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Research Article

A comparative study on the performances of 77 elektronika urised 2-LabUmat2 and Dirui FUS200 - H800 urine analyzers

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Abstract

Objectives: This study aims to compare the analytical performance of the 77Elektronika brand LabUmat2-Urised2 model integrated urine analyzer and Dirui brand FUS200-H800 model integrated urine analyzer.

Methods: Urine samples of 139 patients randomly selected from male and female patients of all age groups who were admitted to Ufuk University Faculty of Medicine, Dr. Ridvan Ege Hospital between 24.02.2020-28.02.2020 were analyzed on both devices.

Results: The results of the samples whose WBC (white blood cell), RBC (red blood cell) and Squamous epithelial were measured using two different methods in microscopic analyzers were perfectly compatible in the same range and with three parameters (Gamma values 0.916; 0.770; 0.961, respectively). For the samples where crystal and cylinder tests were carried out in microscopic analyzers, Cappa values were 0.486 and 0.495, respectively. As the result of Passing-Bablok Regression analysis used for the method comparison of microscopic analyzers, Cusum test results were $p<0.01$, $p=0.01$ and $p=0.65$, respectively for the linearity in the measurement of WBC, RBC and Squamous epithelial. According to the Bland-Altman Compatibility Chart prepared to determine the difference between methods, the difference between the results of the measurements of WBC, RBC and Squamous epithelial in both devices were -29.3±1.96 SD (95% CI, lower limit: -174.6; upper limit: 116); 43.3±1.96 SD (95% CI, lower limit: -119.7; upper limit: 206.2); -4.0±1.96 SD (95% CI, lower limit: -87.8%; upper limit: 79.9), respectively. When the results of the chemical analyzers of each device were compared, the findings showed that there was a high correlation between leukocyte and protein levels. When the compliance of chemical and microscopic units of each device was examined, a high correlation was found for WBC and a medium level correlation for RBC.

Conclusion: Although both devices revealed similar results, confirmation with the manual microscope might be required, especially in pathological samples. Therefore, microscopic analyzers are still needed to be developed concerning method and software although automatic urine analyzers provide standardization and reduce the workload of laboratories.

Keywords: Automated urine analyzer, 77Elektronika Urised2-LabUmat2, Dirui FUS200-H800, urine analysis

Urinalysis is the third most commonly used test in clinical laboratories for in vitro diagnosis following biochemical tests and complete blood count tests to evaluate kidney and urinary tract pathologies [1, 2]. Urinary tract infections and kidney diseases are two main examples of diseases that can be detected or monitored by urinalysis [3]. Urinalysis is a test that is preferred by physicians in routine analyses since urine samples can be easily taken at any time without the need for informing the patient in advance [4].

A urinalysis often consists of three components: physical, chemical and microscopic examination [5]. The physical examination involves evaluation of urine color, appearance, density and odor. The chemical examination is performed using reagent strips intended for rapid and simple identification of urine components. Urinary sediment examination is a clinically important stage of urinalysis, especially when the sample presents alterations in the physical and chemical phases. Thus, all the compounds in the urine sediment should be evaluated adequately [6].

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Manual microscopic examination of the urine sediment has been regarded as the golden standard in laboratory studies for long years. In most laboratories, the examination of centrifuged and unstained natural urine samples under the bright-field microscope is still a part of routine work. However, especially in the preanalytical phase, detailed protocols vary between laboratories. There is no reference method for urine sediment microscopy [7]. A standard urine sediment examination is recommended, especially for pathological samples. However, manual microscopic examination depends on the experience level of the staff (which is often personal, time-consuming, non-standardized), the centrifuge protocol and the amount of remaining urine in the tube after the removal of supernatant [8].

Many manufacturers developed integrated automatic urine analyzers being capable of analyzing these three urinalysis components [5]. Despite various disadvantages, automatic urine analyzers are commonly used in clinical laboratories since it is difficult to standardize urinalysis [9]. The use of automatic urine analyzers eliminated interobserver/intraobserver variation, saving labor and time for high-volume laboratories.

Most urine analyzers test the physical and chemical components of urinalysis based on similar principles. For example, they measure specific gravity being a physical component based on refractometry/refractive index method, while they measure analytics in the chemical components based on reflectance spectroscopy [5]. There are currently a few technologies to examine urine sediment containing microscopic components, such as flow cytometry [5], fluorescent flow cytometry, cell recognition system with digital imaging [10], full-field microscopic imaging [11].

