Clinical and Experimental Health Sciences

Performance Evaluation of the Semi-automated Urine Analyser DFI R-600S

Murat Can, Berrak Güven, Ferhan Adıbelli, Emrah Altunsoy

Zonguldak Bulent Ecevit University, Faculty of Medicine Department of Biochemistry, Zonguldak, Türkiye.

Correspondence Author: Murat Can
E-mail: drcanmurat@yahoo.com

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ABSTRACT

Objective: The major considerations of the urine analysis performed in laboratories are to obtain a fast and accurate test result. Increasing number of instruments and methods have been developed for making it possible. The aim of this study is to compare the performance of the DFI R600S with that of the Roche Cobas U411.

Methods: Five hundred thirty three freshly obtained out – and in-patient routine urine samples collected. We conducted an analysis using results from urine dipstick tests that measure ten parameters: glucose, protein, bilirubin, urobilinogen, pH, specific gravity, ketones, red blood cells, nitrite, and leukocytes. Both analyzers were utilized in the process, followed by a microscopic examination of the urinary sediment.

Results: It was determined that the pH and specific gravity tests showed poor concordance, while the remaining tests exhibited moderate to very good concordance between the manual microscopic method and the individual devices.

Conclusions: The semi-automated test strip analyzer DFI R600S offers low cost, easy to use and reliable first level screening method for urinalysis but it is important to be aware of conditions produce false-positive or false-negative results of the urine dipstick.

Keywords: Urine analysis, dipstick, urine microscopy, Roche Cobas U411, DFI R600S

1. INTRODUCTION

Urine is a biological fluid produced and excreted from the body and urinalysis can give us useful information about the presence or absence of kidney and other diseases (1). In routine laboratory, it is very practical, available and cost-effective test for monitoring and treatment of the disease. In this analysis three different methods are used to assess the appearance, concentration, and content of urine: a visual *exam*, a dipstick *test* and a *microscopic exam (2)*.

In pathological conditions urine composition varies in kind and quantities. Urine dipstick test is a chemical analysis of urine by multi-parameter pads allows a determination of the complete urine status. The chemical changes of urine can indicate various diseases, such as renal disease, liver disease, and some metabolic disorders (3). The strips change color based on the presence and concentration of certain substances like erythrocytes, leukocytes, nitrites, proteins, specific gravity, glucose, ketones, bilirubin, urobilinogen and pH (4). Urine test strip is an inexpensive, simple and non-invasive procedure.

Microscopic examination of urine sediment is considered as gold standard method for urine sediment analysis in the course and management of disorders, because the urine strip tests may not detect microscopic elements such as casts, crystals, yeast, parasites, spermatozoa or rare cell types in the urine is a reflection of changes that take place in the kidney (2). A complete urine analysis includes microscopic examination, allowing for the detection of these elements.

The aim of this study was to determine the performance of a urine test strip analyzer DFI R-600S with Roche Cobas U411 currently used in our laboratory. In this study we also compare the results of the urine analysis performed with dipsticks, to the results obtained with the microscopic examination and to evaluate the dipstick performances.

2. METHODS

2.1. Sample

Five hundred thirty three freshly obtained out – and in-patient routine urine samples which were submitted to our laboratory between 1 September 2024 and 15 September 2024 were included. Routine diagnostic urinalysis, including both strip and microscopic analysis, was performed on fresh urine specimens within one hour of receipt, following the Clinical Laboratory Standards Institute GP16-A3 guidelines (5). The study was approved by the Ethics Committee of the Zonguldak Bulent Ecevit University (Approval date: 04.09.2024 Number2024/15)

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Table 1. Characteristic of Analyzers and Strips

Parameter	Roche Cobas U411	DFI R-600S
Method	Reflectance photometer	Reflectance photometer
Measuring system (Wavelengths)	470 nm, 555 nm, 620 nm	460, 550, 650 nm
Throughput (strips per hour)	600	600
Memory	1000 sample results	5,000 samples results
Size (mm) and weight (kg)	424x339x260 and 11.7 kg	360 x 330 x 240 mm and 5.7 kg
Printer	Thermal printer	Thermal printer
Strip name	Combur 10	DUS
RBC measurement principle	Activity measurement of pseudoperoxidase in hemoglobin	Activity measurement of pseudoperoxidase in hemoglobin
WBC measurement principle	Activity measurement of esterase in leukocytes	Activity measurement of esterase in leukocytes
Nitrite measurement principle	Griess reaction	Griess reaction
Protein measurement principle	Protein error of a pH indicator	Protein error of a pH indicator
Specific gravity measurement principle	Cation extraction	Cation extraction
Glucose measurement principle	Glucose-oxidase/peroxidase reaction	Glucose-oxidase/peroxidase reaction
Ketones measurement principle	Legal's nitroprussid reaction	Legal's nitroprussid reaction
Bilirubin measurement principle	Diazo reaction	Diazo reaction
pH measurement principle	Double pH indicator	Double pH indicator
Urobilinogen measurement principle	Ehrlich's reaction	Ehrlich's reaction

