on the test strips yielding semi-quantitative results.

3. Examination Methods

Using clinical urine samples (n=115), we measured the above-specified parameters with UC-1100, UC-1000, and UC-3500. The exact match concordance rate and the ± 1 rank match concordance rate were calculated using UC-1100 and the other two instruments.

Table 1 Correlation and Comparison of Instruments and Test Strips

Instrument	Test strip
UC-3500	MEDITAPE UC-11A
UC-1000	MEDITAPE UC-12S

Table 2 Parameters and Qualitative/Semi-Quantitative Assessments

Analysis parameters	Display	Analysis result display								Unit
Urobilinogen	URO	Normal		1+	2+	3+	4+			mg/dL
				2.0	4.0	8.0	12.0			
Blood	BLD	BLD	-	+-	1+	2+	3+			cells/ μ L
				10	20	50	250			
Hemoglobin	BLD	BLD	-	+-	1+	2+	3+			mg/dL
				0.03	0.06	0.15	0.75			
Protein	PRO	-	+-	1+	2+	3+	4+			mg/dL
			15	30	100	300	1,000			
Glucose	GLU	-	+-	1+	2+	3+	4+			mg/dL
			50	100	250	500	2,000			
Ketone	KET	-		1+	2+	3+				mg/dL
				10	30	80				
Bilirubin	BIL	-		1+	2+	3+				mg/dL
				0.5	1.0	2.0				
Nitrite	NIT	-		+						
Leukocytes	LEU	-		1+	2+	3+				cells/ μ L
				25	75	500				
Creatinine	CRE	10	50	100	200	300				mg/dL
Albumin	ALB	10	30	80	150	over				mg/L
Specific gravity*	S.G.	1.000	1.005	1.010	1.015	1.020	1.025	1.030		
pH**	pH	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0

* The specific gravity is measured in preset assessment increments of ± 0.005 , ranging from 1.000 to 1.030.

** The pH is measured in preset assessment increments of ± 0.5 , ranging from 5.0 to 9.0.

RESULTS

1. Urobilinogen (URO)

The correlation between UC-1100 and UC-3500 was represented by an exact match concordance rate of 88.7% and a ± 1 rank match concordance rate of 100.0% (**Table 3**).

The correlation between UC-1100 and UC-1000 was represented by an exact match concordance rate of 95.7% and a ± 1 rank match concordance rate of 100.0% (**Table 3**).

2. Blood (BLD)

The correlation between UC-1100 and UC-3500 was represented by an exact match concordance rate of 88.7% and a ± 1 rank match concordance rate of 99.1% (**Table 4**).

The correlation between UC-1100 and UC-1000 was represented by an exact match concordance rate of 93.0% and a ± 1 rank match concordance rate of 100.0% (**Table 4**).

Table 3 Urobilinogen (URO)

UC-1100	4+	0	0	0	0	0
	3+	0	0	1	1	0
	2+	0	1	3	0	0
	1+	4	7	3	0	0
	Normal	91	4	0	0	0
URO		Normal	1+	2+	3+	4+
UC-3500						

Exact Match = 88.7%

± 1 Rank Match = 100.0%

UC-1100	4+	0	0	0	0	0
	3+	0	0	0	2	0
	2+	0	0	4	0	0
	1+	1	11	2	0	0
	Normal	93	2	0	0	0
URO		Normal	1+	2+	3+	4+
UC-1000						

Exact Match = 95.7%

± 1 Rank Match = 100.0%

Table 4 Blood (BLD)

UC-1100	3+	0	0	0	0	3
	2+	0	0	1	3	2
	1+	0	1	2	2	0
	+-	1	7	4	0	0
	-	87	1	1	0	0
BLD		-	+-	1+	2+	3+
UC-3500						

Exact Match = 88.7%

± 1 Rank Match = 99.1%

UC-1100	3+	0	0	0	0	3
	2+	0	0	2	4	0
	1+	0	1	4	1	0
	+-	4	8	0	0	0
	-	88	0	0	0	0
BLD		-	+-	1+	2+	3+
UC-1000						

Exact Match = 93.0%

± 1 Rank Match = 100.0%

3. Protein (PRO)

The correlation between UC-1100 and UC-3500 was represented by an exact match concordance rate of 78.3% and a ± 1 rank match concordance rate of 99.1% (**Table 5**).

