Opinion Paper

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Evaluation of H-800/FUS-100 automatic urine analyzer performance
H-800/FUS-100 otomatik İdrar analizörünün performans değerlendirilmesi

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Abstract

Objective: Automated urine analysis is usually preferred for laboratories with intensive workload. The aim of this study was to evaluate the performance of the automated urine analyser H-800/FUS-100 and detect the error sources.

Materials and methods: One thousand four hundred fifty nine fresh urine samples were analyzed with H-800/FUS-100 automated systems. The urine sediment of the samples with discrepant strip and microscopy results were confirmed by manual microscopy. Precision and carry over studies were performed.

Results: The discrepancy is detected in a ratio of 5.89% between chemical analysis (H-800) and microscopic analysis (FUS-100) of the device. A total of 86 discrepant samples were detected. Fifty six of 86 were erythrocyte discrepancies (65.1%) and 30 of 86 were leukocyte discrepancies (34.9%). The results of carry over analysis for erythrocyte and leukocyte were 21.85% and 13.64%, respectively.

Conclusions: Sixteen (1.09%) of 1459 patients’ results in FUS-100 were discrepant with manual microscopy. Commonly, yeasts and crystals affected erythrocyte counts and calcium oxalate and amorphous crystals affected the leukocyte counts. Images should be reviewed for every sample when automated systems are used for urine analysis. Especially if discrepancy is detected between chemical and microscopic analysis, the results should also be confirmed with manual microscopy.

Keywords: Urine microscopy; Interference; FUS-100; H-800; Erythrocytes; Leukocytes.

Özet

Amaç: Otomatik idrar analizi genellikle yoğun iş yükü olan laboratuvarlarda tercih edilmektedir. Çalışmamızda, H-800/FUS-100 otomatik idrar cihazının performansının değerlendirilmesi ve hata kaynaklarının saptanması amaçlanmıştır.

Gereç ve yöntem: 1459 taze idrar örnekleri H-800/FUS-100 otomatize sisteminde çalışılmıştır. Uyumuz strip ve mikroskobik sonuçları olan idrar sediment örnekleri manuel mikroskobi ile teyit edilmiştir. Presizyon ve carry-over çalışmalardan sonra uyumsuzluk saptanmıştır.

Bulgular: Cihazın kimyasal analizi (H-800) ile mikroskobik analizi (FUS-100) arasında %5,89 oranında bir uyumsuzluk saptanmıştır. Saptanan 86 olgunun %56’sında eritrosit (%65,1), %34,9'u lökosit %13,64 olarak bulunanlar bulunmuştur.

Sonuç: 1459 hasta sonucundan 16 tanesinde (%1,09) manuel mikroskopi ile uyumsuzluk saptanmıştır. Eritrositler için kristaller ve mayaların, lökositler için kalsiyum oksalat ve amorf kristallerinin sayısını etkilediği gözlenmiştir. İdrar analizinde otomatize sistemler kullanıldığında her örnek için görüntüler gözden geçirilmelidir. Özellikle kimyasal ve mikroskopik analiz arasında uyumsuzluk saptandığında, sonuçlar manuel mikroskopi ile tayt edilmelidir.

Anahtar Kelimeler: İdrar mikroskopisi; Interferans; FUS-100; H-800; Eritrosit; Lökosit.
**Introduction**

Urinalysis is one of the most common tests used in medical laboratory and provides information about urinary and renal system in patients [1, 2]. Although the conventional urine sediment microscopy has been standardised by the recommendations of National Committee for Clinical Laboratory (NCCLS) and the European Urinalysis Guidelines, it is labor-intensive, time consuming, uncertain and also has wide interobserver variation [3, 4]. Attention has been given to decrease the variations in manual microscopy and the automated urine analysers have been developed to save time and labor. Automated urine analysis is usually preferred for laboratories with intensive workload [5, 6].

