# Clinical Evaluation of Three Rapid Methods for the Detection of Significant Bacteriuria

ELAINE BIXLER-FORELL, MIRIAM A. BERTRAM, AND DAVID A. BRUCKNER\*

Department of Pathology, Clinical Microbiology, University of California Los Angeles Medical Center, Los Angeles, California 90024

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Random urine specimens (848) were screened for significant bacteriuria by using the 30-min Lumac (3M, St. Paul, Minn.), the 2-min Bac-T-Screen (Marion Laboratories, Inc., Kansas City, Mo.), and the 13-h AutoMicrobic system (AMS) urine identification card (Vitek Systems, Inc., Hazelwood, Mo.). MacConkey and 5% sheep blood agar plates were inoculated with a  $10^{-4}$  dilution of urine and used for the reference method. Bac-T-Screen results were uninterpretable for 9.1% of the specimens owing to either uriné sample pigmentation  $(5.3\%)$  or clogging of the filter  $(3.8\%)$ . Screen-negative urine specimens made up 49.6, 57.2, and 48.5% of the total number of specimens evaluated with AMS, Lumac, and Bac-T-Screen, respectively. False-positive results with Lumac and Bac-T-Screen were 20.6 and 22.3%, respectively. False-negative results for cultures with  $\geq 10^4$  CFU/ml were 22.0% with AMS, 29.4% with Lumac, and 25.5% with Bac-T-Screen, and false-negative results for cultures with  $\geq 10^5$  CFU/ml were 29.6% with AMS, 9.9% with Lumac, and 7.0% with Bac-T-Screen. For each system,  $>70\%$  of false-negatives at  $\geq 10^5$  CFU/ml consisted of mixed or pure cultures of common contaminants. With any of these screening methods, a clinically significant isolate at  $\geq 10^5$  CFU/ml would rarely be missed  $(\leq1.7\%$  for all systems). A cost-effective and rapid approach to urine microbiology could consist of screening out negative specimens by either Lumac or Bac-T-Screen and processing only screen-positive specimens by the AMS.

To accurately evaluate a positive urine culture, true bacteriuria (the continued presence and growth of organisms within the urine of the urinary tract) must be distinguished from contamination (the entry of urethral bacteria into the urine during the collection procedure). The quantitation of an organism in a urine specimen is the criterion used in most laboratories to determine the potential clinical significance of that organism. What constitutes significant bacteriuria is controversial. Factors other than colony count, such as time and method of specimen collection, sample storage conditions, quantitation and types of organisms isolated, and the history, antimicrobial therapy status, and clinical presentation of the patient, must also be considered. Several studies have shown the strong correlation between the isolation of  $\geq 10^5$  CFU of a single organism per ml and urinary tract infection (UTI) in cases of asymptomatic bacteriuria or acute pyelonephritis (14, 15, 25). In addition, specimens from 45 to 70% of patients with UTI symptoms also contain  $\geq 10^5$  CFU of an organism per ml when cultured (5, 8, 21, 31). Therefore, although lower counts can be of clinical significance under some circumstances, for the majority of patients the presence or absence of  $\geq 10^5$  CFU of a probable pathogen per ml may be used as an appropriate indicator of infection.

Urine cultures represent a major portion of the clinical microbiology laboratory workload. Negative urine cultures  $(\leq 10^5 \text{ CFU/ml})$  constitute 70 to 80% of the urine specimens received (1, 16). A rapid and sensitive method for screening out negative urine specimens would benefit the laboratory and patient care by reducing costs and improving response time to clinicians.

Several urine screening methods have been described, including Gram stain (13, 19, 25), quantitative leukocyte counts (20, 21, 31), direct testing of urine sediment (10), electrical impedance (6), particle size distribution (1, 7), various biochemical methods (4, 13, 26-29), the Auto-Microbic system (AMS; Vitek Systems, Inc., Hazelwood, Mo.), and the Autobac and Abbott MS-2 automated systems (9, 16, 22, 23). Problems with these procedures include subjectivity in reading of Gram stains and insensitivity of the biochemical methods. The automated systems currently available are growth dependent, requiring several hours to detect significant bacteriuria.

In this study we examined recently developed, nongrowth-dependent systems which allow the screening out of negative urine specimens in less than <sup>1</sup> h. To assess their sensitivity and ease of operation in a clinical setting, we compared these newly developed, rapid urine screening systems, the Lumac (3M, St. Paul, Minn.) and the Bac-T-Screen (Bacteria Detection Device; Marion Laboratories, Inc., Kansas City, Mo.), with the 13-h growth-dependent AMS urine identification card, with conventional quantitative culture as the reference method.

