Journal of Associated Medical Sciences 2025; 58(3): 237-247

JAMS
Journal of Associated Medical Sciences

Scopus Indexed & Thai-Journal Citation Index Centre (TCI)

Journal of Associated Medical Sciences

Journal homepage: https://www.tci-thaijo.org/index.php/bulletinAMS/index

The performance evaluation of the Dirui MUS3600 and FUS3000Plus automated urine analyzers utilized in the AMS CMU EQA unit's urinalysis proficiency testing program

Tanyarat Jomgeow*, Jirapat Narkdee, Nattawinan Piewlueng

Division of Clinical Microscopy, Department of Medical Technology, Faculty of Associated Medical Sciences, Chiang Mai University, Chiang Mai Province, Thailand.

ARTICLE INFO

Article history:
Received 6 February 2025
Accepted as revised 3 July 2025
Available online 9 July 2025

Keywords:
Urinalysis analyzer, automated urinalysis, Dirui model, MUS3600, FUS3000Plus, method validation

ABSTRACT

Background: Urinalysis is one of the essential laboratory tests for health checks, which requires highly skilled personnel. In medical laboratories, automated urine analyzers are crucial for reducing workloads compared to human methods. However, quality control is necessary to ensure their accuracy and precision. The Dirui MUS3600 and FUS3000Plus automated urinalysis analyzer models are also interested in taking part in the proficiency testing program, and the AMS CMU EQA unit has developed urine control materials for the Thai medical laboratory's urinalysis EQA program.

Objectives: The goal of this study was to evaluate the performance of the Dirui 3600 and FUS3000Plus urine analyzer models for usage in the AMS CMU EQA unit laboratory using method validation items.

Materials and methods: Total of 724 urine samples were collected, and three in-house urine control levels were prepared. Imprecision, accuracy, comparison, and diagnostic performance tests were determined by using MUS3600 and FUS3000Plus compared with the microscopic examination as the standard method.

Results: Both automated models provided excellent results of %CV of within day and between day running shows less than 10%. The agreement between automation and standard methods in physical, chemical, and sediment evaluation was 70-100%. The correlation coefficient for the RBC and WBC parameters compared with the manual microscope method ranged from r=0.88 to 0.93. Linearity results of both models show r=0.99 for RBCs and WBCs, respectively. Results of carry-over also show good reliability results below 0.005%. Moreover, the results of sensitivity and specificity in important urinary diseases indicate sediment for example RBC and WBC show more than 83% of overall results.

Conclusion: The Dirui MUS3600 and FUS3000Plus models of urinalysis analyzers yielded good results, indicating that they are suitable for use in the future for the collection and preparation of specimens for QC material used in the proficiency program that should follow the standard procedure for EQA participants. In addition, both models can produce good urinalysis results in clinical laboratories.

Introduction

Urinalysis is one of the most requested laboratory tests used for diagnosing kidney diseases and other disorders. Recently, automated urinalysis analyzers were used instead of manual methods for better performance and shorter turnaround times, especially in large-scale labs.[1,2] However, a good quality control strategy is necessary for the process in every test from automation. Even though more clinical laboratories in Thailand are

* **Corresponding contributor.**
Author's Address: *Division of Clinical Microscopy, Department of Medical Technology, Faculty of Associated Medical Sciences, Chiang Mai University, Chiang Mai Province, Thailand.*
E-mail address: tanyarat.jomgeow@cmu.ac.th
doi: 10.12982/JAMS.2025.093
E-ISSN: 2539-6056

using urine analyzers, the automated results are not entirely trustworthy. Numerous investigations reveal that all the automated physical, chemical, and sediment evaluation results contain mistakes, so skilled personnel must carefully verify and validate the results of all process especially confirmed sediment evaluation under manual microscope.[3,4,5]

For these reasons, in 2020, we launched the urinalysis proficiency testing program under the AMS CMU EQA unit, Faculty of Associated Medical Sciences, Chiang Mai University. We provide 2 rounds a year with artificial urine to process all standard physical, chemical, and microscopic examination procedures. We currently have over 500 participants in Thailand for routine urinalysis proficiency testing. Our program's urine sediment quality control materials are made from patient urine samples that were discarded, and the sediments were treated using our proprietary formula fixative solution. Since more than 1,200 samples were collected for sediment control material preparation in each round of proficiency testing, the evaluation of the specimens by the manual method created an excessive workload for staff. Additionally, certain participants in the proficiency program employ an automated urine analyzer. Because the manual approach alone does not meet automation performance criteria for all participants, our lab needs to automate all procedures. Since the huge sediment collection process is essential in our lab, we are interested in the imaging technology of the automated urinalysis analyzer, which could deliver accurate and clear screening images of sediment for the collection process.