The correlation between UC-1100 and UC-1000 was represented by an exact match concordance rate of 85.2% and a ± 1 rank match concordance rate of 100.0% (**Table 5**).

4. Glucose (GLU)

The correlation between UC-1100 and UC-3500 was represented by an exact match concordance rate of 89.6% and a ± 1 rank match concordance rate of 100.0% (**Table 6**).

The correlation between UC-1100 and UC-1000 was represented by an exact match concordance rate of 91.3% and a ± 1 rank match concordance rate of 100.0% (**Table 6**).

Table 5 Protein (PRO)

UC-1100	4+	0	0	0	0	1	2
	3+	0	0	0	3	3	0
	2+	0	0	1	3	0	0
	1+	0	4	16	0	0	0
	+-	11	15	0	0	0	0
	-	51	4	1	0	0	0
PRO		-	+-	1+	2+	3+	4+
UC-3500							

Exact Match = 78.3%

± 1 Rank Match = 99.1%

UC-1100	4+	0	0	0	0	0	3
	3+	0	0	0	0	5	1
	2+	0	0	0	4	0	0
	1+	0	2	18	0	0	0
	+-	1	20	3	0	0	0
	-	48	10	0	0	0	0
PRO		-	+-	1+	2+	3+	4+
UC-1000							

Exact Match = 85.2%

± 1 Rank Match = 100.0%

Table 6 Glucose (GLU)

UC-1100	4+	0	0	0	0	6	32
	3+	0	0	0	0	10	0
	2+	0	0	0	2	1	0
	1+	0	2	3	1	0	0
	+-	1	3	1	0	0	0
	-	53	0	0	0	0	0
GLU		-	+-	1+	2+	3+	4+
UC-3500							

Exact Match = 89.6%

± 1 Rank Match = 100.0%

UC-1100	4+	0	0	0	0	0	38
	3+	0	0	0	1	5	4
	2+	0	0	0	2	1	0
	1+	0	0	6	0	0	0
	+-	1	2	2	0	0	0
	-	52	1	0	0	0	0
GLU		-	+-	1+	2+	3+	4+
UC-1000							

Exact Match = 91.3%

± 1 Rank Match = 100.0%

5. Ketone (KET)

The correlation between UC-1100 and UC-3500 was represented by an exact match concordance rate of 98.3% and a ± 1 rank match concordance rate of 100.0% (**Table 7**).

The correlation between UC-1100 and UC-1000 was represented by an exact match concordance rate of 98.3% and a ± 1 rank match concordance rate of 100.0% (**Table 7**).

6. Bilirubin (BIL)

The correlation between UC-1100 and UC-3500 was represented by an exact match concordance rate of 95.7% and a ± 1 rank match concordance rate of 98.3% (**Table 8**).

The correlation between UC-1100 and UC-1000 was represented by an exact match concordance rate of 98.3% and a ± 1 rank match concordance rate of 100.0% (**Table 8**).

Table 7 Ketone (KET)

UC-1100	3+	0	0	0	4
	2+	0	0	4	0
	1+	0	3	2	0
	-	102	0	0	0
KET		-	1+	2+	3+
UC-3500					

Exact Match = 98.3%
 ± 1 Rank Match = 100.0%

UC-1100	3+	0	0	0	4
	2+	0	0	4	0
	1+	1	3	1	0
	-	102	0	0	0
KET		-	1+	2+	3+
UC-1000					

Exact Match = 98.3%
 ± 1 Rank Match = 100.0%

Table 8 Bilirubin (BIL)

UC-1100	3+	0	0	0	3
	2+	0	0	1	1
	1+	0	0	2	0
	-	106	0	0	2
BIL		-	1+	2+	3+
UC-3500					

Exact Match = 95.7%
 ± 1 Rank Match = 98.3%

UC-1100	3+	0	0	2	1
	2+	0	0	2	0
	1+	0	2	0	0
	-	108	0	0	0
BIL		-	1+	2+	3+
UC-1000					

Exact Match = 98.3%
 ± 1 Rank Match = 100.0%

7. Nitrite (NIT)

The correlation between UC-1100 and UC-3500 was represented by an exact match concordance rate of 93.9% and a ± 1 rank match concordance rate of 100.0% (**Table 9**).