## MATERIALS AND METHODS

Urine specimens. Nonselected clean-catch or catheterized urine specimens (848) submitted for culture from inpatient (55%) and outpatient clinic (45%) populations were tested. Urine samples from both adult and pediatric patients were evaluated, and no attempt was made to exclude patients receiving antimicrobial therapy. Urine specimens not processed immediately were refrigerated at 4 to 5°C for a period not longer than <sup>4</sup> h. A single, well-mixed urine sample was used for all three test systems and the reference method. Conventional culture and AMS tests were set up concurrently; concurrent Lumac and Bac-T-Screen testing followed immediately. Gross appearance and turbidity as determined by McFarland standards were recorded for each urine specimen.

Conventional culture. Semiquantitative cultures were performed for all specimens by using a 0.01-ml calibrated loop to make a 1:100 dilution of the urine sample in 1.0 ml of sterile distilled water. MacConkey and 5% sheep blood agar plates were inoculated with a 0.01-ml loopful of the above dilution. Delivery of calibrated loops was quality controlled by using the Evans blue dye procedure described by Barry et al. (2). Plates were incubated in air at 35°C and examined at 24 and 48 h. Colonies were enumerated by defining one colony as containing 104 CFU/ml. Ten or more colonies of the same type per plate were reported as  $\geq 10^5$  CFU/ml. Plates with no growth were reported as containing  $\leq 10^4$ CFU/ml. Isolates were identified by Gram stain and by one of the following methods: API 20E (Analytab Products, Plainview, N.Y.) for fermentative gram-negative bacilli, Uni-N/F Tek (Flow Laboratories, Inc., McLean, Va.) for nonfermentative gram-negative bacili, or standard biochemical procedures for the gram-positive species or any gramnegative isolate not identifiable by the above two commercial systems (18).

AMS. Urine specimens were inoculated into urine identification cards (no. 51-1101; Vitek) and processed on the AMS instrument as specified by the manufacturer. AMS results of  $\langle 10^5 \text{ or } 10^5 \text{ CFU} \rangle$  of any organism(s) per ml were considered a positive screen with the following exception: an AMS result of  $\langle 10^5 \text{ CFU/ml} \rangle$  was considered a false-negative screen when the conventional culture yielded  $\geq 10^5$  CFU/ml.

Bac-T-Screen. Reagents and equipment were supplied by Marion Laboratories, Inc. All urine specimens were screened by the protocol recommended by the manufacturer.

In the Bac-T-Screen procedure, organisms are concentrated on a chemically treated filter disk of controlled pore size and subsequently stained with Safranin O dye. Any intensity of pink or red color on the filter is considered a positive screen.

A filter disk card was inserted into the Bac-T-Screen instrument, and a sterile, calibrated transfer pipette was used to add 1.0 ml of well-mixed urine to the filter chamber. To increase the adherence of organisms to the filter and clarify the sample by lysing erythrocytes and dissolving any precipitates present, a diluent (14.5% glacial acetic acid plus proprietary ingredients) was added to the urine, after which 3 ml each of the urine diluent, 0.01% Safranin 0, and decolorizer (3% glacial acetic acid) were sequentially automatically added to the chamber and passed through the filter by suction. A second decolorization was performed manually. The color intensity of the wet filter (read visually) was compared with the color chart provided on each filter card and ranked as negative for no color,  $+/-$  for very slight pink color, or  $1+$  to  $4+$ . The filter disk was allowed to completely dry in the air, and the color intensity was reinterpreted. Positive (10<sup>4</sup> CFU of formolized bacterial suspension per ml) and negative (sterile distilled water) controls were tested with each batch of urine specimens.

Lumac. Testing was performed as specified by the manufacturer when the bacteriuria screening reagent kit and the Lumac Biocounter provided by 3M was used.

Lumac is based on the bioluminescence assay of microbial ATP (17, 32). Bacterial, yeast, and host somatic cells contain relatively constant concentrations of ATP per cell. According to the manufacturers of this system, somatic cells commonly found in urine (epithelial cells and erythrocytes or leukocytes) can be distinguished from bacterial cells on the basis of their increased sensitivity to lysis by a detergent.

