Analytical Performance of Cobas 6500 for Predicting Urinary Tract Infection

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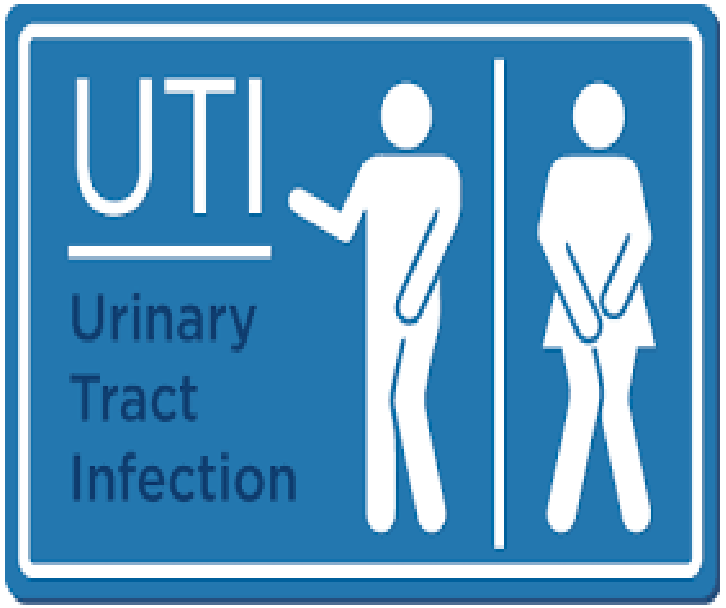
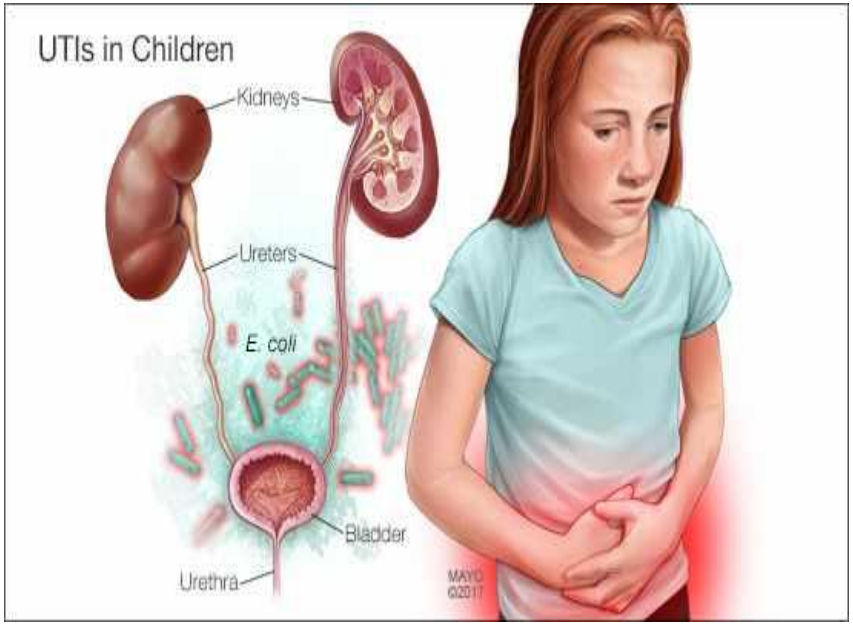
- Urinary tract infection (UTI) is the most common disease in the community, characterized by the presence of microbial pathogens in the urinary tract.



Broeren MA, Bahçeci S, Vader HL, Arents NL. Screening for urinary tract infection with the Sysmex UF-1000i urine flow cytometer. *J Clin Microbiol* 2011;49:1025–1029.
Hsiao C-Y, Yang H-Y, Chang C-H, Lin H-L, Wu C-Y et al. Risk factors for development of septic shock in patients with urinary tract infection. *Biomed Res Int* 2015;2015:1–7.

- It is more common in women particularly, and recurrent infection can cause serious complications especially in children, pregnant women and elderly patients.



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https://newsnetwork.mayoclinic.org/discussion/mayo-clinic-q-and-a-urinary-tract-infections-in-children/

Symptoms of Urinary Tract Infection

- A strong, persistent urge to urinate
- A burning sensation when urinating
- Passing frequent, small amounts of urine
- Cloudy appearance of urine
- Urine can be seen red, bright pink or cola-colored
- Strong-smelling urine
- Pelvic pain

https://www.mayoclinic.org/diseases-conditions/urinary-tract-infection/symptoms-causes/syc-20353447

Urine culture is used as a gold standard method in diagnosis of urinary tract infection, but it also is a major economic burden and also has a long turnaround time.

