The European Research Journal 2022;(3):389-395 Original Article

DOI: 10.18621/eurj.855509 *Urology and Clinical Biochemistry*

# Accuracy of Dongjui analyzer for reducing the number of unnecessary urine cultures in an outpatient setting

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## ABSTRACT

**Objectives:** The purpose of this study was to evaluate the diagnostic performance of the Dongjui DJ-8602 urinary analyzer for reducing the number of unnecessary urine cultures in patients with suspected urinary tract infection (UTI).

**Methods:** This study was designed as a retrospective study performed in patients with suspected UTI from August 1, 2018 to December 1, 2018. Clinical data, C reactive protein, blood hematologic counts were evaluated. Using positive culture results as the gold standard, the cut-off values by the receiver operating characteristic curve technique, sensitivity, and specificity were calculated.

**Results:** The median values of urine leukocyte levels were 31 cells/high power field (HPF) in the culture-positive group and 5 leukocytes/HPF in the culture-negative group, respectively. The area under the curve for leukocyte and bacteria count were 0.753 (95% Cl, 0.642 to 0.862) and 0.581 (95% Cl, 0.438 to 0.725), respectively. A leukocyte count ≥ 2 cells/HPF, resulting the best sensitivity of 96.3% (95% Cl: 81.03% to 99.48%) and a negative predictive value (NPV) of 96.4% (95% Cl: 79.35% to 99.48%).

**Conclusions:** The use of the Dongjui DJ-8602 urinary sediment and chemistry analyzer did not accurately predict the outcome of urine cultures with an unsatisfactory sensitivity and NPVs of bacteria counts.

**Keywords:** Urinalysis, urinary tract infection, urine culture, instrumentation, bacteriuria

Urinary tract infection (UTI) is defined as the presence of microbial pathogens that involve any part of the urinary tract without known functional or anatomical abnormalities of the urinary tract. UTIs are among the most common infections reported in outpatient services [1].

The gold standard for the diagnosis of UTI is midstream urine culture, but it is a laborious and expensive process. Rejection of negative samples with the urinalysis test results has drawn attention to provide reduction in the number of unnecessary cultures [2]. However, there is a variable performance reported in the literature; in some of the studies the absence of cells or bacteria was found to be a useful screen to prevent urine culture, while there are still some concerns in other studies [2-6].

Many manufacturers have developed fully automated, integrated urine analyzers [7]. Automated urinalyzers as a screening system to rule out UTI are evaluated by their diagnostic sensitivity, specificity, accuracy, and area under receiver-operating-characteristic (ROC) curve [8]. Some authors suggest that certain analyzers are controversial to screen urine for UTI [2, 5]. Due to differences in their performance, each

*Received:* ***January 8, 2021;*** *Accepted:* ***January 31, 2022;*** *Published Online:* ***February 2, 2022***

***How to cite this article:*** *Öztürk M, Üstündağ Y, Satır A, Huysal K. Accuracy of Dongjui analyzer for reducing the number of unnecessary urine cultures in an outpatient setting. Eur Res J 2022;(3):389-395. DOI: 10.18621/eurj.855509*

e-ISSN: 2149-3189

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one needs to be evaluated separately. It is important to know how confident is each prediction outcome, otherwise false positive or false negative results can create diagnostic uncertainty. Manufacturer claims need to be verified independently, with the introduction of a new automated analyzer in a laboratory [2, 9].

Recently, the Dongjui DJ-8602 urinary sediment and chemistry analyzer (Xuzhou Dongjiu Electronic Technology Co., Ltd, China) a fully automatic system that includes one DJ-860 automatic urine sediment analyzer and one DJ-900 automatic urine chemistry analyzer was introduced.

The purpose of this study was to evaluate the diagnostic performance of the Dongjui DJ-8602 urinary analyzer as a means of reducing the number of urine samples requiring culture in patients with suspected UTI.