In this study, we compared the analytic performances of 77 ELEKTRONIKA brand LabUmat2-Urised2 model integrated urine analyzer and DIRUI brand FUS200-H800 model integrated urine analyzer, and examined the internal correlation in WBC and RBC results obtained by chemical and microscopic analyzers for both integrated systems.

Materials and Methods

This study was conducted to perform a statistical comparison of the data obtained by analyzing the urine samples taken from 139 randomly selected patients of both sexes and all age groups, who applied to all polyclinics of Ufuk University Faculty of Medicine, Dr. Ridvan EGE Hospital between 24.02.2020 and 28.02.2020, using DIRUI brand FUS200-H800 model automatic urine analyzer and 77 ELEKTRONIKA brand Urised2-LabUmat2 model automatic urine analyzer.

Automated urine analyzers

The technical specifications of the microscopic analyzer and chemical analyzer of the automatic urine analyzers used in this study are given in the following tables (Table 1 and Table 2). The microscopic analyzers have different measurement methodologies, which is the most distinguishing feature.

Statistical analysis

The Kolmogorov-Smirnov test was used to verify the normality of parameters that were analyzed by the sediment and chemical analyzers of both brands. The gamma test statistic was used to calculate the correlation depending on match-

Table 1. Technical specifications of the microscopic analyzers

	FUS200	Urised2
Throughput	Up to 120 tests/hour	Up to 120 tests/hour
Methodology	Flow cell digital imaging technology	Whole view field microscopic image (built-in camera)
Batch size	50 samples/270 samples optional	100 test tubes
Min. sample volume	3ml non-centrifugal urine, 1ml aspiration volume	2 ml
Detected particle classes	Red blood cells, white blood cells, epithelial cell, casts, crystals, bacteria etc totally 12 visible components in urine	RBC (red blood cells); WBC (white blood cells and WBC clumps); HYA (hyaline casts); PAT (pathological casts); EPI (squamous epithelial cells); NEC (non-squamous epithelial cells); BACc (bacteria cocci); BACr (bacteria rods) YEA (yeast) CRY (crystals): [CaOxm (calcium-oxalate monohydrate), CaOxd (calcium-oxalate dihydrate), URI (uric acid), TRI (triple phosphate)]; MUC (mucus); SPRM (sperm); Further classes for manual subclassification are also available!

Table 2. Technical specifications of the chemical stripe analyzers

	H800	LabUmat2
Max. throughput	Up to 240 tests/hour	Up to 240 tests/hour
Strips capacity	200 strips	150 strips
Methodology	Reflectance photometer	Reflectance photometer
Min. sample volume	4 ml	2 ml
Memory	Max 10.000 results	Max 10.000 results
Batch size	110 test tubes	100 test tubes
Test Wavelengths	572, 610, 660 nm	4 discrete wavelengths
Evaluated parameters	Urobilinogen, Bilirubin, Ketones, Blood, Protein, Nitrite, Glucose, Leucocytes, pH, Specific gravity	Bilirubin, Urobilinogen, Ketones, Protein, Glucose, Ascorbic acid, Nitrite, Leucocytes, Blood, pH, Specific gravity

ing and non-matching of the data in cross tables to perform the correlation analysis of non-parametric microscopic data of WBC, RBC and squamous epithelium parameters obtained by the sediment analyzers (Urised2 and FUS200). The Cohen's Kappa (κ) analysis was used to show that the measurement results of crystals and cylinders, whose microscopic analysis results were given as positive and negative, were in agreement. It was considered that the Gamma and Kappa values lower than 0.4 represented poor agreement, the values between 0.4 and 0.75 fair agreement, and the values higher than 0.75 excellent agreement [12]. Since the Urised2 and FUS200 analyzers use different microscopic analysis methods, the WBC, RBC and squamous epithelium results were compared using Passing-Bablok and Bland-Altman plots for association and differences. The Spearman correlation test was used to detect the correlation between the results obtained by the chemical analyzers of both device brands and to investigate the internal agreement of chemical and microscopic analyses for both devices. The correlation coefficient (r) was interpreted as follows; r<0.3 indicates a negligible correlation, r between 0.3-0.5 a low correlation, r between 0.5-0.7 a moderate correlation, r between 0.7-0.9 a high correlation, and r>0.9 a very high correlation [13].