There are a variety of automated urinalysis analyzers used in clinical laboratories. Almost all chemical examinations use the principle of the photoelectric colorimetric method, whereas sediment evaluation uses imaging technology or the flow cytometry principle.[6,7] Several studies reported the advantages of imaging technology in the screening of sediment evaluation.[8,9,10] Cho EJ *et al*. revealed that a combination using automated urinalysis systems based on flow cytometry or digital imaging techniques could efficiently replace manual microscopic examination.[11] This research team also reported on the comparison of 5 different principles of automated urinalysis analyzers that could reduce the manual process when utilized in an appropriate way.[12] The comparative study of Dirui FUS200 and Urised 3 with manual microscopic examination reported by Yalcinkaya E. *et al*., in 2019 shows strong correlations existed between FUS200 and manual microscopy and are helpful for the diagnosis of pathological urine samples.[13] Moreover, according to a study by Benovska M. *et al*. in 2018, the FUS-2000 hybrid analyzer's microscopic component performs well analytically and closely matches light microscopy of urine sediment.[14]

Based on the earlier articles, we are considering the new Dirui instrument versions. The first model is the FUS3000Plus, a hybrid model with all-in-one modules, and the other one is the MUS3600 model, which integrates two modules of an automated urine analyzer. The instruments contain similar principles in the part of the microscopic examination with FUS2000, which had been shown good analytical performance of the analyzer and highly agreement with light microscopy of urine sediment.[14] Both models are based on dry chemistry: photoelectric colorimetry and flow-type micro-imaging technology covering 15 chemistry parameters and urine sediment image recognition, respectively.[15] To evaluate the performance of the Dirui MUS3600 and FUS3000Plus automated urine analyzers for future use in quality control sample processing in proficiency programs, we present the method validation items here, including imprecision, accuracy, comparison, and diagnostic performance tests.

Materials and methods

Sample collection and process

A total of 724 urine samples were collected from the Laboratory of Clinical Microscopy and the Laboratory of Kidney Disease Unit, Maharaj Nakorn Chiang Mai Hospital, from June 2023 to March 2024. The ethical committee of the Faculty of Associated Medical Sciences, Chiang Mai University, has permitted ethical proof documents (AMSEC-67EM-012). Collected urine samples were separated into two groups. The first group was used for the method evaluation test items, whereas the second group was used to prepare in-house sediment control material for sediment evaluation (3 levels: low, medium, and high level). The results of physical examination of control materials were identified with 3 medical technologist experts while the chemical examination confirmed by chemistry analyzer (VITROS®XT 7600 Integrated system) and cell count were confirming by hematologic analyzer (Sysmex XT1000i). After determining the urinalysis were done by using MUS3600 and FUS3000Plus, urine sediment was collected, fixed and stored at 2-8 °C. The sediment was evaluated under a microscope by using wet preparation of 22x22 mm. cover glass (number/HPF or number/LPF) and the improved Neubauer hemacytometer (cells/µL) by 3 expert medical laboratory staffs. Specimens that were stored for more than 2 hrs at room temperature or specimens with turbid containing numerous amorphous, debris, squamous epitheliums or microorganisms that obscured vision to detect sediment type clearly under the microscope were excluded.

Imprecision test

Method validation was done based on ICH guideline Q2 (R2): validation of analytical procedure, 2023.[16] Imprecision tests of physical, chemical, and sediment evaluation of Dirui MUS3600 and FUS3000Plus were done using in-house control materials (Table 1). The reproducibility of each control level was determined by analyzing 20 times within-day running and 20 times between-days running. Imprecision tests of physical and chemical examination results have been calculated by the agreement of results using % concordance of qualitative or semi-quantitative results. The imprecision of WBCs and RBCs evaluation was analyzed by mean, SD, and %CV by using sediment that confirmed concentration by counting

with an improved Neubauer hemacytometer (cells/µL) before determining by automation. The acceptance of imprecision in physical and chemical examination is more than 80% concordance, while in RBCs and WBCs parameters accepted by %CV are less than 10.

Table 1. Characteristics of in-house three-level urine control materials.