## METHODS

This study was designed as a retrospective study performed in routine care adult patients with suspected UTI admitted to the urology outpatient clinic from August 1, 2018 to December 1, 2018. Data were retrospectively reviewed for the diagnostic performance of Dongui urinalysis system results for excluding culture negative patients. The protocol of the study was conducted in accordance with the Second Declaration of Helsinki.

Only patients with both clinical information and laboratory tests at admission were available were involved. The time for completing the laboratory data in relation to the receipt time was 2 hours after receipt. Exclusion criteria were: catheter urines, urines obtained via invasive procedures, pregnant women, children. Patients were excluded if they had been hospitalized, had been prescribed antimicrobial agents, had been seen by physicians within one month before entering the study. All of these attempts were performed to reduce the number of false-negative culture test results.

Variables recorded to patient files were taken: cloudy urine, foul-smelling urine on examination, any nocturia, dysuria, urgency, urine frequency, flue like symptoms, fever, mid-back pain, lower abdominal cramping, tiredness or fatigue, burning sensation in the bladder, symptom duration/day.

The following markers measured as part of routine care recorded were taken from the laboratory information system (LIS) data: C-reactive protein (CRP) (normal range < 3.0 mg/dl), blood hematologic counts on the Coulter LH 750 cell analyzer (Beckman Coulter, Inc., Miami, USA). The neutrophile-lymphocyte count ratio (NLR) was calculated by dividing the absolute neutrophil count by the absolute lymphocyte count. The platelet to lymphocyte count ratio was calculated by dividing the absolute platelet count to lymphocyte count (PLR).

Urine culture results recorded to LIS data from urine samples sent to the laboratory were evaluated. A sample was considered culture-positive if it contained a pure culture of ≥ 105 of colony forming units /mL [10]. Pathogenic microorganisms were identified using the Vitek 2 automated system (BioMerieux, St. Louis, Missouri, USA).

Urinalysis test results by the DJ-8602 urinary sediment and chemistry analyzer (Xuzhou Dongjiu Electronic Technology Co., Ltd, China) recorded to LIS were evaluated. DJ-8602 urinary sediment and chemistry analyzer is a fully automatic system which includes one DJ-860 automatic urine sediment analyzer and one DJ-900 automatic urine chemistry analyzer. The automatic urine sediment analyzer system uses planar flow technology and morphological identification technology applying the support vector machine image processing method.

Microscopic internal quality control results studied with an Urit QC22 Control (level 2; lot 6318600402 and negative control lot, 20170301) during the study period. Urit Strip internal quality control results studied with an IQ-11 (lot 55180007). Our laboratory was participated in the urinalysis external quality control program (KBUDEK, İstanbul, Turkey).

### Statistical Analysis

Statistical analyses were performed using SPSS 21.0 for Windows (SPSS Inc., Chicago, IL, USA), with culture results defined as the 'gold standard.' Samples were divided into two groups: culture negative and culture positive. Parameters with a normal distribution were evaluated using the Kolmogorov-Smirnov test. Comparison of quantitative data and intergroup comparisons of parameters were performed using Student's t-test or the Mann-Whitney U test. The chi-square test was used for the comparison of quali-