The statistical analyses were performed using the SPSS program (Version 22.0., Armonk, NY, IBM Corp.) and MedCalc Statistical Software (Version 19.2.0., MedCalc Software Ltd., Acacialaan 22, Ostend, Belgium). When the p-value was lower than 0.05, the result was considered statistically significant.

Results

In this study, the data obtained by analyzing 139 urine samples using a combination of two different analyzers were compared statistically.

To test the consistency of the results, we analyzed two levels of urine internal quality control (IQC) samples once a day, 20 times a day, for in-study precision calculation and 20 different days for in-study precision. The imprecision of each measurement method was determined by the coefficient of variation (CV%).

Two levels of urine particle IQC were studied for RBC and WBC on the Urised 2 device, while two levels of urine particle IQC were studied on the FUS 200 device. When Inter-study imprecision was evaluated, the RBC level 1 IQC average in Urised 2 was zero, so the standard deviation (SD) of CV% could not be calculated. While the level 2 IQC average was calculated as 19.96 cell/HPF, 25.6% CV, SD 5.11 and bias -0.664. Level 1 IQC mean was determined as 1.43 cell/HPF, 24.41%CV, SD 0.35 and bias -0.320, while level 2 IQC mean was found as 21.28 cell/HPF, 16.76%CV, SD 3.57 and bias 0.075 when calculated for WBC. The level 1 IQC mean was calculated as 0.85 particles/µL, 43.1%CV, SD 0.37 and bias -0.915 from the two levels of urine particle IQC samples studied in the FUS 200 device, while level 2 IQC mean was calculated as 1096.6 particles/µL, 3.17%CV, SD 34.73 and bias 0.064. When in-study uncertainty was evaluated, the RBC level 1 IQC average in Urised 2 was again zero. While CV% and SD could not be calculated, the level 2 IQC average was calculated as 20.86 cell/HPF, 17.04%CV, SD 3.56 and bias -0.648. When calculated for WBC, the level 1 IQC average was 1.54 cell/HPF, 14.99%CV, SD 0.23 and bias -0.267, while level 2 IQC average was 20.74 cell/HPF, 14.42% CV, SD 2.99 and bias 0.048. The level 1 IQC mean was calculated as 0.9 particles/µL, 34.2%CV, SD 0.31 and bias -0.910 from the two-level urine particle IQC samples studied in the FUS 200 device, while the level 2 IQC mean was calculated as 1121.6 particles/µL, 2.89% CV, SD 32.45 and bias 0.088.

WBC counts of 119 (85.6%) samples, RBC counts of 126 (90.6%) samples, squamous epithelium cell counts of 131 (94.2%) samples were measured by microscopic analyzers based on two different methods, and the WBC, RBC and squamous epithelium cell counts were in the same range and in excellent agreement for all three parameters. The Gamma values were 0.916, p<0.001; 0.770, p<0.001; 0.961, p<0.001, respectively (Table 3).

The results of 133 samples that were subjected to crystal measurement by microscopic analyzers were negative with both methods. The results of three samples were positive with both methods. The Kappa weighted value was 0.486 with p<0.001, indicating a moderate agreement.

Table 3. Comparison of the WBC, RBC and Squamous Epithelium Cell counts measured by microscopic analyzers

WBC[a]	FUS200 (cell/HPF[c])						RBC[b]	FUS200 (cell/HPF[c])						Squamous epithelium	FUS200 (cell/HPF[c])					
Urised2 (cell/HPF[c])	0-5	6-20	21-50	51-100	>100	Total	Urised2 (cell/HPF[c])	0-5	6-20	21-50	51-100	>100	Total	Urised2 (cell/HPF[c])	0-5	6-20	21-50	51-100	>100	Total
0-5	111	0	0	0	0	111	0-5	118	9	0	0	0	127	0-5	117	1	0	0	0	118
6-20	10	2	2	0	0	14	6-20	0	5	0	0	0	5	6-20	6	12	1	0	0	19
21-50	0	3	4	1	0	8	21-50	0	3	1	1	0	5	21-50	0	0	2	0	0	2
51-100	0	0	1	2	2	5	51-100	0	0	0	0	0	0	51-100	0	0	0	0	0	0
>100	0	0	0	1	0	1	>100	0	0	0	0	2	2	>100	0	0	0	0	0	0
Total	121	5	7	4	2	139	Total	118	17	1	1	2	139	Total	123	13	3	0	0	139
Gamma	0.916						Gamma	0.770						Gamma	0.961					
p	<0.001						p	<0.001						p	<0.001					

[a]WBC: Whight blood cell; [b]RBC: Red blood cell; [c]HPF: High power field

The results of 136 samples that were subjected to cylinder measurement by microscopic analyzers were negative with both methods. The results of the two samples were positive with both methods. The Kappa weighted value was 0.495 with $p<0.001$, indicating a moderate agreement (Table 4).

