

# The Validity of the Uriscreen Test for Early Detection of Urinary Tract Infection in Children

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**ABSTRACT.** *Objective.* To determine the validity of the Uriscreen, a rapid diagnostic test based on the detection of urine catalase for the early detection of urinary tract infection (UTI) in children, compared with standard urinalysis and dipstick tests.

*Study Design.* Cross-sectional study.

*Study Population.* Children 1 month to 17 years of age who presented to the emergency department of a pediatric tertiary care center between March and November of 1996 with symptoms suggestive of UTI.

*Methods.* Urine specimens obtained from a random sample of 121 patients were evaluated simultaneously for possible UTI by Uriscreen (catalase test), urinalysis (microscopic pyuria), dipstick (leukocyte esterase and nitrite), and quantitative urine culture. All specimens were collected by one of three sterile techniques (midstream void technique, bladder catheterization, or suprapubic aspiration), as appropriate for age, and tested immediately. Using the quantitative urine culture as the gold standard (reference test), the sensitivity, specificity, and positive and negative predictive values of all the screening tests were determined and compared. Age, sex, temperature, presenting symptoms, and method of urine collection were recorded for each participant.

*Results.* Of the 121 patients, 35 (28.9%) had positive culture results: 30 girls (85.7%) and 5 boys (14.3%). Compared with urinalysis and dipstick tests, Uriscreen had the highest sensitivity (100% vs 88.6% and 97.1%, respectively) and the highest negative predictive value (100% vs 95% and 98.6%, respectively), but the poorest specificity (68.6% vs 88.4% and 82.5%, respectively) and positive predictive value (56.4% vs 75.6% and 69.4%, respectively).

*Conclusions.* The clinical use of Uriscreen for the presumptive diagnosis of UTI in children is limited and not significantly superior to urinalysis or the dipstick test. However, because of its 100% sensitivity and negative predictive value and its ease of use, rapidity, and low cost, it is recommended highly for ruling out the diagnosis of UTI. In laboratories, a negative Uriscreen result may prevent the need for performing expensive urine cultures. *Pediatrics* 1999;104(4). URL: <http://www.pediatrics.org/cgi/content/full/104/4/e41>; catalase, pyuria, urinary tract infection, urinalysis, dipstick, screening test, children, infants.

ABBREVIATIONS. UTI, urinary tract infection; CFU, colony-forming units; PPV, positive predictive value; NPV, negative predictive value.

Urinary tract infection (UTI) is a common illness of childhood affecting  $\leq 5\%$  of females and 1% to 2% of males<sup>1,2</sup> with a prevalence of 5.3% among febrile infants seen in an emergency department.<sup>3</sup> In this age group, prompt treatment is essential because even a brief delay can cause permanent complications.<sup>1,3,4</sup> However, prompt treatment depends on rapid diagnosis. The rapid screening techniques introduced to date, such as urinalysis and dipstick tests (Chemstrip urine test; Boehringer Mannheim, Indianapolis, IN), although attractive because of ease of performance and short time of detection of pyuria or bacteriuria, have been shown to be unsatisfactory.<sup>1,3,5,6</sup>

Uriscreen is a new, rapid (2 minutes), and simple bedside screening test for the presumptive diagnosis of UTI.<sup>7</sup> It is based on the detection of the enzyme catalase that is present in most of the bacteria that attack the urinary tract, leukocytes, erythrocytes, and the kidney cells, thereby enabling the detection of both bacteriuria and pyuria and potentially improving the reliability of the early diagnosis of UTI. Studies of adults have reported that Uriscreen had the highest sensitivity of all screening tests for UTI.<sup>8</sup> In children, however, in whom both symptomatology and methods of urine collection for culture differ from those of adults, Uriscreen has been evaluated so far as a screening test for bacteriuria in the absence of symptoms<sup>9</sup> but not for the presumptive diagnosis of UTI.

The purpose of the present study was to determine the validity of Uriscreen compared with standard urinalysis and dipstick tests for the early detection of UTI in children.

## METHODS

The study population consisted of a random sample of children 1 month to 17 years of age who presented to the Emergency Department of Schneider Children's Medical Center of Israel between March and November of 1996 with symptoms suggesting UTI. Inclusion criteria were: for infants, fever with no apparent source, vomiting, decreased appetite, and irritability; for toddlers, abdominal pain and voiding frequency with or without fever; and for older children, dysuria, frequency, urgency, and abdominal/flank pain with or without fever. Children receiving antibiotic therapy were excluded from the study. Age, sex, temperature, symptoms, and method of urine collection were recorded for each participant. The departmental routine for urine collection for culture is as follows: suprapubic aspiration for neonates; bladder

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catheterization for girls  $\leq 3$  years of age; and urine bags for boys until they are toilet-trained.