2.2. Analyzers

The urine test strip analyzer Roche Cobas U411 (Roche, Basel, Switzerland) and R-600S (DFI Co, Gyeongsangnam-do, Korea) were used for semiquantitative measurement of analytes in human urine and commercially available control materials according to the manufacturer's instruction. Calibration, maintenance, and bilevel (normal and abnormal) urine quality control procedures for all devices were completed to ensure they were prepared to provide patient results before the study. Table 1 presents the general characteristics of the analyzers and the strips. The sensitivity of the Urine Test Strips of the manufacturer were shown at Table 2.

Table 2. The sensitivity of the Strips

Parameter	Roche Combur 10	DFI DUS
RBC	5 – 10 Ery/µl	10 – 15 Ery/µl
WBC	20 – 25 Leu/µl	20 – 25 Leu/µl
Nitrite	0.05 – 0.07 mg/dl	0.05 – 0.10 mg/dl
Protein	8 – 12 mg/dL	15-30 mg/dL
Glucose	30 – 40 mg/dl	75-125 mg/dl
Ketones	3 – 6 mg/ dl	5-10 mg/ dl
Bilirubin	0.4 – 0.6 mg/dl	0.8-1.0 mg/dl

2.3. Manual Microscopic Analysis

Urine samples were first assayed semiautomated urine analyzers than 10 mL urine samples were centrifuged (NF 400, Nuve, Turkey) at 400 ×g for 5 minutes and examined by manual microscopy. The supernatant was discarded. The precipitate was resuspended in the test tube, then 20 µL of the precipitate was taken on a glass slide and covered by coverslips. All microscopic examination (DMLS, Leica, Japan) results were completed by two laboratory expert, and the mean values were calculated.

2.4. Statistical Analysis

All statistical calculations were performed with SPSS Statistics 18.0 (Statistical Package for Social Sciences version 18.0, IBM Corporation, Armonk, NY, USA). Erythrocytes and leukocytes were classified semi-quantitatively (0–5, 6–10, 11–20, >20 cell/HPF). The semi-quantitative elements were also classified as positive or negative, positive results being those exceeding the cutoff values, defined as 5/HPF for leukocytes and erythrocytes. We calculated the exact match concordance rate (%) and concordance rate (%) with ±1 grading difference rates (%) between Cobas U411 and R-600S. Cohen's kappa coefficient ($\varkappa$) was calculated for concordance between the methods and the values of the Cohen's kappa coefficient are characterized as poor (0–0.21). fair (0.21–0.40), moderate (0.40–0.60), good (0.61–0.80), and very good (0.81–1.00) agreement, respectively (6).

3. RESULTS

3.1. Red Blood Cell

The kappa coefficient between manual microscopy and Cobas U411 was moderate ($\varkappa$ =0.464) with an exact match concordance rate of 65% and a ± 1 rank match concordance rate of 84%. The kappa coefficient between manual microscopy and R-600S was moderate ($\varkappa$ =0.438) with an exact match concordance rate of 62% and a ± 1 rank match concordance rate of 92% (Figure 1).

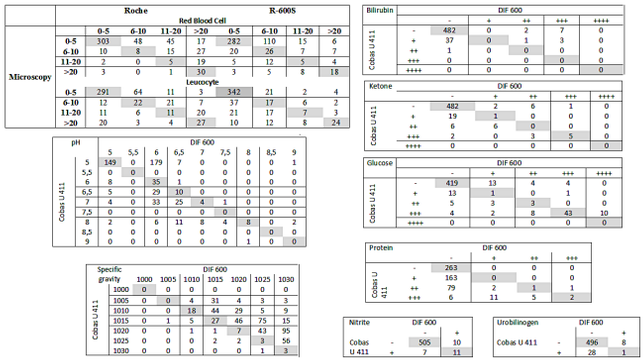

Figure 1. *Cross Tabulation of Urine Dipstick Parameters*

3.2. Leucocyte

The kappa coefficient between manual microscopy and Cobas U411 was moderate ($\varkappa$ =0.472) with an exact match concordance rate of 66% and a ± 1 rank match concordance rate of 90%. The kappa coefficient between manual microscopy and R-600S was good ($\varkappa$ =0.533) with an exact match concordance rate of 73% and a ± 1 rank match concordance rate of 90% (Figure 1).