Two systems using different Technologies have been defined to automate manual urine microscopy. One of them uses flow cytometry technique [7]. The other system uses a video camera to capture the images of the urine particles according to their dimensions [8]. Both of the systems have increased precision and labor productivity [9, 10]. The FUS-100 (Dirui, Changchun, China) is a new, digital image-based automatic particle recognition system and uses a video camera to capture the digital images of the samples from planar flow cell technique. The H-800 (Dirui, Changchun, China) is an automated urine dipstick analyser that uses automated reflectance photometry technique. The FUS-100 and the H-800 are integrated and compose the full automatic microscopic and chemical urine analysis system. If there is discrepancy between chemical and microscopic analysis results, the results must be reviewed on the view station and must be confirmed by manual microscopy.

We aimed to evaluate the performance of the automated urine microscopy analyser FUS-100 (Dirui, Changchun, China) and the automated urine dipstick analyser H-800 (Dirui, Changchun, China) and detect the error sources.

A total of 1459 fresh urine samples were analyzed with H-800/FUS-100 automated systems and the urine sediment of the samples with discrepant strip and microscopy results were confirmed by two skilled technicians in manual microscopy who were blinded to the test results for 1-week period at June 2013. All samples were completely processed within 2 h after receiving. Precision tests: low, medium and high urine pools were prepared and analyzed 20 times consecutively during 1 day for within-run imprecision. For between-run imprecision, positive and negative quality control samples of the manufacturer’s recommendation were analyzed for 10 days. The precision was assessed by the percentage coefficient of variation (CV%). Carry over: Carry over or the contamination across samples was detected by analyzing two highly concentrated samples with RBC and WBC for 3 times (H1, H2, H3), followed by the normal urine for three consecutive times on the FUS 100 analyzer (D1, D2, D3). The carry over was calculated using the formula of \((D1–D3)/(H3–D3)\times100\). D1 is the first and D3 is the third measurement of the normal urine. H3 is the third measurement of the highly concentrated urine.

**Discussion**

In our study the FUS-100 automated urinalysis system demonstrated acceptable precision. Within-run imprecision of the FUS-100 for RBC were 38.4%, 31.37%, 6.07% and 42.64%, 19.48%, 4.6% for WBC for low, medium and high pool, respectively. Between-run CVs of RBC, WBC for positive were 8.6% and 27.76%, respectively (Table 1).

| Cell type | Mean cell (cells/HPF) ± SD | CV (%) |
|-----------|---------------------------|--------|
| RBC       | 1.58 ± 0.60a              | 38.4   |
|           | 5.8 ± 1.82b               | 31.37  |
|           | 60.95 ± 3.70c             | 6.07   |
| WBC       | 0.94 ± 0.40a              | 42.64  |
|           | 3.85 ± 1.13b              | 19.48  |
|           | 99.35 ± 4.59c             | 4.6    |

CV, coefficient of variation; RBC, red blood cell; WBC, white blood cell; HPF, high power field; a low urine pool, b medium urine pool, c high urine pool.

**Figure 1:** False positive erythrocyte results.
Table 2: The comparison of discrepant erythrocyte results of the device with manual microscopy.

|                                         | n  | %     |
|-----------------------------------------|----|-------|
| Total                                   | 56 |       |
| 1. Chemical (negative) Microscopy (positive) | 12 | 21.4  |
| The device microscopy is concordant with manual microscopy (false negative chemical analysis) | 3  | 25    |
| The device microscopy is discrepant with manual microscopy (false positive device microscopy) | 9  | 75    |
| 2. Chemical (positive) Microscopy (negative) | 44 | 78.6  |
| The device microscopy is concordant with manual microscopy (false positive chemical analysis) | 41 | 93.2  |
| The device microscopy is discrepant with manual microscopy (false negative device microscopy) | 3  | 6.8   |

Figure 2: False positive leukocyte results.