**Table1. Clinical and laboratory characteristics of patients**

| | UTI n (%) | No UTI n (%) | *p* value |
|---|---|---|---|
| **Age (years) (mean ± SD)** | 48 ± 15 | 40 ± 12 | 0.090 |
| **Gender** | | | |
| Male | 21% | 9% | |
| Female | 79% | 91% | |
| **BMI (kg/m$^2$) (mean ± SD)** | 24.8 ± 3.3 | 25.4 ± 4.8 | 0.594 |
| **Diabetes mellitus** | 20% | 4.5% | **< 0.001** |
| **Clinical predictors of diagnosis** | | | |
| Foul smelling urine | 59.2% | 45.7% | 0.216 |
| Cloudy urine | 44.4% | 45.7% | 0.905 |
| Dysuria | 95.6% | 96.8% | 0.326 |
| Nocturia | 42.9% | 44.6% | 0.225 |
| Urgency | 81% | 47% | **0.006** |
| Urinary frequency | 93% | 98% | 0.101 |
| Flue like symptoms | 14.8% | 18.0% | 0.692 |
| Fever | 7.4% | 7.4% | 0.995 |
| Mid-back pain | 40.7% | 42.5% | 0.867 |
| Burning sensation | 77.7% | 78.7% | 0.916 |
| Lower abdominal cramping | 22.2% | 35.1% | 0.207 |
| Tiredness or fatique | 37.0% | 29.7% | 0.303 |
| Suprapubic warm sensation | 59.2% | 61.% | 0.196 |
| **Symptom duration/day (median [IQR])** | 4 (4) | 4(4) | 0.778 |
| **Laboratory data** | | | |
| CRP (mg/dl) | 4.7 (26) | 3.0 (1.6) | **0.030** |
| **Haemogram test** | | | |
| WBC (×10$^9$/L) | 8.4 (4.1) | 7.1 (3.1) | **0.020** |
| Neutrophil (×10$^9$/L) | 5.4 (3.6) | 4.2 (1.7) | 0.090 |
| Lymphocyte (×10$^9$/L) | 2.2 (0.7) | 2.3 (0.8) | 0.228 |
| NLR | 2.3 (1.8) | 1.7 (0.9) | 0.023 |
| Platelet | 266 (66) | 276 (77) | 0.953 |
| PLR | 132 (69) | 121 (43) | 0.144 |
| MPV (fL) | 8.1 (1.0) | 8.6 (1.4) | 0.067 |
| RDW (%) | 139 (2.8) | 136 (1.7) | 0.330 |
| **Urine** | | | |
| **Dipstick** | | | |
| LE ≥ 1+ | 81.4% | 45.7% | **0.004** |
| $NO_2$ | 33.3% | 4.2% | **< 0.001** |
| **Microscopy** | | | |
| Leukocyte (count/HPF) | 31 (130) | 5 (14) | **< 0.001** |
| Erythrocyte | 8 (36) | 4 (12) | **0.019** |
| Bacteria(count/HPF) | 0 (43) | 0 (6) | 0.198 |

BMI = body mass index, CRP = C-reactive protein, WBC = white blood cell, NLR = neutrophil to lymphocyte ratio, PLR = platelet to lymphocyte ratio, MPV = mean platelet volume, RDW = red cell distribution width, HPF = high power field, IQR = interquartile range; SD = standard deviation. Chi-square test for Association

tative data. ROC curves were created to identify the cut-off points for variables.

Using positive culture results as the gold standard, sensitivity, specificity, positive predictive value (PPV; the post-test probability of an outcome for positive tests), negative predictive value (NPV; the post-test probability of an outcome for negative tests ), accuracy (the proportion of true results in the population), positive likelihood ratio (LR+) (the probability of a person who has the disease testing positive divided by the probability of a person who does not have the disease testing positive), negative likelihood ratio (LR–) (the probability of a person who has the disease testing negative divided by the probability of a person who does not have the disease testing negative), diagnostic odds ratio LR+/LR- and accuracy (true positives + true negatives)/ all cases were calculated.

## RESULTS

In total, 121 patients were found to be eligible for study enrollment. Table 1 shows characteristics of patients on admission. The study group ranged in age from 18 to 74 years. Significant bacterial growth was detected in 27 (20.18%) specimens. Escherichia coli grew in 23 (95%) of the positive cultures. The CRP ($p$ = 0.030), WBC ($p$ = 0.020) and NLR ($p$ = 0.023) levels were higher in patients with UTI.

The median values of urine leukocyte levels were 31 cells/HPF and 8 cells/high power field (HPF) for erytrocytes with the DJ-8602 urinary sediment and chemistry analyzer in the culture-positive group and 5 leukocytes/HPF and 4 erytrocytes/HPF in the culture-negative group, respectively (see Table1).