Urinalysis parameters		L1: Low level	L2: Medium level	L3: High level
Physical examination	Color	Yellow	Amber/brown/green	Orange/red
	Appearance	Clear	Slightly cloudy	Cloudy/heavy cloudy
	pH	5.0-6.5	6.6-7.5	7.6-8.5
	Specific gravity	1.001-1.010	1.011-1.020	1.021-1.030
Chemical examination	Protein	Negative (0 mg/dL)	0.1-0.3 gm/L	1.0-3.0 gm/L
	Glucose	Negative (0 mg/dL)	100-200 mg/dL	500-1,000 mg/dL
	Blood	Negative	5-10 cells/HPF	100-200 cells/HPF
	Nitrite	Negative	Positive	NA
	Leukocyte esterase	Negative	50-100 cells/HPF	20-30 cells/HPF
	Ketone	Negative	Positive	NA
	Urobilinogen	Normal	Abnormal	NA
	Bilirubin	Negative	Positive	NA
Microscopic examination	WBCs	Lot 1: 0-1 cells/HPF	Lot 1: 5-10 cells/HPF	Lot 1: 20-30 cells/HPF
		Lot 2: 0-1 cells/HPF	Lot 2: 30-50 cells/HPF	Lot 2: >100 cells/HPF
	RBCs	Lot 1: 0-1 cells/HPF	Lot 1: 5-10 cells/HPF	Lot 1: 20-30 cells/HPF
		Lot 2: 0-1 cells/HPF	Lot 2: >100 cells/HPF	Lot 2: >100 cells/HPF
	Epithelial cells	0-1 cell/HPF	5-10 cells/HPF	NA
	Yeast/budding yeast	0-1 cell/HPF	5-10 cells/HPF	NA
	Cast	Negative	0-1/LPF	NA
	Crystals	Negative	0-1/LPF	NA

Note: NA: not available

Accuracy test

Recovery spike tests were done by using non-spiked samples at the concentration of RBCs (350, 700, 1,500, 2,500, 5,000, 10,000 cells/µL) and WBCs (100, 200, 400, 800, 1,000 cells/µL), which were prepared by counting with an improved Neubauer hemacytometer (cells/µL). Then spiked samples were created by adding equal volumes of non-spiked samples, making 2 folds of each concentration (100% added concentration) as shown in Table 2. Then 5 spiked samples were evaluated by Dirui MUS3600 and FUS3000Plus before calculating % recovery. The formula used to calculate the %recovery is

% recovery = (concentration of spiked sample - concentration of non-spiked sample) x 100 concentration of added sample

The acceptance of % recovery is between 90-110.

Table 2. Accuracy assessment of the Dirui MUS3600 and FUS3000Plus analyzers based on the percent recovery (% recovery) of spiked urine samples. Acceptable recovery is defined within the range of 90% to 110%, according to standard validation criteria (N=20).

Parameters	Dirui MUS3600				Dirui FUS3000Plus			
	Non-spiked concentration	Spiked concentration	Added concentration	%Recovery	Non-spiked concentration	Spiked concentration	Added concentration	%Recovery
RBCs	5,000	9,783	5,000	95.66	5,000	10,150	5,000	103
	2,500	4,793	2,500	91.72	2,500	4,815	2,500	92.60
	1,250	2,461	1,250	96.88	1,250	2,572	1,250	105.76
	700	1,456	700	108	700	1,368	700	95.43
	350	725	350	107.14	350	696	350	98.86
WBCs	1,000	2,044	1,000	104.40	1,000	1,960	1,000	96
	800	1,540	800	92.50	800	1,615	800	101.88
	400	791	400	97.75	400	818	400	104.50
	200	417	200	108.50	200	411	200	105.50
	100	203	100	103	100	195	100	95

Comparison test

Urine samples (N=40) were determined twice, and physical, chemical, and sediment examination results were compared between two Dirui automation models, the Siemens strip reader (Clinitek Advantus® urine chemistry analyzer) as a current instrument and the manual microscopic examination as the standard method. The percentage of concordance and the correlation coefficient between methods were calculated. The acceptance of % concordance is the agreement of the result between 2 methods within ±1 different grade.

Linearity test

High concentrations of WBCs and RBCs were diluted into 5 dilutions (0-10,000 cells/cu.mm for RBCs and 0-2,500 cells/cu.mm. for WBCs), and each dilution was determined by duplicate sediment analysis by both automation models. Then the linear regression of detected results and expected concentration was analyzed.

Carryover test

Triplicate high control levels (H1, H2, H3) and triplicate low control levels (L1, L2, L3) were determined by both Dirui automation models. Quantitative parameters, RBCs and WBCs, were calculated %carryover. The percentage of carryover was calculated by using the formula:

$$\% \text{ Carryover} = (L1-L3)/(H3-L3) \times 100.$$

The acceptance of % carryover is not over than 0.01%.

Diagnostic performance test

Urine sediments (N=270) were collected and identified. The identified sediment type was separated into 14 categories containing normal and pathognomonic sediment types: RBC, WBC, non-squamous epithelial cells, bacteria, yeast cells or budding yeast or pseudo-hyphae, infectious crystal (struvite), RBC cast, dysmorphic RBC, calcium oxalate crystal, uric acid crystal, fatty cast, hyaline cast, granular cast, and waxy cast**.** Then each group was evaluated by 3 expert laboratory staffs under a microscope and compared with results detected by MUS3600 and FUS3000Plus. Then, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated.

Statistical analysis

Microsoft Excel 2016 was used to analyze calculations of the mean, SD, %CV, %agreement, %carryover, linear regression, correlation coefficient, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV).