Using a sterile technique, a urine sample was obtained from every child by suprapubic aspiration, bladder catheterization, urinary bag collection, or clean catch as appropriate for age. Within 15 minutes of collection, specimens underwent four tests simultaneously: Uriscreen (catalase test); dipstick tests (nitrite and leukocyte esterase); urinalysis (microscopic pyuria); and quantitative urine culture. The quantitative urine culture was processed first and served as the gold standard (reference test) for the diagnosis of UTI. Uriscreen and dipstick results were examined by a single observer to avoid interobserver variability. Urine microscopy specimens and cultures were processed by routine procedures in the laboratories of Schneider Children's Medical Center of Israel.

## Laboratory Tests

### Uriscreen

A commercial kit (Diathec Diagnostica Ltd, Rehovot, Israel) was used for the Uriscreen according to the manufacturer's instructions. A 1.5 to 2 mL aliquot of urine was placed into a test tube containing the Uriscreen reagent powder. Four drops of 10% hydrogen peroxide were added to the test tube, and the mixture was shaken gently for 5 seconds. A positive finding was defined as the formation of foam sufficient to form a complete ring or layer on the surface of the liquid within 1 to 2 minutes of the addition of the hydrogen peroxide. This reaction is indicative of catalase activity and  $\geq 5 \times 10^4$  colony-forming units (CFU) per mL or 10 somatic cells (leukocytes, erythrocytes, or kidney cells) per high power field. The test result was considered negative in the absence of foam production or when the ring of foam was incomplete after 2 minutes.

### Dipstick

An aliquot of noncentrifuged urine was tested for the presence of nitrate-reducing bacteria or leukocyte esterase with the Multistix 10 SG (Bayer, Elkhart, IN) strip. The test result was considered positive if the dipstick turned pink or red for nitrites or purple (from trace to +2) for leukocytes within 2 minutes of contact with the urine.

### Urinalysis

All urine samples (noncentrifuged) were screened initially with an automated urine analyzer (Urotron RL9; Boehringer Mannheim). Specimens found to be positive underwent centrifugation, and the sediment was examined by standard microscopy. A positive result was defined as  $>10$  leukocytes per high power.

### Quantitative Urine Culture

Our hospital laboratory uses the commercial Diaslide method (Diathec Diagnostica Ltd) for urine culture, as described previously.<sup>10</sup> In brief, the device consists of a hinged case containing two opposing agar media separated by a sampler with a handle at one end and two bent sampler tips at the opposite end. First, the tips of the sampler are dipped into the urine. Then the sampler is pulled out through the casing, simultaneously inoculating both agar surfaces with a streaking dilution. Individual colonies can be observed even when bacterial concentrations exceed  $10^6$  CFU/mL. The number of colonies on the Diaslide have been shown to correlate linearly with the findings on dilution plating (in CFU/mL).

A positive result was defined as  $10^5$  CFU/mL for urine collected from a clean catch or urine bag,  $10^3$  CFU/mL for urine collected by bladder catheterization, and  $10^2$  CFU/mL for urine collected by suprapubic aspiration.

## Statistical Analysis

The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) for the three screening methods were calculated against the urine culture (reference group) for the diagnosis of UTI. Overall accuracy also was calculated and compared.

Validity is determined by four factors: degree to which the test result confirms the presence of a disease (sensitivity); proportion of individuals with a negative test result who really do not have the disease (NPV); confidence with which the test result rules out

a specific disease (specificity); and proportion of individuals with a positive result who really have the disease (PPV). A high specificity lowers the laboratory load of cultures, because it indicates a high detection rate of true negative samples, whereas the PPV determines the test's cost-effectiveness because every positive test result dictates that the sample be sent for additional expensive culture.