The Passing-Bablok regression analysis was used to compare the two methods since the working mechanisms of the microscopic analyzers of the two devices are different. The regression analysis showed that there was an apparent deviation from linearity in WBC and RBC measurements ($p<0.05$; $p=0.01$, respectively), i.e., these two methods were not in agreement in the measurement of these parameters; however, no apparent deviation from linearity was observed between two methods in the squamous epithelium cell count measurement ($p=0.65$), i.e., the results obtained by the two methods were in agreement.

Besides the regression analysis, the Bland-Altman agreement plots were used to determine the difference between the methods in comparison of two methods. According to the Bland-Altman graph, the difference between the measurements by two devices was calculated as -29.3±1.96 SD (95%CI, upper limit: -174.6; upper limit: 116) for WBC, 43.3±1.96 SD (95%CI, upper limit: -119.7; upper limit: 206.2) for RBC and -4.0±1.96 SD (95%CI, upper limit: -87.8; upper limit: 79.9) for Squamous epithelium.

The obtained interclass correlation coefficients when the results of the two chemical strip analyzers were compared to the Spearman correlation are shown in Table 5.

When the agreement of chemical analyzer and microscopic analyzer within the two devices was examined based on the WBC and RBC parameter measurements, it was observed that there was a high correlation for WBC and a moderate correlation for RBC between the measurements by Urised2-LabUmat2 and FUS200-H800 devices (Table 6).

Discussion

Manual urine sediment analysis is labor-intensive and time-consuming, as well as shows variations among observers, and has a low repeatability level [12]. The currently used automatic urine analyzers increase the result repeatability and reproductivity of tests, thus improving efficiency and work volume in laboratories. They also decrease the time and labor required to process urine samples [5].

In this study, we evaluated the performances of two fully automatic urine analyzers by comparing the physical, chemical and microscopic results of the urine samples from the same patients. The evaluated parameters were urine density for the physical measurement; Protein, Urobilinogen, Bilirubin, Ketone, Nitrite, Glucose, Erythrocyte, Leukocyte and pH for the chemical measurement; and WBC, RBC, Squamous epithelium, Cylinder and Crystal. We also examined the chemical and microscopic (WBC and RBC) measurement internal consistencies of the two fully automatic analyzers.

Table 4. Comparison of the Cylinder and Crystal counts measured by microscopic analyzers

Cylinder	FUS 200			Crystal	FUS 200		
Urised 2	**Negative**	**Positive**	**Total**	**Urised 2**	**Negative**	**Positive**	**Total**
Negative	136	0	136	Negative	133	1	134
Positive	2	1	3	Positive	3	2	5
Total	138	1	139	Total	136	3	139
Kappa weighted value	0.495			Kappa weighted value	0.486		
p	<0.001			p	<0.001		

Table 5. Correlation of the results of the parameters measured by LabUmat2 and H800 analyzers

Strip parameters	r	p
pH	0.872	<0.001
Density	0.986	<0.001
Protein	0.904	<0.001
Glucose	0.894	<0.001
Urobilinogen	0.482	<0.001
Erythrocyte	0.884	<0.001
Leukocyte	0.918	<0.001
Ketone	0.522	<0.001
Nitrite	0.702	<0.001
Bilirubin	0.391	<0.001

Table 6. Agreement between Urised 2-LabUmat 2/FUS 200-H 800 strip and microscopy

Urised 2-LabUmat 2	r	p
WBC	0.812	<0.001
RBC	0.636	<0.001
FUS 200-H 800	**r**	**p**
WBC	0.750	<0.001
RBC	0.564	<0.001

We observed that in the density tests to be used for physical examination of urine, the results obtained by the two urine analyzers very closely correlated with each other (r=0.986; p<0.001). A study performed by Bakan et al. with 540 urine samples to compare the test results of Cobas 6500 and Iris IQ200 automatic urine analyzers showed that the urine density test results obtained by the two devices strongly correlated with each other (r=0.920; p=0.001) [9]. A study performed by Yüksel et al. with 332 urine samples to compare the test results of H800-FUS100 and LabUmat-Urised urine analyzers showed that the urine density test results obtained by the two devices strongly correlated with each other (r=0.782; p<0.01) [10].