Results

The within-day and between-day running results for the imprecision test of MUS3600 and FUS3000Plus were done using the three levels of in-house control materials shown in Table 3. For quantitative analysis available parameters, the %coefficient of variation of RBCs or WBCs evaluation shows from 1.97 to 4.71. in lot 1 (low to high level) and from 3.79 to 9.23 in lot 2 (low to extremely high level), while the qualitative and semi-quantitative parameters as physical and chemical examination results show 85-100% concordance in overall parameters (data not shown). The accuracy test results of MUS3600 and FUS3000Plus in RBCS and WBCs detection are shown in Table 2. The percentage of recovery tests in spiked samples displayed an acceptable range from 91.72 to 108.50%.

Table 3. Imprecision analysis of urinary sediment evaluation by the Dirui MUS3600 and FUS3000Plus analyzers.

QC materials			%CV of within-day running		%CV of between-day running	
			MUS3600 (N=20)	FUS3000Plus (N=20)	MUS3600 (N=20)	FUS3000Plus (N=20)
Lot 1	Level 1	RBCs	0	0	0	0
		WBCs	0	0	0	0
	Level 2	RBCs	2.38	1.93	3.49	2.97
		WBCs	1.97	2.07	3.64	3.75
	Level 3	RBCs	2.77	2.35	4.28	4.71
		WBCs	2.85	2.23	3.91	4.22
Lot 2	Level 1	RBCs	0	0	0	0
		WBCs	0	0	0	0
	Level 2	RBCs	3.99	3.79	4.06	5.48
		WBCs	4.73	6.01	7.66	9.23
	Level 3	RBCs	4.05	3.53	7.52	8.96
		WBCs	5.21	8.18	8.43	8.71

Note: The coefficient of variation (%CV) was calculated for both within-day (N=20) and between-day (N=20) runs to assess reproducibility.

The comparison test revealed that a chemical analysis of 40 urine samples revealed 92.5-100% agreement between the Siemen strip reader and the two Dirui automation models. The percentage concordance within one grade difference ranges from 81.4 to 92.4%, while the correlation coefficient for the RBC and WBC parameters ranges from r=0.88 to 0.93. Other sediment parameters, on the other hand, exhibit correlation coefficients from r=0.65 to 0.83 and percentage concordance within one grade difference ranging from 65.6 to 86.6% (Tables 4, 5, and 6).

With five dilutions of RBC and WBC samples, MUS3600 and FUS3000Plus were used to assess the concentration detectable performance of tests on the various specified concentrations by automation. MUS3600 and FUS3000Plus offer linearity concentration at r=0.99 for RBCs and WBCs, respectively, according to the data displayed in Figure 1A-1D. Carry-over testing was used to demonstrate that a high concentration of the prior sample could not contaminate the subsequent sample; the overall percentage carry-over for both models is 0.001-0.003% (data not shown).

Table 4. The Comparison test in % concordance of chemical examination and sediment evaluation from Dirui MUS3600 and FUS3000Plus compared with the previously used equipment, Siemen strip reader (duplicate experiments).

Chemical parameters	**%Concordance of detection when compared automation results with the Siemen strip reader (N=40)**	
	Dirui MUS3600	Dirui FUS3000Plus
pH	95	97.5
Specific gravity	97.5	100
Protein	97.5	100
Glucose	100	100
Blood	92.5	95
Leukocyte esterase	95	97.5
Nitrite	100	100
Ketone	97.5	95
Bilirubin	100	100
Urobilinogen	100	100

Table 5. Percent concordance of urine sediment evaluation results between automated analyzers (Dirui MUS3600 and FUS3000Plus) and manual microscopic examination (N=619). Comparison of sediment parameters evaluated by automated systems versus manual microscopy.

Sediment parameters	**%Concordance of sediment evaluation when compared automation results with microscopic examination(N=619)**	
	Dirui MUS3600	Dirui FUS3000Plus
RBCs	92.4	89.5
WBCs	82.7	81.4
Squamous epithelial cells	84.7	86.6
Non-squamous epithelial cells	77.1	73.2
Hyaline casts	72.7	69.6
Granular casts	65.9	67.0
Crystals	72.9	71.7
Bacteria	78.0	79.6
Yeast cells/budding yeast	65.6	66.4
Sperm	76.7	80.1

Note: Percent concordance refers to the agreement between results obtained from the automated analyzers and those from the reference microscopic method.

Table 6. Correlation coefficients (r) of urinary sediment evaluation results obtained from the Dirui MUS3600 and FUS3000Plus analyzers compared with manual microscopic examination performed by expert medical technologists.