The correlation between UC-1100 and UC-1000 was represented by an exact match concordance rate of 92.2% and a ± 1 rank match concordance rate of 100.0% (**Table 9**).

8. Specific Gravity (S.G.)

The correlation between UC-1100 and UC-3500 was represented by an exact match concordance rate of 30.4% and a ± 1 rank match concordance rate of 68.7% (**Table 10**).

The correlation between UC-1100 and UC-1000 was represented by an exact match concordance rate of 47.8% and a ± 1 rank match concordance rate of 94.8% (**Table 10**).

Table 9 Nitrite (NIT)

UC-1100	+	5	10
	-	98	2
NIT		-	+
		UC-3500	

Exact Match = 93.9%
 ± 1 Rank Match = 100.0%

UC-1100	+	0	14
	-	92	9
NIT		-	+
		UC-1000	

Exact Match = 92.2%
 ± 1 Rank Match = 100.0%

Table 10 Specific Gravity (S.G.)

UC-1100	1.030	0	0	0	0	3	6	4
	1.025	0	0	0	1	10	3	5
	1.020	0	0	0	4	8	2	9
	1.015	0	0	4	6	2	5	7
	1.010	0	0	13	10	3	2	3
	1.005	0	1	1	2	0	0	1
	1.000	0	0	0	0	0	0	0
S.G.		1.000	1.005	1.010	1.015	1.020	1.025	1.030
		UC-3500						

Exact Match = 30.4%
 ± 1 Rank Match = 68.7%

UC-1100	1.030	0	0	0	0	0	1	14
	1.025	0	0	0	0	7	7	2
	1.020	0	0	0	12	5	2	2
	1.015	0	0	15	6	2	2	1
	1.010	0	9	21	1	1	0	0
	1.005	2	2	1	0	0	0	0
	1.000	0	0	0	0	0	0	0
S.G.		1.000	1.005	1.010	1.015	1.020	1.025	1.030
		UC-1000						

Exact Match = 47.8%
 ± 1 Rank Match = 94.8%

9. Leukocytes (LEU)

The correlation between UC-1100 and UC-3500 was represented by an exact match concordance rate of 73.9% and a ± 1 rank match concordance rate of 98.3% (**Table 11**).

The correlation between UC-1100 and UC-1000 was represented by an exact match concordance rate of 87.0% and a ± 1 rank match concordance rate of 99.1% (**Table 11**).

10. pH

The correlation between UC-1100 and UC-3500 was represented by an exact match concordance rate of 64.3% and a ± 1 rank match concordance rate of 95.7% (**Table 12**).

The correlation between UC-1100 and UC-1000 was represented by an exact match concordance rate of 67.0% and a ± 1 rank match concordance rate of 99.1% (**Table 12**).

Table 11 Leukocytes (LEU)

UC-1100	3+	0	0	1	11
	2+	1	5	7	1
	1+	21	4	0	0
	-	63	0	1	0
LEU		-	1+	2+	3+
UC-3500					
Exact Match = 73.9%					
±1 Rank Match = 98.3%					
UC-1100	3+	0	0	1	11
	2+	1	2	10	1
	1+	10	15	0	0
	-	64	0	0	0
LEU		-	1+	2+	3+
UC-1000					
Exact Match = 87.0%					
±1 Rank Match = 99.1%					