In a cuvette, a  $25-\mu l$  sample of well-mixed urine was treated with 50  $\mu$ l of a 10:1 mixture of nucleotide-releasing reagent for somatic cells (NRS) and Somase (a calciumactivated ATPase enzyme) for <sup>25</sup> min at 35°C. NRS makes the membrane of somatic cells (microbial cells are unaffected) permeable to small molecules, thereby releasing ATP. Freed ATP is then destroyed by the Somase. After incubation, each sample was manually placed in the counting chamber of the Lumac instrument, into which  $100 \mu$ Ci each of two reagents was automatically injected. Injection of nucleotide-releasing reagent for bacterial cells (NRB) makes the cell wall and membrane of microbial cells permeable to small molecules. The released ATP was assayed by the injection of the second reagent, firefly luciferin-luciferase (Lumit PM). Luciferin and luciferase combine in the presence of  $Mg^{2+}$ ,  $O_2$ , and ATP to produce light. Photons emitted were measured for 10 <sup>s</sup> and displayed as relative light units. A reading of  $\geq 200$  relative light units was considered <sup>a</sup> positive screen. Positive (50 ng/ml of ATP standard), negative (ATP standard treated with Somase), and reagent blank controls were tested with each batch of urine specimens.

Statistical calculations. Statistical significance was determined by chi-square analysis; observed differences in data were considered significant and noted in the text if  $P \le 0.05$ was obtained. Sensitivity, specificity, and predictive value of a positive and negative result were calculated as follows: sensitivity,  $TP/(TP + FN)$ ; specificity,  $TN/(TN + FP)$ ; predictive value of a positive,  $TP/(TP + FP)$ ; and predictive value of a negative,  $TN/(TN + FN)$ ; TP represents true-positives, TN represents true-negatives, FP represents falsepositives, and FN represents false-negatives (3).

## RESULTS

Of the 848 urine specimens tested by conventional quantitative culture, 471 (55.5%) contained  $\langle 10^4 \text{ CFU/ml and} \rangle$ were considered negative. The remaining 377 (44.5%) were positive, with colony counts of  $\geq 10^4$  CFU/ml. The quantitation and identification of the organisms recovered from positive urine specimens are given in Table 1.

Bac-T-Screen results could not be obtained on 32 (3.8%) of the urine specimens owing to clogging of the filter by the

TABLE 1. Quantitation and identification of organisms recovered from urine specimens containing  $\geq 10^4$  CFU/ml by conventional quantitative culture

Organism	No. of specimens with:		
	$\geq 10^4$ but $\leq 10^5$ CFU/ml	$\geq 10^5$ CFU/ml	
Escherichia coli	8	66	
Klebsiella pneumoniae	3		
Pseudomonas aeruginosa	5	9	
<b>Proteus mirabilis</b>		6	
Enterobacter cloacae		$\overline{c}$	
Gardnerella vaginalis		3	
Group D enterococcus		$\overline{\mathbf{3}}$	
Group B streptococcus		0	
Coagulase-negative staphylococcus	25	3	
Viridans group streptococcus	9	3	
Lactobacillus spp.	15	12	
Corynebacterium spp.	16	10	
Yeast	6	15	
Other gram-negative bacteria	7	6	
Mixed cultures	30	98	

 $a$  A total of 848 urine specimens were evaluated (471 were negative and 377 were positive at  $\geq 10^4$  CFU/ml).

samples. Of these specimens, 25 (78.1%) were positive at  $\geq 10^5$  CFU/ml by conventional culture. A variety of organisms were recovered from the filter-clogging urine specimens. Examination of the urine specimens in terms of color and degree of turbidity as determined by McFarland standards could not be used to predict which specimens would clog the Bac-T-Screen filter. Highly colored or bloody urine specimens (45 [5.3%]) produced an uninterpretable Bac-T-Screen filter because sample pigmentation masked the true color of the Bac-T-Screen filter disk.