Sediment parameters	Correlation coefficient (r) when compared automation results with microscopic examination (N=619), 95% Confidence intervals	
	Dirui MUS3600	Dirui FUS3000Plus
RBCs	0.93	0.91
WBCs	0.88	0.87
Squamous epithelial cells	0.72	0.75
Non-squamous epithelial cells	0.82	0.78
Hyaline casts	0.67	0.73
Granular casts	0.71	0.65
Crystals	0.69	0.71
Bacteria	0.75	0.83
Yeast cells/budding yeast	0.75	0.74
Sperm	0.77	0.72

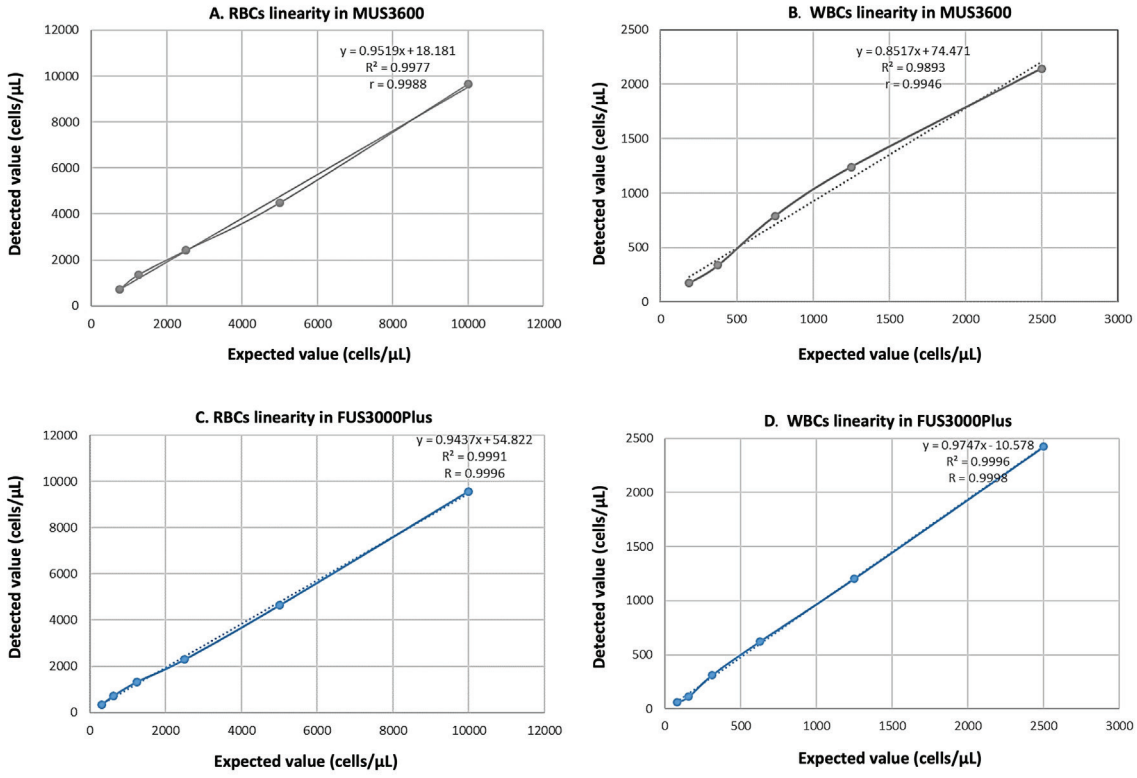

Figure 1. Linearity analysis of red blood cells (RBCs) and white blood cells (WBCs) using the Dirui MUS3600 and FUS3000Plus automated urine analyzers. A and B: linear correlation for RBCs and WBCs, respectively, on the MUS3600, C and D: corresponding linearity for the FUS3000Plus

Prior to testing the diagnosis performance of sediment evaluation with both automation models, 3 expert MTs classified urine sediments, and Table 7 displayed the percentages of sensitivity, specificity, PPV, and NPV. Overall sediment group sensitivity and specificity ranged from 50.0 to 100%. WBCs, RBCs, and non-squamous epithelial cells show over 80% of cellular sediments. Good specificity and sensitivity, above 80% and 70% respectively, were demonstrated in the microorganism group. The results indicate that the pathological cast has 80-100% specificity and about 60% sensitivity, whereas the hyaline cast has good sensitivity and specificity. Calcium oxalate crystals exhibit high sensitivity and specificity, whereas infectious crystals (struvite) and uric acid crystals only exhibit 60% sensitivity and over 95% specificity.

Table 7. Diagnostic performance evaluation of the Dirui MUS3600 and FUS3000Plus analyzers in the detection of urinary sediment, compared with manual microscopic examination as the reference standard.