Table 12 pH

UC-1100	9.0	0	0	0	0	0	0	0	0	1
	8.5	0	0	0	0	0	0	0	0	1
	8.0	0	0	0	0	0	1	2	1	4
	7.5	0	0	0	0	0	4	0	0	0
	7.0	0	0	0	0	6	5	0	0	0
	6.5	0	0	1	13	6	0	0	1	0
	6.0	0	4	19	7	0	0	0	0	0
	5.5	7	19	3	0	0	0	0	0	0
	5.0	10	0	0	0	0	0	0	0	0
pH		5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0
UC-3500										
Exact Match = 64.3%										
±1 Rank Match = 95.7%										
UC-1100	9.0	0	0	0	0	0	0	0	0	1
	8.5	0	0	0	0	0	0	0	1	0
	8.0	0	0	0	0	0	2	3	3	0
	7.5	0	0	0	0	1	2	1	0	0
	7.0	0	0	0	1	8	2	0	0	0
	6.5	0	0	5	12	4	0	0	0	0
	6.0	1	7	21	1	0	0	0	0	0
	5.5	7	19	2	0	0	0	0	0	0
	5.0	10	1	0	0	0	0	0	0	0
pH		5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0
UC-1000										
Exact Match = 67.0%										
±1 Rank Match = 99.1%										

11. Creatinine (CRE)

The correlation between UC-1100 and UC-3500 was represented by an exact match concordance rate of 71.3% and a ± 1 rank match concordance rate of 100.0% (**Table 13**).

The correlation between UC-1100 and UC-1000 was represented by an exact match concordance rate of 77.4% and a ± 1 rank match concordance rate of 100.0% (**Table 13**).

12. Albumin (ALB)

The correlation between UC-1100 and UC-3500 was represented by an exact match concordance rate of 73.9% and a ± 1 rank match concordance rate of 100.0% (**Table 14**).

The correlation between UC-1100 and UC-1000 was represented by an exact match concordance rate of 81.7% and a ± 1 rank match concordance rate of 100.0% (**Table 14**).

Table 13 Creatinine (CRE)

UC-1100 (mg/dL)	300	0	0	0	1	1
	200	0	0	2	8	0
	100	0	17	27	7	0
	50	2	39	3	0	0
	10	7	1	0	0	0
CRE		10	50	100	200	300
		UC-3500 (mg/dL)				

Exact Match = 71.3%

± 1 Rank Match = 100.0%

UC-1100 (mg/dL)	300	0	0	0	1	1
	200	0	0	3	7	0
	100	0	10	37	4	0
	50	0	39	5	0	0
	10	5	3	0	0	0
CRE		10	50	100	200	300
		UC-1000 (mg/dL)				

Exact Match = 77.4%

± 1 Rank Match = 100.0%

Table 14 Albumin (ALB)

UC-1100 (mg/L)	Over	0	0	0	4	16
	150	0	0	2	8	0
	80	0	9	9	0	0
	30	14	16	1	0	0
	10	36	0	0	0	0
ALB		10	30	80	150	Over
		UC-3500 (mg/L)				

Exact Match = 73.9%

± 1 Rank Match = 100.0%

UC-1100 (mg/L)	Over	0	0	0	2	18
	150	0	0	2	8	0
	80	0	4	12	1	0
	30	8	24	0	0	0
	10	32	4	0	0	0
ALB		10	30	80	150	Over
		UC-1000 (mg/L)				

Exact Match = 81.7%

± 1 Rank Match = 100.0%

13. Protein/Creatinine (P/C) ratio

The correlation between UC-1100 and UC-3500 was represented by an exact match concordance rate of 81.7% and a ± 1 rank match concordance rate of 98.3% (**Table 15**).

The correlation between UC-1100 and UC-1000 was represented by an exact match concordance rate of 84.3% and a ± 1 rank match concordance rate of 98.3% (**Table 15**).

14. Albumin/Creatinine (A/C) ratio

The correlation between UC-1100 and UC-3500 was represented by an exact match concordance rate of 83.5% and a ± 1 rank match concordance rate of 97.4% (**Table 16**).

The correlation between UC-1100 and UC-1000 was represented by an exact match concordance rate of 86.1% and a ± 1 rank match concordance rate of 96.5% (**Table 16**).