The color intensity interpretation of 89 Bac-T-Screen filters changed when wet and dry reading were compared. Of these, 43 resulted in a change in overall interpretation of the screen from positive to negative  $(+/-)$  to negative) and 5 resulted in a change from negative to positive (negative to  $+/-$ ). The remaining 41 involved changes in interpretation within the  $+/-$  to  $4+$  color intensity categories, but the overall screen interpretation remained positive. When wet and dry readings were compared, the total number of urine specimens negative by Bac-T-Screen increased from 48.5 to 52.8%, agreement with negative conventional culture (specificity) increased from 66.9 to 72.0%, and false-positives decreased from 22.3 to 17.2%. False-negatives at  $\geq 10^4$ CFU/ml increased from 2.5 to 28.9% and false-negatives at  $\geq 10^5$  CFU/ml increased from 7.0 to 9.5%, to give an overall decrease in agreement with positive conventional culture (sensitivity) from 64.2 to 60.7%. Since none of the abovementioned differences between wet and dry readings were statistically significant, all  $P > 0.05$ , only wet readings were used in subsequent data analyses comparing Bac-T-Screen with the other urine screen methods evaluated.

A summary of the results obtained when the AMS, Lumac, and Bac-T-Screen were compared with conventional culture is shown in Table 2. False-positive results with the Lumac and Bac-T-Screen were 20.6 and 22.3%, respectively  $(P > 0.1)$ . The false-positive rate for the AMS could not be calculated because conventional culture was per-

TABLE 2. Comparison of the AMS, Lumac, and Bac-T-Screen for detecting significant bacteriuria

	No. (%) of specimens positive by:		
Specimen (no. tested)	AMS	Lumac	Bac-T- Screen <sup>a</sup>
Screen-negative urine (848) Agreement with negative	421 (49.6) 338 (71.8)	485 (57.2) 374 (79.4)	411 (48.5) 315 (66.9)
conventional culture at $\langle$ 10 <sup>4</sup> CFU/ml (specificity) (471)			
Agreement with positive conventional culture at $\geq 10^4$ CFU/ml (sensitivity) (377)		280 (74.3) 266 (70.6) 242 (64.2)	
Agreement with positive conventional culture at $\geq 10^5$ CFU/ml (sensitivity) (243)		203 (83.5) 219 (90.1)	191 (78.6)
False-positive screens at $\langle 10^4 \text{ CFU/ml (471)} \rangle$	ь	97 (20.6)	105(22.3)
False-negative screens at ≥10 <sup>4</sup> CFU/ml (377)	83 (22.0)	111 (29.4)	96(25.5)
False-negative screens at $\geq 10^5$ CFU/ml (243)	72 (29.6)	24 (9.9)	17 (7.0)

<sup>a</sup> Data based on wet readings of filter disks.

-, Data could not be compared because AMS can detect organisms at levels of  $\leq 10^4$  CFU/ml.

TABLE 3. False-negative screens from the AMS, Lumac, and Bac-T-Screen when conventional culture demonstrated  $\geq 10^5$  CFU/ml

Conventional culture isolate present	No. of false-negatives by:		
at $\geq 10^5$ CFU/ml	<b>AMS</b>	Lumac	Bac-T-Screen
Escherichia coli	o	2	
Citrobacter freundii			
Klebsiella pneumoniae			
Proteus mirabilis			
Pseudomonas aeruginosa			
Gardnerella vaginalis			
Group D enterococcus			
Coagulase-negative staphylococcus			0
Group D enterococcus, coagulase- negative staphylococcus			0
Yeast <sup>a</sup>			0
Mixed or pure culture of probable contaminants (Lactoba- cillus spp., Corynebacterium spp., viridans group strep- tococci, or mixed-culture coagu- lase-negative staphylococcus)	58		13

<sup>a</sup> AMS screen result,  $\langle 10^5 \rangle$  yeast cells per ml.

formed at a  $10^{-4}$  dilution and the AMS is capable of detecting organisms below this level at  $\geq 10^3$  CFU/ml.

The Lumac screened out the greatest number of urine specimens as negative (57.2%) and maintained the best agreement with negative conventional culture, with a specificity of 79.4% when compared with the AMS ( $P < 0.01$ ) and the Bac-T-Screen  $(P < 0.001)$ . The Bac-T-Screen gave the lowest number of false-negative screens at  $\geq 10^5$  CFU/ml (7.0%), but the difference between this value and the 9.9% observed with the Lumac was not statistically significant (P  $> 0.01$ ). In contrast, the AMS gave 29.6% false-negatives at  $\geq 10^5$  CFU/ml (P < 0.001). The AMS had the highest sensitivity for detecting  $\geq 10^4$  CFU/ml (74.3%). This value was significantly higher than for the Bac-T-Screen  $(P < 0.01)$ but was not a statistically significant increase when compared with the Lumac ( $P > 0.1$ ). At the  $\geq 10^5$ -CFU/ml level of detection, the Lumac, with a sensitivity of 90.1%, was significantly better than both the AMS ( $P < 0.05$ ) and the Bac-T-Screen  $(P < 0.001)$ .