Sediment parameters	MUS3600				FUS3000Plus				N=270
	%sensitivity	%specificity	PPV	NPV	%sensitivity	%specificity	PPV	NPV	
RBC	92.22	91.94	94.32	89.06	92.31	95.08	96.55	89.23	152
WBC	96.43	83.33	98.54	66.67	96.38	85.71	98.52	70.59	
Non-squamous epithelial cells	80.30	81.33	79.10	82.43	79.10	82.35	77.94	83.33	
Bacteria	72.73	97.40	96.55	78.13	73.75	97.22	96.72	76.92	
Yeast cells or budding yeast or pseudo-hyphae	71.43	87.38	72.92	86.54	71.74	86.79	70.21	87.62	
Infectious crystal (struvite)	64.00	98.43	88.89	93.28	62.50	97.66	83.33	93.28	
RBC cast	66.67	100.00	100.00	95.83	66.67	100.00	100.00	95.83	26
Dysmorphic RBC	41.18	88.89	87.50	44.44	58.82	88.89	90.91	53.33	
Calcium oxalate crystal	95.45	84.62	91.30	91.67	95.00	80.00	86.36	92.31	35
Uric acid crystal	64.29	95.24	90.00	80.00	64.29	90.48	81.82	79.17	
Fatty cast	50.00	100.00	100.00	80.00	50.00	100.00	100.00	80.00	12
Hyaline cast	81.48	83.33	88.00	75.00	80.00	75.00	80.00	75.00	45
Granular cast	66.67	84.62	75.00	78.57	66.67	80.77	70.59	77.78	
Waxy cast	57.14	97.37	80.00	92.50	60.00	97.37	75.00	94.87	

Discussion

The analytical performance of automated urine analyzers has been documented in some investigations using method evaluation items. The manufacturer's QC materials are utilized as control materials in the general method evaluation. Certain elements of the QC material, such as the type of sediment, the quantity of chemicals, or the concentration of sediments, cannot provide enough information. In this study, we create several levels of internal quality control materials to be used in the automated urinalysis analyzer technique assessment. These QC materials are available in various appearances for physical, chemical, and sediment concentrations from low to very high levels. They are appropriate for all aspects of method evaluation, particularly imprecision, accuracy, linearity, and carry-over testing.

To verify the stability and homogeneity of the control material in the future, it is first essential to prove the imprecision test. Since the findings of the physical and chemical tests are qualitative and semi-quantitative, the agreement percentage should be applied to these criteria. Upon physical examination, both models' within-day and between-day runs exhibited 100% concordance in terms of color and appearance found in normal and also abnormal urine (data not shown). Although there is no general research on these two characteristics, our lab thinks they are important for participant proficiency testing and also influence clinical changes in patients, such as hematuria or pyuria, which are manifestations of glomerular diseases and show changes in the color and appearance of urine. Yang WS's study investigation confirmed our findings.[17] The author concluded that urine RBC counting using the UF-1000i or Cobas 6500 urine analyzers underestimates the severity of hematuria in glomerular diseases because dysmorphic RBCs are prone to hemolysis and/or are not sufficiently recognized.

The result of specific gravity values exhibits 85–100% concordance while the pH imprecision test likewise indicates 100% concordance. Except for the blood and leukocyte esterase parameters, which are 95% and 90% in agreement, all parameters for the chemical analysis exhibit 100% concordance. We found that several variables are impacted, including sediment debris during the final week of QC material storage, which can lead to inaccurate data. Even when determining the exceptionally high concentrations of RBC and WBC displayed in Table 3, the sediment evaluation of both Dirui models demonstrates good precision at less than 10%. These findings are consistent with other reports in several Dirui automation models, such as the 2019 reports by Kucukgergin C. and staff and Yalcinkaya E. *et al*.[18,19]

We have performed a recovery test using the spiked samples to confirm the test's accuracy. There was a good percentage of recovery shown. Additionally, for inter-laboratory comparison, we introduced our own QC materials for physical, chemical, and sediment examination. The accuracy test results for Dirui MUS3600 and FUS3000Plus in physical and chemical evaluation revealed 90-100% concordance with the target value from professional MT and chemistry processes. Except for the percentage of agreement in the sediment determination of QC material No. 2 from the first round, which was only 66.70% of precise grading, the results show more than 80% of all parameters in both models. Examining this error, we found that MUS3600 models evaluated sediment higher than FUS3000Plus models for a single grade, although the clinical feature difference was insignificant. Since our laboratory's MUS3600 is the only instrument in Thailand that is compared among FUS3000Plus, the mode data for the 15-19 sites in the inter-laboratory comparison group are somewhat higher in MUS3600 but perfectly in agreement with FUS3000Plus. Since this procedure is not typically used for method validation, these results have not been included in this article. But for us, the statistics validated the test's correctness.

The comparison test was analyzed by % concordance, and the correlation coefficient revealed excellent results compared with the strip reader, and that was compared with microscopic examination. Although some parameters, such as cast, crystal, and microorganism, show lower % concordance than cellular components, both automation reports these sediments in unclassified groups to allow users to correct the results. These comparison results suggested that MUS3600 and FUS3000Plus perform as well as the method used in our laboratory.