3.3. Nitrite

The kappa coefficient between Cobas U411 and DIF 600 was very good ($\varkappa$ =0.842) with an exact match concordance rate of 97% and a ± 1 rank match concordance rate of 100% (Figure 1).

3.4. Protein

The kappa coefficient between Cobas U411 and DIF 600 was moderate ($\varkappa$ =0.407) with an exact match concordance rate of 47% and a ± 1 rank match concordance rate of 82% (Figure 1).

3.5. Glucose

The kappa coefficient between Cobas U411 and DIF 600 was moderate ($\varkappa$ =0.587) with an exact match concordance rate of 87% and a ± 1 rank match concordance rate of 96% (Figure 1).

3.6. Ketone

The kappa coefficient between Cobas U411 and DIF 600 was very good ($\varkappa$ =0.806) with an exact match concordance rate of 92% and a ± 1 rank match concordance rate of 99% (Figure 1).

3.7. Bilirubin

The kappa coefficient between Cobas U411 and DIF 600 was good ($\varkappa$ =0.781) with an exact match concordance rate of 90% and a ± 1 rank match concordance rate of 98% (Figure 1).

3.8. Urobilinogen

The kappa coefficient between Cobas U411 and DIF 600 was very good ($\varkappa$ =0.807) with an exact match concordance rate of 93% and a ± 1 rank match concordance rate of 100% (Figure 1).

3.9. pH

The kappa coefficient between Cobas U411 and DIF 600 was poor ($\varkappa$ =0.138) with an exact match concordance rate of 39% and a ± 1 rank match concordance rate of 50% (Figure 1).

3.10. Specific gravity

The kappa coefficient between Cobas U411 and DIF 600 was poor ($\varkappa$ =0.095) with an exact match concordance rate of 11% and a ± 1 rank match concordance rate of 49% (Figure 1).

4. DISCUSSION

A good analytical and diagnostic accuracy were recommended for urinalysis. Our study confirmed that the combination of chemical strip analysis and sediment microscopic analysis reliably distinguishes normal from positive samples, based on the concordance between the manual method and the two instruments.

The dipstick test for hematuria is a sensitive and rapid but nondiagnostic screening test (7). The decreased urine specific gravity (below 1.010) and increased pH (above 7.0) may result in hemoglobin release and microscopy can fail to detect urinary red blood cells (8). In our study group we dont have any dipstick hematuria without microscopic hematuria. Some dipstick tests should also check the urinary ascorbic acid to predict potential false-negative results (9). In contrast to the COBAS U411, test strips used in DFI R600S have a ascorbic acid pad. In 26 sample ascorbic acid result positive and seven of them in DFI R600 S and two of them in COBAS U411 demonstrated false negative microscopic hematuria. Also hemoglobinuria, myoglobinuria, menstrual blood, concentrated urine, strenuous exercise and strong oxidizing agents (soaps, detergents, sodium hypochlorite, hydrogen peroxide) are influenced the red blood cell pad (8) and cause differences in results between microscope and dipstick. Therefore, dipstick hematuria should be verified by microscopic examination to to confirm the presence of red blood cells.

In sediment analysis both urine analyzers showed sufficient performance for leucocyte in comparison to manual microscopy. The dipstick test gives false results for leukocyte count because of possible causes, such as elevated glycosuria, proteinuria, bilirubinuria, some oxidizing drugs or vitamin C (10). In 28 urine sample DFI R600S results were negative and the COBAS U411 results were positive, in 30 urine sample the COBAS U411 results were negative and the DFI R600S results were positive and in 5 samples both analyzer were negative when compared to microscopy contained a large amount of glucose or protein. The presence of glucose or protein may lead to false-negative results by reducing the sensitivity of the reaction to leukocyte esterase. In 3 urine sample DFI R600S results were positive and the COBAS U411 results were negative, in 14 urine sample the COBAS U411 results were positive and the DFI R600S results were negative and in one samples both analyzer were positive when compared

to microscopy contained a large amount of bilirubin or urobilinogen. The presence of bilirubin or urobilinogen may lead to false-positive results due to the color of the urine.