Table 15 P/C ratio

UC-1100	2+	1	0	3	18
	1+	0	9	22	2
	Normal	1	48	4	1
	Dilute	6	0	0	0
P/C		UC-3500			
		Dilute	Normal	1+	2+

Exact Match = 81.7%

± 1 Rank Match = 98.3%

UC-1100	2+	0	0	3	19
	1+	0	1	28	3
	Normal	0	47	8	0
	Dilute	3	1	0	2
P/C		UC-1000			
		Dilute	Normal	1+	2+

Exact Match = 84.3%

± 1 Rank Match = 98.3%

Table 16 A/C ratio

UC-1100	2+	1	0	1	2	18
	$\geq 1+$	0	0	0	3	0
	1+	0	13	37	0	1
	Normal	1	33	0	0	0
	Dilute	5	0	0	0	0
A/C		UC-3500				
		Dilute	Normal	1+	$\geq 1+$	2+

Exact Match = 83.5%

± 1 Rank Match = 97.4%

UC-1100	2+	0	0	2	0	20
	$\geq 1+$	0	0	0	3	0
	1+	0	9	42	0	0
	Normal	0	32	2	0	0
	Dilute	2	1	0	0	2
A/C		UC-1000				
		Dilute	Normal	1+	$\geq 1+$	2+

Exact Match = 86.1%

± 1 Rank Match = 96.5%

DISCUSSION

We evaluated the clinical performance of UC-1100. Despite its compact size and lightweight design, UC-1100 demonstrated high throughput and the capability to simultaneously measure 12 parameters, comparable to UC-3500. The UC-1100's integrated image capture and analysis functionality significantly enhance the reliability of urinalysis results. By enabling users to visually evaluate test strip images, the system helps distinguish true positive reactions from those potentially caused by interfering substances. Furthermore, the ability to review strip placement and detect the presence of foreign materials allows for prompt recognition and correction of procedural errors. This dual capability not only improves the accuracy of test results but also strengthens quality assurance in routine laboratory workflows.

Overall, the UC-1100's image analysis features represent a valuable advancement in minimizing analytical errors, reducing the risk of false positives, and increasing confidence in urinalysis findings. In addition, the ability of UC-1100 to connect to U-WAM promotes operational efficiency, making it a convenient choice for use in small-sized hospitals and clinics, as well as a backup instrument in larger hospitals and testing centers.

The UC-1100 test results demonstrated good correlation with the existing UC-3500 and UC-1000, indicating a satisfactory performance for routine analysis. However, there were some parameter result discrepancies between UC-1100 and the existing analyzers. Result differences observed for blood, protein, bilirubin, S.G., leukocytes, and pH were attributed to factors such as measurement techniques, variations in urine color, and the presence or absence of color correction mechanisms.

In one sample, UC-1100 indicated a negative result for blood while UC-3500 indicated a positive result. Upon reviewing the test strip images, it was revealed that the red blood cell reaction was weakly positive, and the reflectivity value of UC-1100 was close to positive. Based on these findings, we hypothesized that measurement variations caused this discrepancy.

In one sample with discordant protein result, UC-3500 was positive while UC-1100 was negative. This sample had a strong urine color, and the absence of a color correction function in UC-1100 likely contributed to the false-negative result.

For bilirubin, in two samples, UC-3500 demonstrated false-positive results, whereas UC-1100 indicated negative findings. In both cases, the UC-3500 results were strongly positive. It was determined that the corrective function for identifying false-positive bilirubin reactions worked only with UC-1100. A false-positive bilirubin reaction can occur due to a coupling reaction between the diazonium salt in the bilirubin pad and a phenolic metabolite excreted in urine after administration of drugs such as etodolac. The resulting color ranges from pink to reddish-brown, differs from the color observed in a normal bilirubin reaction. The false-positive bilirubin reaction can be corrected using specific software criteria, so that a negative result can be obtained in cases where abnormal color development is observed on the bilirubin pad.³⁾ With UC-1100, a negative correction was applied, resulting in an accurate negative result. However, UC-3500 indicated abnormal coloration, therefore negative correction was not applied, resulting in a discrepancy between the results. These findings suggest that the difference was due to subtle variations in the threshold for negative correction.

For S.G. testing between UC-1000 and UC-1100, only one sample showed a relatively large discrepancy, resulting in a lower S.G. value with the latter. We confirmed that the color development of the test strip demonstrated that UC-1100 provided the correct measurement value. Therefore, we concluded that this discrepancy was due to technique variation.