The linearity test shows reliable results of RBCs and WBCs concentration between expected results and detected results within the wide range of concentration from 0-10,000 cells/µL and 0-2,500 cells/µL for RBCs and WBCs, respectively. The carry-over test of both parameters shows 0.001-0.003%, indicating no interference from previous high-concentration specimens to the next sample. We also determined the carry-over test six months later, and the results also show a carry-over of less than 0.005% (data not shown).

Additionally, we identified the Dirui MUS3600 and FUS3000Plus diagnostic performance tests. In most sediment parameters, the specificity in both models is greater than 80%. On the other hand, the sensitivity is reduced in cast and crystal characteristics and exhibits great results in detecting cellular components. The results for the detection of fatty casts and dysmorphic RBCs, which have only 41.18% and 50% specificity, respectively, may be due to the sediment types of high light reflection and irregular shape. However, there are some reports regarding the performance of the Dirui FUS-200 analyzer. For instance, Yuksel *et al*. found that the FUS-100's sensitivity for RBCs and WBCs is 73% and 68%, respectively, and Kocer D. *et al*. found that the analytical sensitivity for bacterium recognition and quantification was insufficient.[19,20] Moreover, the study reported by Bartosova K et al. also suggested that a manual microscope is still required for sediment confirmation in a variety of automation models.[21] It was also found that the diagnostic performance improved upon the Dirui MUS3600 and FUS3000Plus's imaging software update version.

There were the several limitations of this study: first, the automation was unable to recognize certain large-sized

sediment kinds or when it is clumping, such as uric acid crystal, triple phosphate crystals, and epithelial cells clumping but stilled good to identified WBC clumping. Second, the automation was unable to run a urine sample that was less than three milliliters in volume, but it still lost some volume and produced no results. This issue blocked us from having adequate volume to operate and caused us to switch to the manual technique.

For some sediment types that were varied and complicated in shape and dimension, for example, pathological casts, crystals, and dysmorphic RBCs, we found that the automation also reported them in the unclassified category or the other of each type (other crystal or other cast). Therefore, users must check these categories carefully. However, from our results, we suggested that the microscopic examination is still necessary in case of confirmation of pathognomonic sediments.

Conclusion

Our results indicated that the MUS36000 and FUS3000Plus urine automated analyzers are sufficient, accurate, precise, and dependable enough to screen urine sediment in the clinical laboratory rather than using manual microscopy in the AMS CMU EQA Center Unit. However, for clinical diagnosis purposes, certain pathologically specific urine sediments should be confirmed by manual microscopy when used in the hospital laboratory.

Ethical approval

The ethical committee of the Faculty of Associated Medical Sciences, Chiang Mai University, has permitted ethical proof documents (AMSEC-67EM-012).

Funding

This research received no funding from any agency in the public, commercial, or not-for-profit sectors.

Conflict of interest

The authors declare no conflict of interest.

CReDIT authorship contribution

Tanyarat Jomgeow: conceived the study, designed the experiments, and performed the experiment, data analysis and manuscript preparation; **Jirapat Narkdee** and **Nattawinan Piewlueng**: sample collection, perform automated and manual urinalysis data interpretation. All authors approved the final version.

Acknowledgements

The authors thank AMS CMU EQA unit staffs for their valuable helping on distribution of quality control material to hospital laboratories.

References

[1] Oyaert M, Delanghe JR. Semiquantitative, fully automated urine test strip analysis. J Clin Lab Anal. 2019; 33(5): e22870. doi: 10.1002/jcla.22870.

[2] Tantisaranon P, Dumkengkhachornwong K, Aiadsakun P, Hnoonual A. A comparison of automated urine analyzers cobas 6500, UN 3000-111b and iRICELL 3000 with manual microscopic urinalysis. Pract Lab Med. 2021; 24: e00203. doi: 10.1016/j.plabm.2021.e00203.

[3] Hannemann-Pohl K. Automation of urine sediment examination: a comparison of the Sysmex UF-100 automated flow cytometer with routine manual diagnosis (microscopy, test strips, and bacterial culture) Clin Chem Lab Med. 1999; 37: 753-64. doi: 10.1515/CCLM.1999.116.

[4] Sterry-Blunt RE, Randall KS, Doughton MJ, Aliyu SH, Enoch DA. Screening urine samples for the absence of urinary tract infection using the sediMAX automated microscopy analyser. J Med Microbiol. 2015; 64(6): 605-9. doi: 10.1099/jmm.0.000064.