Mambatta AK, Jayarajan J, Rashme VL, Harini S, Menon S, Kuppusamy J.Reliability of dipstick assay in predictingurinary tract infection. J Family Med Prim Care 2015;4:265-8

Huysal K, U. Budak Y, Ulusoy Karaca A, Aydos M, Kahvecioğlu S, Bulut M, Polat M.
Diagnostic accuracy of UriSed automated urine microscopic sediment analyzer and dipstick parameters in predicting urine culture test results. Biochem Med (Zagreb) 2013 Jun; 23(2): 211–217.

- Urinary biochemical parameters can be evaluated using the urine dipstick screening test.
- This test is thought to be an inexpensive and rapid diagnostic alternative.

Rehmani R. Accuracy of urine dipstick to predict urinary tract infections in an emergency department. J Ayub Med Coll Abbottabad. 2004;16(1):4–7.
Lammers RL, Gibson S, Kovacs D, Sears W, Strachan G. Comparison of test characteristics of urine dipstick and urinalysis at various test cutoff points. Ann Emerg Med. 2001;38(5):505–512.

Aim

- In this study, we aimed to compare the dipstick and sediment analysis (leukocyte esterase and leukocyte) results of fully automated Cobas 6500 urine analyser with gold standard urine culture results.

Materials and Methods

- Retrospectively
- 571 patients with order for urine dipstick test, urine sediment analysis and urine culture

- Urine dipstick test and sediment analysis were performed in fully automated urine analyser.

- Cobas 6500 (Roche Diagnostics, Mannheim, Germany)
  - Cobas u 701 microscopy analyzer
  - Cobas u 601 urine analyzer (Fully automated urine strip system)

Urine culture

- A bacterial count of $\geq 10^5$ CFU/mL was considered as positive

- A calibrated 4 mL bacteriologic loop was used to inoculate urine onto 5% Columbia blood agar (RTA, Turkey) and Eosin Methylene Blue (EMB) agar plates (RTA, Turkey) within 30 min of collection. Inoculated plates were incubated aerobically at 37 °C for 24 to 48 h.

Statistical Analysis

Sensitivity, specificity, positive and negative predictive values and ROC curve analysis were performed for leukocyte esterase and leukocyte according to urine cultures.

Results

Dipstick test	**Culture (+)**	**Culture (-)**	Total
Leukocyte esterase (+)	256	85	341
Leukocyte esterase (-)	93	137	230
Total	349	222	

Sediment analysis	**Culture (+)**	**Culture (-)**	Total
Leukocyte (+)	247	77	324
Leukocyte (-)	102	145	247
Total	349	222	

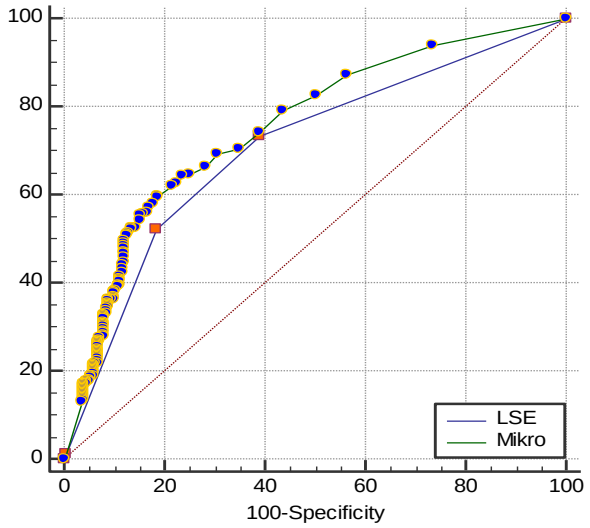
The sensitivity of dipstick **leukocyte esterase** was found to be 73.35%, whereas the specificity was 61.71%. Positive and negative predictive values were 75.07% and 59.56%, respectively.

	Leukocyte esterase	**Leukocyte**
Sensitivity (%)	73.35	70.77
Specificity (%)	61.71	65.31
PPV (%)	75.07	76.23
NPV (%)	59.56	58.7
AUC	0.707	0.753

Leukocytes showed 70.77% sensitivity with 65.31% specificity with positive and negative predictive values of 76.23% and 58.7%, respectively.

	Leukocyte esterase	Leukocyte
Sensitivity (%)	73.35	70.77
Specificity (%)	61.71	65.31
PPV (%)	75.07	76.23
NPV (%)	59.56	58.7
AUC	0.707	0.753

- The area under the curve (AUC) for leukocyte esterase was 0.707 and leukocyte was 0.753.



Conclusion

- Leukocyte esterase in urine dipstick test and microscopic leukocyte tests had comparable results in predicting UTI.

- Clinical decisions based on dipstick urine and sediment analysis could be both time and cost effective and may reduce the need for the conventional urine culture.

thank you
danke
謝謝
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