## RESULTS

A total of 121 children were included in the study: 82 girls (67.8%) and 39 boys (32.2%). Of these children, 35 had a positive urine culture result: 30 girls (85.7%) and 5 boys (14.3%). These children were mostly from the older age group (Table 1). Of the 35 positive samples, 22 (3 boys and 19 girls) were obtained by clean catch, 8 by bladder catheterization (2 boys and 6 girls), 3 by urinary bag collection (3 girls), and 2 by suprapubic aspiration (2 girls). Of the cultures, 27 were positive for *Escherichia coli*, 2 for *Klebsiella*, 2 for *Enterococcus*, 2 for *Pseudomonas*, 1 for group B streptococcus, and 1 for *Staphylococcus* coagulase negative.

Table 2 compares the findings for the urine culture and for the three screening tests for the diagnosis of UTI. Values for the Uriscreen were: 100% sensitivity, 68.6% specificity, 56.4% PPV, and 100% NPV. As demonstrated in Table 3, the sensitivity and the NPV of Uriscreen were 100%, which is superior to the corresponding values found for both urinalysis (88.6% and 95%) and dipstick (97.1% and 98.6%). However, it was poorest in specificity, in PPV, and in overall accuracy.

## DISCUSSION

A clinically useful screening test for UTI should be simple, rapid, inexpensive, and, most important, accurate. The 2-minute bedside Uriscreen easily fulfills the criteria of simplicity and rapidity, and its cost (71 cents per test) is reasonable compared with urine microscopy (\$13 per test including laboratory work) and dipstick (27 cents per test). This work focused on the validity and accuracy of the Uriscreen in children presenting to the emergency department with symptoms suggestive of UTI.

According to the present study, of the three screening tests, Uriscreen had the highest sensitivity and NPV (100%), but the poorest specificity, PPV, and overall accuracy (Table 3) for the detection of UTI. These data indicate that the Uriscreen does not miss positive culture results, but its high rate of false-positive results (31.4%) dictates that more urine samples be confirmed by laboratory study compared with the other two tests. Therefore, for the positive

**TABLE 1.** Demographic Characteristics of Children With Positive Cultures ( $n = 35$ )

Characteristic	Number of Patients (%)
Gender	
Male	5 (14.3)
Female	30 (85.7)
Age	
0–2 mo	2 (5.7)
3 mo–2 y	8 (22.9)
3–7 y	14 (40)
8–17 y	11 (31.4)

**TABLE 2.** Comparison of Urine Culture (Reference Test) and Screening Tests for Diagnosis of UTI (*n* = 121)

Urine Culture	Uriscreen		Dipstick		Microscopy	
	Positive	Negative	Positive	Negative	Positive	Negative
Positive	35 (100%)	0 (0%)	34 (97.1%)	1 (2.9%)	31 (88.6%)	4 (11.4%)
Negative	27 (31.4%)	59 (68.6%)	15 (17.4%)	71 (82.6%)	10 (11.6%)	76 (88.4%)

**TABLE 3.** Comparison of Sensitivity, Specificity, PPV, and NPV, and Accuracy of Uriscreen, Dipstick, and Urine Microscopy Analyses in the Early Diagnosis of UTI

Test	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
Uriscreen	100	68.6	56.4	100	77.7
Dipstick	97.1	82.5	69.4	98.6	86.8
Microscopy	88.6	88.4	75.6	95	88.4

diagnosis of UTI in children, Uriscreen is not superior to urinalysis or dipstick tests, and considering its higher cost compared with the dipstick test, it does not mandate a change in the current practice. On the other hand, owing to its 100% sensitivity and 100% NPV, a negative Uriscreen result reliably predicts a negative urine culture. The possibility to easily, rapidly, and reliably rule out the diagnosis of UTI is very important for the clinician. For example, when assessing children and young infants with fever in the ambulatory setting, a negative Uriscreen result would assure clinicians that they have not missed the diagnosis of UTI, thereby avoiding the need to refer the child for additional work-up. Similarly, in the laboratory setting, a negative Uriscreen result would eliminate the need to perform expensive urine cultures. Furthermore, although the dipstick test showed similar sensitivity and NPV (Table 3) to the Uriscreen, so that it could serve also to rule out UTI, nevertheless, these values were not as good as the 100% reliability provided by Uriscreen. Considering the better reliability of Uriscreen in combination with the overall cost of a patient visit, the small difference in cost between the two (44 cents) becomes negligible. Thus, for rapidly and reliably ruling out the diagnosis of UTI, both in the clinical and laboratory settings, Uriscreen can be recommended highly. However, we emphasize that these findings are based on a relatively small sample and larger series are needed for verification.