ROC curves for leukocyte and bacterial counts of the urine sediment analyses are presented in Fig. 1. The AUC for leukocyte counts was 0.753 (95% Cl, 0.642 to 0.862), compared with 0.581 (95% Cl, 0.438 to 0.725) for bacteria; showing acceptable discrimination power for UTI only for urine leukocyte count with a Dongjui DJ-8602 urinary sediment and chemistry analyzer (Table 2) [8].

When cut-off points for microscopy results were analysed, a leukocyte count ≥ 2 cells/HPF, resulting in a sensitivity of 96.3% (95% Cl: 81.03 to 99.48) and a NPV of 96.4 (95% Cl: 79.35 to 99.48) (Table 3). An optimum cut-off a leukocyte count ≥ 7 cells/HPF yielded a sensitivity of 70.3% (95% CI: 49.82%-86.25%) and a specificity of 58.51% (95% CI: 47.88%-68.59%). Bacterial counts were not different between UTI and nonUTI groups ($p$ = 0.198) (Fig. 2).

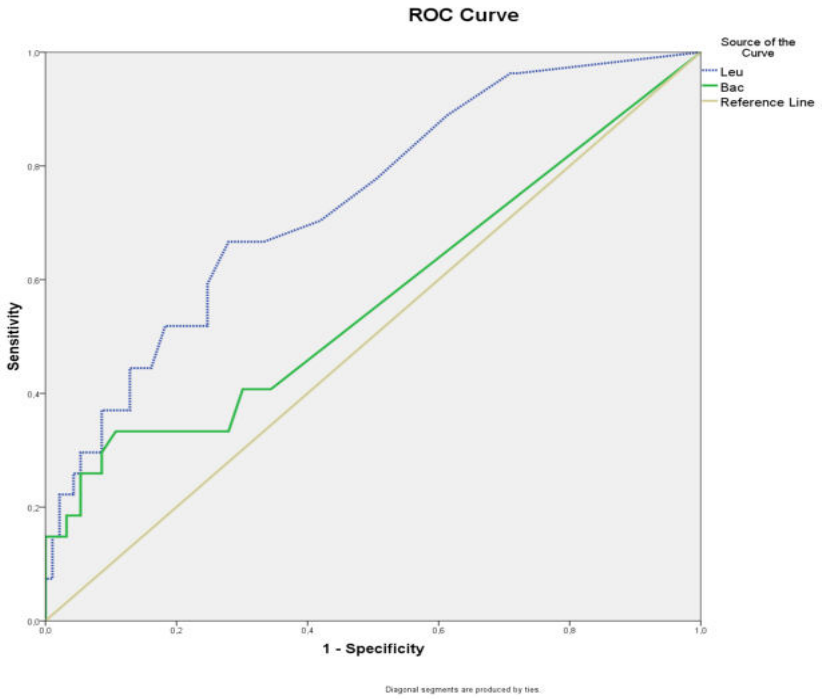


**Fig. 1. Receiver operating characteristics (ROC) curve for the whole group to determine the negative culture with urinalysis test results. The optimum cut-off point for WBC was 4 cells/HPF.**

**Table 2. Diagnostic performances of urinalysis test results for distinguishing culture positive patients from urinalysis**

| Variables | AUC | SE | Significance | 95% CI |
|---|---|---|---|---|
| Leukocyte | 0.753 | 0.057 | **< 0.001*** | 0.642-0.864 |
| Erythrocyte | 0.647 | 0.059 | **0.020** | 0531-0.763 |
| Bacteria | 0.581 | 0.073 | 0.221 | 0.438-0.725 |
| Cylendir | 0.542 | 0.069 | 0.532 | 0.406 -0.677 |
| Crystal | 0.518 | 0. 068 | 0.789 | 0.385 -0.650 |

AUC = area under curve, SE = standard error, CI = confidence interval. *Null hypothesis = true area = 0.5