When comparing UC-1100 and UC-3500, S.G. differences were observed in several samples. Because the S.G. pad on the test strips does not react to glucose or protein, discrepancies in measurement values may occur in samples with high concentrations of these components. Of the 32 samples, in which the S.G. measured by UC-1100 was $\geq$ two ranks lower than the values measured by UC-3500, 31 were confirmed to have elevated glucose or protein content. The remaining sample may have yielded a

falsely low value with the test strip or a falsely high value with the UC-3500 refractometer; however, the exact cause of this discrepancy is unclear. On the other hand, samples with high S.G. values on UC-1100 were found to have high bilirubin and urobilinogen levels, and in both cases, the urine was dark in color. These discrepancies are thought to be due to urine color changes and the absence of a color compensation mechanism in UC-1100.

In one leukocyte case, the UC-1100 result was strongly positive, and the UC-3500 result was negative. The sample also showed a positive bilirubin reaction, and the urine was noticeably colored. This discrepancy likely occurred because UC-1100 does not have a function to correct for urine color. In another case, the UC-1100 result was negative, and the UC-3500 result was positive. We concluded that the result differences were due to the coloration of the pad, which was influenced by the noticeable dark urine color. In comparison to UC-1000, in one discordant leukocyte case, the UC-1100 result was strongly positive, and the UC-1000 result was negative. In this case, we confirmed the coloration of the test strip, which indicated that UC-1100 provided the correct measurement value. For UC-1000, both the reflectance and the test strip image indicated the result was on the border between [1+] and [-] and was judged as [-]. This was thought to be due to subtle differences in the reaction of the test strip pad, likely influenced by the measurement technique.

In one sample, UC-1000 showed a different pH result compared with UC-3500. Based on the overall pad coloration, it was presumed that the sample had a strongly dark urine color, and that the presence or absence of urine color correction influenced the results. Additionally, confirmation using pH test paper showed results equivalent to those obtained with UC-1100. Similarly, one sample showed a higher value on UC-1100 compared to UC-1000. Measurement results obtained by both analyzers were close to the threshold value. The actual discrepancy was equivalent to one rank which indicated that the differences in the result were influenced by measurement technique.

The UC-3500 test strips differ from those used with UC-1000 and UC-1100, which have no blank pads.

Therefore, UC-1000 and UC-1100 cannot correct for sample color discrepancies. The parameters measured by UC-1100 and the existing analyzers showed a good overall correlation. Discrepancies of $\geq$ two ranks in the value table were infrequent and primarily attributed to measurement technique, urine color and/or urine color correction mechanisms which accounted for only a small fraction of the total samples analyzed.

The UC-1100's ability to measure P/C and A/C ratios is clinically significant, as these parameters are essential for early detection and monitoring of kidney damage. Recent evidence suggests that identifying a nephrotic-range P/C ratio during AKI can frequently uncover previously unrecognized glomerular diseases, supporting the inclusion of the P/C ratio in the diagnostic work-up for AKI, especially when hematuria is present.⁵⁾ As noted in previous studies,⁶⁾ macroalbuminuria is a key marker of CKD progression and increased cardiovascular risk. UC-1100 supports effective monitoring and timely intervention in CKD management, underscoring its value in comprehensive patient screening and management.

However, we observed two discordant P/C ratio results when comparing UC-1100 with UC-3500. In one instance, a sample with a high protein concentration and intense urine color yielded inconsistent results. The absence of a color correction function in UC-1100 likely contributed to the false-negative result for protein in the sample with strong dark urine color, where UC-3500 detected a positive result. In another case, a one-rank difference in protein measurement was observed between the two analyzers. This discrepancy is likely attributable to measurement variability, as the reflectance values for protein were close to the cutoff thresholds for both UC-1100 and UC-3500. Although creatinine values were identical on both instruments, applying these results to the P/C ratio calculation table led to a discrepancy in the final ratio. Similarly, two discordant P/C ratio results were observed when comparing UC-1100 with UC-1000, both attributable to the calculation table, as the reflectance values for protein were near the cutoff points.