We noted that of our 27 Uriscreen false-positive samples, 12 showed a significant number of erythrocytes with only a few leukocytes on urinalysis. This finding can be explained in some cases by the high body temperature of the children (erythrocyturia may be associated with high fever) or a viral etiology. In the remainder, the false-positive result may

have been attributable to an inappropriate reading of the ring formed on the Uriscreen test tube, that is, to the lower threshold of a single subjective observer to judge a test result to be positive. The latter is supported by the Uriscreen's 100% sensitivity but low (68.6%) specificity. False-positive results also can occur in the presence of multiple contaminating species of bacteria or when a significant number of kidney cells are present in the absence of bacteria (Uriscreen tests for both cells and bacteria). False-negative results can occur in cases of fewer than 10 somatic cells per high power field or, again, with improper application of the technique. In our study, similar to the results of the Mayo Clinic study, there were no false-negative results.<sup>7</sup>

As shown in Table 4, the sensitivity, specificity, PPV, and NPV of Uriscreen in our study were comparable with those of previous studies. Although variability among studies exists, in general, these data confirm our finding that the Uriscreen test is very sensitive for the early detection of UTI but not very specific.

Of the above mentioned studies, only the study by Palmer et al,<sup>9</sup> besides this paper, evaluated the use of Uriscreen in the pediatric population. Compared with their findings, we showed significantly better values for sensitivity and NPV and poorer values for specificity and PPV (Table 4). These differences can be explained, in part, by differences in patient selection and in study purpose and methodology. First, whereas Palmer et al<sup>9</sup> screened asymptomatic (suggesting lack of infection) children undergoing urodynamic evaluation (for various problems) for the presence of bacteriuria, we investigated symptomatic children for the presence of UTI. Second, many of their patients had dysfunctional voiding with residual urine in the bladder in whom bacterial colo-

**TABLE 4.** Sensitivities, Specificities, PPV, and NPV of Uriscreen for the Early Detection of UTI in Various Studies

Study	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Congdon and Federko <sup>11</sup>	91.5	43.2	32.8	94.4
Carrroll et al <sup>8</sup>	92	89	83	95
Berger et al <sup>12</sup>	83	71	70	71
Pezzlo et al <sup>7</sup>	89	71	47	96
Mayo Clinic in Pezzlo et al <sup>7</sup>	100	67	35	100
Dalton et al <sup>13</sup>	87	78		
Palmer et al <sup>9</sup>	65.2	85.7	57.7	89.2
Present study	100	68.6	56.4	100

nization at times in excess of 100 000 CFU/mL with or without pyuria is common. Furthermore, unlike in our study, children on suppressive or therapeutic antibiotic regimens were not excluded. These factors may account for the very low sensitivity in the earlier study. Regarding methodology, Palmer et al<sup>9</sup> performed bladder catheterizations (reliable method) for urine collection in all children, whereas we used various methods including midstream collections that are sometimes contaminated. This difference may account for the better specificity in their study.

Previous comparisons among Uriscreen, dipstick, and urinalysis for the diagnosis of UTI have yielded varying results. Berger et al<sup>12</sup> found, as we did, that Uriscreen was the most sensitive but the least specific test; Pezzlo et al<sup>7</sup> reported the same sensitivity (95%) and NPV (99%) for both Uriscreen and dipstick test (Chemstrip LN; BioDynamics, Indianapolis, IN), but poorer specificity for Uriscreen (58% vs 73%, respectively); and in contrast, Dalton et al<sup>13</sup> found a lower sensitivity and a comparable moderate specificity for Uriscreen compared with dipstick test. Interestingly, despite these differences, both Berger et al<sup>12</sup> and Pezzlo et al<sup>7</sup> advocated the use of Uriscreen based on their results, whereas Dalton et al<sup>13</sup> concluded that Uriscreen did not have advantages over the other tests evaluated.

Finally, our study is based on 35 positive cultures. Because larger groups yield better conclusions, our study needs confirmation in a larger sample size.

#### CONCLUSION

In summary, Uriscreen is a rapid, simple, and inexpensive screen for pyuria and bacteriuria. Although the Uriscreen test detects all positive results, its clinical use for the early detection of UTI in children is limited because of its relatively low specificity and high rate of false-positive results. In this

regard, Uriscreen is not superior to urinalysis or dipstick tests. However, owing to its 100% sensitivity and 100% NPV, Uriscreen can be recommended highly as a rapid tool to rule out the diagnosis of UTI in both the clinical and the laboratory setting.

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