The comparison of the chemical analysis test results of the fully automatic urine analyzers showed a low correlation for bilirubin and urobilinogen, a moderate correlation for ketone, a high correlation for nitrite, pH, glucose, erythrocyte, and a very high correlation for leukocyte and protein. In a study performed by Yuksel et al. with 332 urine samples to compare the results obtained by H800-FUS100 and LabUmat-Urised urine analyzers, the findings showed that there was a correlation at different levels between the two devices for bilirubin (r=0.246), urobilinogen (r=0.383), ketone (r=0.599), nitrite (r=0.350), pH (r=0.805), protein (r=0.501), glucose (r=0.665), erythrocyte (r=0.865) and leukocyte (r=0.764) [10]. In a study performed by Bakan et al. with 540 urine samples to compare the test results obtained by Cobas 6500 and Iris IQ200 automatic urine analyzers, they found a correlation between the measurement results of Cobas u601 and IChem Velocity strip for bilirubin (r=0.190), urobilinogen (r=0.440), ketone (r=0.580), nitrite (r=0.810), pH (r=0.770), protein (r=0.890), glucose (r=0.880), erythrocyte (r=0.870) and leukocyte (r=0.920). They concluded that the results of the two devices were correlated at different levels for parameters other than bilirubin; however, there was no correlation between the devices for bilirubin [9]. In a study performed by Budak et al. with 412 urine samples to compare the results obtained by three automatic urine analyzers; Iris iQ200 (AX-4280), Sysmex UF-1000i (Urisys 2400) and UriSed-LabUmat, they reported the correlation between the results of the chemical analyzers as percentage (%) and found a correlation between Urisys 2400 X Ax-4280 [pH: 80.3%, bilirubin: 98.3%, protein: 76.2%, glucose: 99%, urobilinogen: 95.8%, ketone: 97.8%, nitrite: 97%, leukocyte: 83.2%, RBC: 89.5%] and Urisys2400 X LabUmat [pH: 68.2%, bilirubin: 97.8%, protein: 91.9%, glucose: 96.6%, urobilinogen: 89.8%, ketone: 97%, nitrite: 98%, leukocyte: 87.6%, RBC: 88.5], and LabUmat X Ax-4280 [pH: 95.7%, bilirubin: 99.2%, protein: 74.7%, glucose: 98.5%, urobilinogen: 93.2%, ketone: 97.6%, nitrite: 98%, leukocyte: 79.8%, RBC: 88.9%.

In our study, the WBC, RBC and Squamous epithelium cell counts measured by the microscopic analyzers based on two different methods were in the same range and there was an excellent agreement for all the three parameters (Gamma value 0.916, p<0.001; 0.77, p<0.001; 0.961, p<0.001, respectively). We also found the Kappa value to be 0.486 for the cylinder measurement comparison and 0.495 for the crystalline measurement comparison between the devices, and a moderate agreement between the devices for the measurement of these two parameters. In a study performed by Yalçınkaya et al. with 440 urine samples based on the comparison of FUS200 and Urised3 microscopic urine analyzers with the Deming regres-

sion analyzer, the correlation coefficients for WBC and RBC measurements performed by the two devices were 0.961 and 0.961, respectively. When they examined the concordance between the two microscopic analyzers for negative-positive test results, they found the Kappa value to be 0.79 (good agreement) for WBC and 0.42 (moderate agreement) for RBC [14]. In a study performed by İnigo et al. with 1934 urine samples to compare the results obtained by SediMax and Sysmex UF1000i analyzers, they performed the Spearman correlation analysis between the devices and found a very strong correlation for WBC (r=0.928) and a strong correlation for RBC (r=0.631) and Squamous epithelium cell counts (r=0.631) between the devices [15]. In a study performed by Preenun et al. with 101 samples to compare the results of Urised analyzer with manual microscopy, they found the gamma values to be 0.837 for WBC, 0.918 for RBC and 0.939 for Squamous epithelium cell counts, and a very high level of correlation between the results obtained by the fully automatic analyzer and the manual method. In this study, they found the Kappa value to be 0.798 between Urised analyzer and the manual microscopy for the crystalline measurement [12]. In a study performed by Ince et al. with 209 randomly selected urine samples to compare FUS200 and Iris iQ200 analyzers, they found the Kappa value to be 0.81 for RBC and WBC, 0.61 for epithelium cell measurement, 0.69 for crystalline measurement and 0.04 for cylinder measurement between the two devices and concluded that there was a very good agreement for RBC and WBC measurement, a moderate agreement for epithelium cell and crystalline measurement, but no agreement for cylinder measurement between the two devices [16].