[5] Shayanfar N, Tobler U, von Eckardstein A, Bestmann L. Automated urinalysis: first experiences and a comparison between the Iris iQ200 urine microscopy system, the Sysmex UF-100 flow cytometer and manual microscopic particle counting. Clin Chem Lab Med. 2007; 45(9): 1251-6. doi: 10.1515/CCLM.2007.503.

[6] Oyaert M, Delanghe J. Progress in automated urinalysis. Ann Lab Med. 2019; 39 (1): 15-22. Available from: https://doi: 10.3343/alm.2019.39.1.15.

[7] Larkey NE, Obiorah IE. Advances and progress in automated urine analyzers. Clin Lab Med. 2024; 44(3): 409-21. doi: 10.1016/j.cll.2024.04.003.

[8] Lamchiagdhase P, Preechaborisutkul K, Lomsomboon P, Srisuchart P, Tantiniti P, Khan-u-Ra N, Preechaborisutkul B. Urine sediment examination: a comparison between the manual method and the iQ200 automated urine microscopy analyzer. Clin Chim Acta. 2005; 358(1-2): 167-74. doi: 10.1016/j.cccn.2005.02.021.

[9] Anderlini R, Manieri G, Lucchi C, Raisi O, Soliera AR, Torricelli F, Varani M, Trenti T. Automated urinalysis with expert review for incidental identification of atypical urothelial cells: An anticipated bladder carcinoma diagnosis. Clin Chim Acta. 2015; 451:252-6. doi: 10.1016/j.cca.2015.10.005.

[10] Zaman Z, Fogazzi GB, Garigali G, Croci MD, Bayer G, Kránicz T. Urine sediment analysis: Analytical and diagnostic performance of sediMAX - a new automated microscopy image-based urine sediment analyser. Clin Chim Acta. 2010; 411(3-4): 147-54. doi: 10.1016/j.cca.2009.10.018.

[11] Cho EJ, Ko DH, Lee W, Chun S, Lee HK, Min WK. The efficient workflow to decrease the manual microscopic examination of urine sediment using on-screen review of images. Clin Biochem. 2018; 56: 70-4. doi: 10.1016/j.clinbiochem.2018.04.008.

[12] Cho J, Oh KJ, Jeon BC, Lee SG, Kim JH. Comparison of five automated urine sediment analyzers with manual microscopy for accurate identification of urine sediment. Clin Chem Lab Med. 2019; 57(11): 1744-53. doi: 10.1515/cclm-2019-0211.

[13] Yalcinkaya E, Erman H, Kirac E, Serifoglu A, Aksoy A, Isman FK. Comparative performance analysis of Urised 3 and DIRUI FUS-200 automated urine sediment analyzers and manual microscopic method.

Medeni Med J. 2019;34(3):244-51. doi: 10.5222/ MMJ.2019.23169.

[14] Benovska M, Wiewiorka O, Pinkavova J. Evaluation of FUS-2000 urine analyzer: analytical properties and particle recognition. Scand J Clin Lab Invest. 2018; 78(1-2): 143-8. doi: 10.1080/ 00365513. 2017. 1423108.

[15] Dirui MUS3600 product brochure. [cited 2024 Dec 5]. Available from: http://en.dirui.com.cn/list-20-1.html.

[16] ICH Q2(R2) Guideline on validation of analytical procedures [cited 2024 Dec 20]. Available from: https://www.ema.europa.eu/en/documents/ scientific-guideline/ich-q2r2-guideline-validation-analytical-procedures-step-5-revision-1_en.pdf.

[17] Yang WS. Automated urine sediment analyzers underestimate the severity of hematuria in glomerular diseases. Sci Rep. 2021; 11(1): 20981. doi: 10.1038/ s41598-021-00457-6.

[18] Kucukgergin C, Ademoglu E, Omer B, Genc S. Performance of automated urine analyzers using flow cytometric and digital image-based technology in routine urinalysis. Scand J Clin Lab Invest. 2019; 79(7): 468-74. doi: 10.1080/00365513.2019.1658894.

[19] Yuksel H, Kiliç E, Ekinci A, Evliyaoglu O. Comparison of fully automated urine sediment analyzers H800-FUS100 and LabUMat-UriSed with manual microscopy. J Clin Lab Anal. 2013; 27(4): 312-6. doi: 10.1002/ jcla.21604.

[20] Kocer D, Sarıguzel FM, Karakukcu C. Cutoff values for bacteria and leukocytes for urine sediment analyzer FUS200 in culture-positive urinary-tract infections. Scand J Clin Lab Invest. 2014; 74(5): 414-7. doi: 10.3109/00365513.2014.900189.

[21] Bartosova K, Kubicek Z, Franekova J, Louzensky G, Lavrikova P, Jabor A. Analysis of Four Automated Urinalysis Systems Compared to Reference Methods. Clin Lab. 2016; 62(11): 2115-23. doi: 10.7754/Clin. Lab.2016.160316.