Erythrocytes: In our study, 56 erythrocyte discrepancy was determined in 86 discrepant samples. Among the erythrocyte discrepant samples, 12 of 56 had no blood in chemical analysis but in microscopic analysis they had positive results. When compared with manual microscopy, it was shown that 9 of 12 had false positive results were reported by the FUS 100. Based on these findings it was determined that the FUS 100 reported false positive results in the presence of yeasts and crystals (Figure 1). In 3 of 12 the FUS 100 microscopy had concordant results with manual microscopy but the chemical blood measurements were false negative. Forty four of 56 erythrocyte discrepant samples had chemically positive blood results while the FUS 100 microscopy was negative in terms of erythrocytes. Forty one of 44 samples had concordant results with manual microscopy and the FUS 100 microscopy. The FUS 100 reported false negative results for 3 of 44 samples. In dipstick urinanalysis the H800 had false positive blood results (Table 2).

Leukocytes: In current study, 30 leukocyte discrepancy was determined in 86 discrepant samples. Among the leukocyte discrepant samples, 17 of 30 had no leukocyte in chemical analysis but in microscopic analysis they had positive results. Sixteen of 17 had concordant results with manual microscopy. For 1 of 17, the device microscopy reported false positive result. Calcium oxalate crystals caused the false positive result for this sample (Figure 2). Thirteen of 30 samples had positive leukocyte results in chemical analysis by the H 800 but negative microscopy results by the FUS 100. When compared with manual microscopy the H 800 reported 10 false positive results. The FUS 100 reported false negative results for 3 of 13 samples (Table 3).

There is not a performed carry over study for FUS-100 analyzer to our knowledge. The high carry over we detected for WBC and RBC is an important finding and can cause false positive results for both RBC and WBC counts in the negative urines studied after a positive urine. The carry over detected for FUS-100 seems to be a problem

Table 3: The comparison of discrepant leukocyte results of the device with manual microscopy.

|                                         | n  | %     |
|-----------------------------------------|----|-------|
| Total                                   | 30 |       |
| 1. Chemical (negative) Microscopy (positive) | 17 | 56.7  |
| The device microscopy is concordant with manual microscopy (false negative chemical analysis) | 16 | 94.1  |
| The device microscopy is discrepant with manual microscopy (false positive device microscopy) | 1  | 5.9   |
| 2. Chemical (positive) Microscopy (negative) | 13 | 43.3  |
| The device microscopy is concordant with manual microscopy (false positive chemical analysis) | 10 | 76.9  |
| The device microscopy is discrepant with manual microscopy (false negative device microscopy) | 3  | 23.1  |
related with the insufficient cleaning of the flow cell for very high cell counts (Table 4).

In conclusion, an average discrepancy of 5.89% was detected between H800 and FUS 100 devices. Sixteen (1.09%) of 1459 patients’ results were discrepant with manual microscopy. Commonly, yeasts and crystals affected erythrocytes counts and calcium oxalate and amorphous crystals affected the leukocytes counts. Yeasts, crystals, calcium oxalate and amorphous crystals caused false positive results.

Images should be reviewed for every sample when automated systems are used for urine analysis. Especially if discrepancy is detected between chemical and microscopic analysis, the results should also be confirmed by manual microscopy. The samples should be carefully monitored especially if studied following the urines with high RBC and WBC counts.

Table 4: Carry over analysis of the FUS-100 analyzer.

|        | H1 | H2 | H3 | D1 | D2 | D3 | Carry over % |
|--------|----|----|----|----|----|----|--------------|
| RBC (cells/HPF) | 200 | 183 | 184 | 41 | 2  | 1  | 21.85        |
| WBC (cells/HPF)  | 617 | 614 | 741 | 108| 8  | 8  | 13.64        |

Carry over % = \((D1−D3)/(H3−D3)\) × 100. RBC, red blood cell; WBC, white blood cell; HPF, high power field; H1, first measurement of the sample with high RBC/WBC levels; H2, second measurement of the sample with high RBC/WBC levels; H3, third measurement of the sample with high RBC/WBC levels; D1, first measurement of the sample with low RBC/WBC levels; D2, second measurement of the sample with low RBC/WBC levels; D3, third measurement of the sample with low RBC/WBC levels.

Conflict of interest statement: None declared.

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