A study performed by Budak et al. with 412 urine samples to compare the results obtained by three automatic urine analyzers; Iris iQ200 (AX-4280), Sysmex UF-1000i (Urisys 2400) and UriSed-LabUmat, showed that there was an agreement of 91.5% between UF-1000i and UriSed, 92.2% between iQ200 and UriSed, and 89.5% between UF-1000i and iQ200 for the RBC measurement results. The same study also showed that there was an agreement of 82.2% between UF-1000i and UriSed, 83.7% between iQ200 and UriSed, and 86.6% between UF-1000i and iQ200 for the WBC measurement results, and an agreement of 85.1% between UF-1000i and UriSed, 87.6% between iQ200 and UriSed, and 90.2% between UF-1000i and iQ200 for the epithelium cell count measurement results [17].

In a study performed by Laiwejpithaya et al. with 277 urine samples to compare the quantitative measurement results of RBC, WBC and epithelium cell counts obtained by UriSed 3 and UX-2000 automatic urine analyzers with the manual urine microscopy results, they reported that UriSed 3 and UX-2000 devices had an almost similar performance for RBC and WBC measurements, but Urised3 was more reliable in the measurement of epithelium cell counts [11].

In this study, when the internal agreement of chemical analyzer and microscopic analyzer of the two devices was examined based on the WBC and RBC parameter measurements, it was observed that there was a high correlation for the WBC measurement results and a moderate correlation for the RBC measurement results between Urised2-LabUmat2 and FUS200-H800 devices. In a study performed by Bakan E et al. with 540 urine samples to compare the internal chemical and microscopic agreement of Cobas 6500 and Iris IQ200 automatic urine analyzers, they found that the correlation coefficient was to be 0.74 and 0.65 for WBC and RBC counts measured by the chemical and microscopy components of Cobas 6500, respectively. In the same study, they found that the correlation coefficient was to be 0.74 and 0.76 for WBC and RBC agreement, respectively, between the chemical and microscopy components of Iris IQ200 [9].

Since the measurement methods of the microscopic units of the devices compared in this study were different, the Passing-Bablok regression analysis revealed that there was an apparent deviation from linearity for the WBC and RBC measurements, i.e., there was no agreement between these two methods for the measurement of these parameters; however, there was no apparent deviation from linearity between these two methods for the Squamous epithelium cell count measurement, thus indicating an agreement between the measurement results obtained by the two methods. The Bland-Altman difference plots and bias levels revealed that the automatic microscopy units of the two devices showed an acceptable performance in the measurement of WBC, RBC and Squamous epithelium cell count measurements.

Conclusion

This study concluded that the performances of the two automatic urine analyzers under comparison were close to each other. However, it was concluded that, especially in pathological conditions, the chemical and microscopic analysis results obtained by the two automatic analyzers are needed to be verified with manual methods.

Since automatic urine analyzers have many advantages, such as their ability to eliminate pre-analytic and analytic error sources in measurements, to reduce inter-individual variations between manual analyses and standardize the results, to analyze a large number of urine samples in a quick and highly reproducible manner, and to minimize the need for manual analysis, it is inevitable to use them. However, although automatic urine analyzers are based on different measurement methods and technologies, they are still insufficient for complete microscopic identification of shaped elements in urine, and hence studies are needed to improve their microscopic identification capabilities on a software and technology basis.

The limitations of our study are as follows: In our study, a larger number of samples could have been randomly selected and also a larger number of pathological samples could have been included and the scope of the comparison could have been expanded. If there had been a greater number of

pathological samples, crystal type and cylinder type distinctions and comparisons could also have been made. In addition, the results of both brands of devices could have been compared by the manual microscopy method used as the reference method.

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