For the A/C ratio, three and four discordant cases were identified when comparing UC-1100 to UC-3500 and UC-1000, respectively. These discrepancies were also attributed to the calculation table, as the reflectance values for creatinine and albumin were close to the cutoff thresholds, resulting in only a one-rank difference in creatinine and albumin measurements. These findings suggest the P/C and A/C ratio discrepancies between the analyzers are primarily due to measurement values being close to the cutoff thresholds, as well as to differences in calculation table interpretations.

Both UC-1000 and UC-1100 are semi-automated urine chemistry analyzers, but UC-1100 introduces several notable advancements that enhance usability and operational efficiency (**Table 17**). The larger 7.0" color LCD touchscreen offers a more user-friendly interface compared to the UC-1000's smaller 5.7" display, potentially improving workflow and ease of use. UC-1100 also provides double the internal data storage capacity, accommodating up to 10,000

analysis results, which is particularly beneficial for higher-throughput environments or facilities requiring long-term data retention. Additional features such as enhanced connectivity options including LAN support and barcode logon, as well as improved security and user management, further distinguish UC-1100 as a novel, network-ready analyzer. While both models share the same core analytical capabilities and throughput, the upgrades make UC-1100 a more versatile and future-ready platform, well-suited to the demands of contemporary laboratory settings.

Despite its compact size, the parameters measured on UC-1100 are identical to those measured by UC-3500, and the former can process samples with a throughput of 480 samples per hour. Therefore, we believe that UC-1100 will improve the efficiency of daily operations at various clinical sites. The compact analyzer may be a practical option for both small-sized hospitals or clinics and large-sized healthcare facilities or testing centers, as a backup instrument.

Table 17 Comparison: UC-1100 vs UC-1000

Feature/Specification	UC-1100	UC-1000
Display	7.0" color LCD display	5.7" color LCD display
Data Storage Capacity	Up to 10,000 analysis results	Up to 5,000 analysis results
Test Strips Supported	MEDITAPE UC-12S, MEDITAPE UC-10S	Same as UC-1100
Method	Reflectance photometry	Same as UC-1100
Throughput	480 samples/hour (7.5 s/sample)	Same as UC-1100
Connectivity	2×USB, 1×LAN, 1×Serial port	2×USB, 1×Serial connector
Host Computer Connection	RS-232C and LAN (network)	RS-232C (serial)
Barcode Logon	Supported (barcode ID for user logon)	Not supported (password only)
Cybersecurity Features	Explicit section on cybersecurity (physical security, account management, virus protection, etc.)	Not explicitly mentioned
User Management	Up to 100 users, supports barcode logon, auto logon, password policies	Up to 20 users, password only
Physical Dimensions (W×D×H)	315×215×145 mm	315×215×135 mm
Weight	3 kg or less	Same as UC-1100

CONCLUSION

The comparative evaluation of UC-1100 with UC-3500 and UC-1000 demonstrated that UC-1100, despite its compact size, is capable of measuring as many parameters as UC-3500. The UC-1100's results showed good correlation with those of the existing analyzers, supporting its reliability and utility in diverse clinical settings. With its high throughput, ease of use, and robust performance, UC-1100 represents a practical and versatile option for primary urinalysis screening across a wide range of healthcare environments.

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Note: The Japanese certification numbers for the instruments and test strips are provided in the following tables.

Instrument	Medical Device Manufacturing and Marketing Notification Number	Manufacturer/Distributor
UC-1100 Semi-Automated Urine Chemistry Analyzer	28B1X10014000064	Sysmex Corporation
Semi-Automated Urine Chemistry Analyzer UC-1000	28B1X10014000047	Sysmex Corporation
Fully Automated Urine Chemistry Analyzer UC-3500	28B1X10014000044	Sysmex Corporation

Test Strip	Medical Device Certification Number	Manufacturer/Distributor
MEDITAPE UC-11A	227ABEZ00099000	Sysmex Corporation
MEDITAPE UC-12S	227ABEZ00099000	Sysmex Corporation
MEDITAPE UC-10S	227ABEZ00099000	Sysmex Corporation