**Table 3. The discriminative and predicting power of the each individual urinalysis variable**

| Parameter | SE (%) (95% CI) | SP (%) (95% CI) | PPV (%)* (95% CI) | NPV (%)* (95% CI) | LR+ (95% CI) | LR- (95% CI) | Accuracy (%)* (95% CI) |
|---|---|---|---|---|---|---|---|
| **Dipstick** | | | | | | | |
| LE ≥ 1+ | 81.48 (61.92-93.70) | 54.26 (43.66-64.58) | 33.85 (27.80-40.47) | 91.07 (81.90-95.83) | 1.78 (1.34-2.37) | 0.34 (0.15-0.77) | 60.33 (51.04-69.11) |
| NO2 ≥ 1+ | 66.67 (46.04-83.48) | 95.74 (89.46-98.83) | 81.82 (62.45-92.41) | 90.91 (85.41-94.47) | 15.67 (5.79-42.39) | 0.35 (0.20-0.59) | 89.26 (82.33-94.15) |
| **Microscopy** | | | | | | | |
| WBC[1] (≥ 2) | 96.3 (81.03-99.91) | | 27.96 (25.07-31.04) | 96.43 (79.35-99.48) | 1.35 (1.17-1.57) | 0.13 (0.02-0.91) | 43.80 (34.80-53.11) |
| WBC[2] (≥ 7) | 70.37 (49.82-86.25) | 58.51 (47.88-68.59) | 32.76 (25.69-40.70) | 87.30 (78.95 to 92.65) | 1.70 (1.20-2.39) | 0.51 (0.28-0.93) | 61.16 (51.87-69.88) |
| Bacteria[1] (≥ 3) | 40.74 (22.39-61.20) | 70.21 (59.90-79.21) | 28.21 (18.47-40.53) | 80.49 (74.61-85.28) | 1.37 (0.79-2.37) | 0.84 (0.60-1.18) | 63.64 (54.40-72.19) |
| Bakteri[2] (≥ 18) | 33.33 (16.52-53.96) | 86.17 (77.51-92.43) | 40.91 (24.94-59.06) | 81.82 (77.30-85.60) | 2.41 (1.16-5.02) | 0.77 (0.59-1.02) | 74.38 (65.65-81.88) |

LE = leukocyte esterase, $NO_2$ = nitrite, SE = sensitivity, SP = specificity, NPV = negative predictive value, PPV = positive predictive value, LR+ = positive likelihood ratio, LR− = negative likelihood ratio, Accuracy = correctly classified %. *These values are dependent on disease prevalence. [1]Highest sensitivity, [2]Cut-off

## DISCUSSION

Like others before us, we found that negative urine cultures constitute a large percentage of the clinical laboratory workload in our hospital [2, 3, 5, 11]. Only the ROC analysis of the urinary leukocyte counts of the Dongjui DJ-8602 urine sediment analyzer shows an acceptable AUC value of 0.753. However, this value is not outstanding and when used alone may lead to diagnostic uncertainty [13].

In our study, the sensitivity, specificity, and AUC of leukocyte count were higher than those of bacteria count; similar to Kocer *et al*.'s [12] findings. A screening analyzer to reduce the number of negative urine culture samples is reliable only when a high sensitivity and high negative predictive values are obtained. And ideally, the sensitivity should be > 90-95% to rule out disease [14, 15]. The cut-off point should be low enough to exclude the minimum urine samples.

A detailed analysis showed that the WBC ≥ 2 cells / HPF gave only one false negative result, with a sensitivity of 96.3% and a NPV of 96.4%. This cut-off point will reduce the number of samples sent to the laboratory for culture. However, the harmful effects of false negative findings should be taken into account. On the other hand, predicting negative results may prevent the risk of unnecessary initiation of antibiotic treatment.