In our study we found very good match concordance between urine analyzers in nitrite. Causes of false-negative nitrite results include a short time between urine collection and testing, urine pH below 6.0, organisms that further reduce nitrite to ammonia, blood, dilute urine, proteinuria, glycosuria, presence of urobilinogen, and certain medications such as ascorbic acid (11). False-positive nitrites can occur with contaminated urine specimens, exposure to air, and the use of phenazopyridines (12). The DFI R600S showed false negatives in seven cases and false positives in ten cases, particularly involving large amounts of blood, proteinuria, or glycosuria. Hence, a positive nitrite result is very likely to indicate a true urinary tract infections.

Proteinuria is defined as urinary protein excretion of greater than 150 mg per day. The dipstick method is most sensitive to albumin. Hematuria, alkaline urine pH, high urine specific gravity and antibiotics such as penicillin or sulfonamides can give false positive results and non albumin urinary proteins and low urine specific gravity can give false negative results (13). Our results showed good level of agreement, only for negative protein results. The dipstick test has a high negative predictive value for proteinuria and can identify individuals at risk of rapid kidney function decline (14). It has the advantage of ruling out overt proteinuria with a spot urine sample, eliminating the need for specially collected samples. Additionally, due to its simplicity and low cost, the dipstick test can still be used as a primary screening method (15). If a subsequent dipstick test result is positive, work up should undergo a quantitative measurement of protein excretion, which can be done with a 24-hour urine specimen.

Glucose appears in urine when plasma glucose concentration exceeds the renal threshold. Fasting urine glucose measurement may not be suitable for diabetes screening, as plasma glucose levels may not be high enough to cause significant glycosuria. The potential of glycosuria for diabetes screening has been underestimated, and urine glucose measurement is not recommended due to its low sensitivity (16). While urine glucose can be used for mass screening, it cannot reflect fluctuations in blood glucose levels, unlike blood glucose measurements (17-18).

Dipstick testing showed acceptable performance for detection of glucose in comparison with Roche Cobas U411. Urine dipstick tests are inexpensive, non-invasive and easy to use to obtain additional information about a patient's condition. Urine dipsticks detect the presence of acetoacetate in urine by a colorimetric reaction with nitroprusside. In current clinical practice, ketosis is frequently tested using a urine dipstick that measures acetoacetate concentrations but although it detects severe ketosis, it is not successful in moderate to mild levels (19). Our results showed very good concordance for clinical usage.

Bacteria in the gut metabolize conjugated bilirubin by removing the glucuronic acid, after which bilirubin is reduced to the colorless pigment urobilinogen by bilirubin reductase, through the action of intestinal microflora (20). Most urobilinogen is excreted in the feces, small quantities of urobilinogen is transported by the blood into the kidneys and found in normal urine, The goal of urine bilirubin screening is to potentially reveal a pathologic liver or gall bladder condition early, before jaundice is apparent (13). Comparing the urinary bilirubin result with the urobilinogen result may assist in distinguishing between red cell hemolysis, hepatic disease, and biliary obstruction (13). In the case of bilirubin and urobilinogen, similar results were observed for both reagent and dipstick measurement This suggests that both methods are similarly useful for assessment bilirubin and urobilinogen presence in urine.

The pH test area contains indicators which change colour between pH 5 and pH 9. Wesarachkitti B et found poor concordance level of approximately 40% was obtained for pH between Sysmex UX-2000 vs Cobas 6500 (21). Single dipstick pH measurements have been shown to produce an unacceptable rate of clinically significant deviation [22]. Based on our chemical strip performance evaluation in this study, the concordance rate for strip pH was not satisfactory too. Differences for strip parameters might be due to altered chemical design of pads, the calibration of readers for optical absorbance or interferences. The most accurate method to measure urine pH is the use of a glass electrode (23). Urine specific gravity generally gives useful information about the patient's hydration status and the concentrating ability of kidneys. The DFI R600S gave poor results when compared to Roche Cobas U411. The results observed for specific gravity were very similar with highly consistent observations by Tanaka et al. (24).

This present study may have some limitations. First, some parameters such as protein, glucose, ketones, bilirubin, specific gravity and pH were not measured with other methods. Second, we did not compare dipstick results to a reference of *urine culture*. Third, we couldnt classify patients according to their symptoms that may potentially affect the observed results and such results should be interpreted with caution. Therefore, future studies are recommended which can better address the limitations seen in our findings.

5. CONCLUSION

To the best of our knowledge this is the first study evaluating the performance of DFI R600S by comparing that with Cobas U411 and microscopy analysis. Both systems have satisfactory agreement with microscopic exam. We only find inconsistencies for pH and specific gravity between analyzers. In conclusion the semi-automated test strip analyzer DFI R600S offers low cost, easy to use and reliable first level screening method for urinalysis but it is important to be aware of the limitations of the urine dipstick.

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