Our results were comparable to previous studies with automated microscopy methods such as digital imaging with laminar flow (İQ 200) and verified digital images (sediMAX, FUS-100, Cobas u 700, Atel-

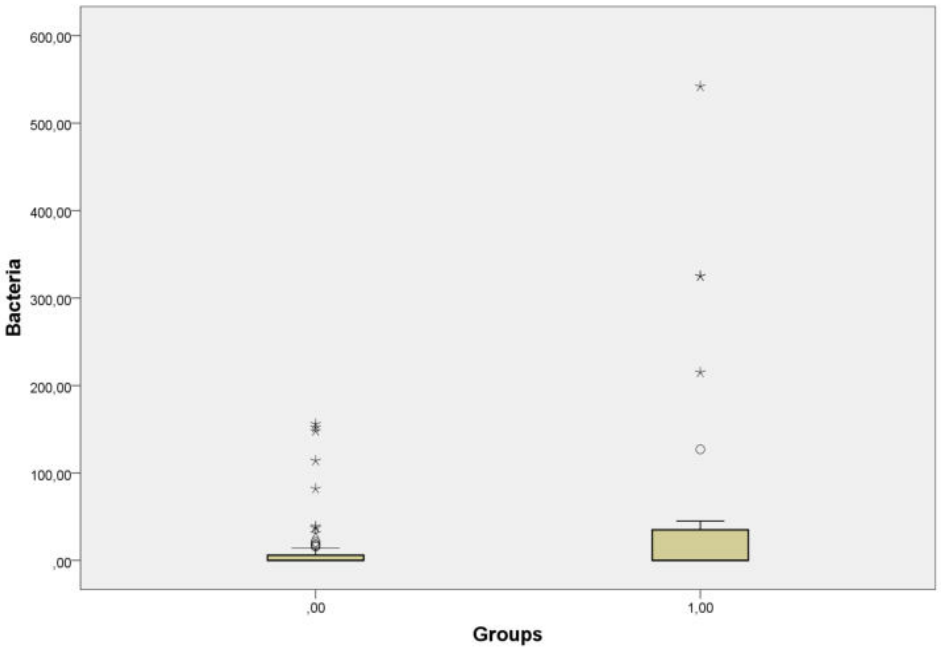


**Fig. 2. Comparison of quantitative bacterial counts between groups. Bacteria: count/HPF; Group 0: Patients without UTI, Group 1: Patients with UTI. Box represents the confidence interval (95%).**

lica 1500) that leukocyte parameter is better than those of bacteria count [16] . However differences based on the definition of negative urine, variation in cut off levels applied, patient populations and clinical situations makes it difficult to directly compare study results [16].

In our study, we found that the bacteriuria parameter of the Dongjui DJ-8602 urine sediment analyzer, which uses an image analysis method has poor discriminatory power for UTI. Our results are consistent with other studies that the bacteriuria parameter with automated microscopy cannot be used alone to reduce the number of negative urine culture samples [17-20].

The sensitivity of the urine dipstick test for nitrites was low (66.7%) with higher levels of specificity (95.74%) comparable to those of the other studies [2, 21, 22]. The sensitivity of LE was acceptable (81.48%.) [15]. Results produced by dipstick should not be overly relied upon for screening [23, 24].

## Limitations

The main limitations of this study include the use of retrospective data, inclusion of data from only one urology department. A single cut off value of 105 colony-forming unit (CFU)/ml was used for the culture. Also, the delay from initiation until publication is a weakness.

## CONCLUSION

In conclusion, we found that the use of the Dongjui DJ-8602 urinary sediment and chemistry analyzer did not accurately predict the outcome of urine cultures with low sensitivity and NPVs of bacteria counts.

*Authors' Contribution*

Study Conception: MÖ, YÜ, KH; Study Design: YÜ, KH; Supervision: MÖ, YÜ, AS, KH; Funding: MÖ, YÜ, AS, KH; Materials: MÖ, YÜ, AS, KH; Data Collection and/or Processing: MÖ, YÜ, AS, KH; Statistical Analysis and/or Data Interpretation: MÖ, YÜ, AS, KH; Literature Review: MÖ, YÜ, AS, KH; Manuscript Preparation: MÖ, YÜ, AS, KH and Critical Review: MÖ, YÜ, AS, KH.

*Conflict of interest*

The authors disclosed no conflict of interest during the preparation or publication of this manuscript.

*Financing*

The authors disclosed that they did not receive any grant during conduction or writing of this study.

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