Table 3 includes a list of organisms involved in false-negative urine screens when the conventional culture was positive with  $10^5$  CFU/ml. For each system,  $>70\%$  of the

TABLE 4. Significant<sup>a</sup> false-negative screens from the AMS, Lumac, and Bac-T-Screen when conventional culture demonstrated  $\geq 10^5$  CFU/ml

Specimen	No. of specimens detected by:		
	AMS	Lumac	Bac-T-Screen
Total false-negatives	72	24	
Significant false-negatives	14		
% Significant false-negatives vs total $\geq 10^5$ CFU/ml culture- positive specimens	5.8	2.9	17
% Significant false-negatives vs total specimens evaluated	1.7	0.8	0.5

<sup>a</sup> A clinically significant isolate per milliliter of sample was defined as  $\geq 10^5$ CFU of any organism commonly involved in UTIs.

false-negative urine specimens contained pure or mixed cultures of common contaminants, i.e., Lactobacillus spp., Corynebacterium spp., viridans group Streptococcus spp., and coagulase-negative Staphylococcus spp. If these specimens are deleted from the false-negative data analysis, the number of clinically significant false-negatives can be determined (Table 4). Expressing the significant false-negatives as a percentage of the total number of urine specimens studied, the incidence of false-negatives involving clinically significant isolates at  $\geq 10^5$  CFU/ml is low for all three methods (AMS, 1.7%; Lumac and Bac-T-Screen, <1.0%).

Of the urine specimens received, 13 (1.5%) and <sup>2</sup> (0.2%) were in insufficient quantity for testing with the Bac-T-Screen and AMS, respectively. No urine sample was insufficient for screening with the Lumac.

Processing time was approximately 2 min per specimen with the Bac-T-Screen. When urine specimens were screened in batches of five or more, Lumac processing, excluding incubation time, averaged 2.5 min per specimen.

# DISCUSSION

The development of rapid and inexpensive screening procedures for significant bacteriuria offers substantial advantages over the reliable but slow quantitative culture technique currently used in most laboratories. Immediate processing of specimens and reporting of results would lead to less specimen handling, decreased labor costs, and increased overall laboratory efficiency. The costly administration of unnecessary antibiotics could be prevented by the rapid reporting of screen-negative urine specimens to clinicians. Screening methods would be ideally suited to the detection of significant bacteriuria in asymptomatic populations, such as pregnant women and geriatric patients, who have a greater risk of developing complicated UTI.

Both the Lumac and Bac-T-Screen are non-growthdependent methods. Screen results can easily be made available within <sup>1</sup> h after receipt of the urine specimen in the laboratory. The AMS is <sup>a</sup> growth-dependent method and therefore requires a longer period for completion (13 h); however, the advantage gained is that the AMS not only detects significant bacteriuria but also identifies the common urinary tract pathogens.

The Lumac and Bac-T-Screen have been designed as screens only, to separate out negative urine specimens, which do not require culture, from specimens which have a higher probability of being culture positive. These methods detect total microbial population. They cannot determine whether the organism population is mixed or whether one organism is present in predominant numbers.

All three methods screened out the majority of culturenegative urine specimens, with low percentages of falsenegative screens involving clinically significant organisms at the  $\geq 10^5$ -CFU/ml level. The Bac-T-Screen gave the lowest number of false-negatives at  $\geq 10^5$  CFU /ml (7.0%), with the highest predictive value for a negative urine culture at the  $\langle$  10<sup>5</sup>-CFU/ml level (95.9%). This value is in close agreement with the study of Hoyt and Ellner, in which the predictive value of a negative Bac-T-Screen result was determined to be 94% (11). The Lumac screened out the highest number of urine specimens as negative while maintaining a false-negative rate (9.9%) comparable to that of the Bac-T-Screen. Predictive values for a negative urine culture for the Lumac and AMS were 95.1 and 88.9%, respectively. Differences in negative predictive values for the three methods were not statistically significant ( $P > 0.1$ ). When only clinically significant isolates at  $\geq 10^5$  CFU/ml were considered, the predictive values for a negative result increased for all systems to 99.0% for Bac-T-Screen, 98.6% for Lumac, and 97.8% for AMS.

A false-negative Lumac screen can result if the concentration of microbial ATP in the urine is marginal at the time of testing. This could occur if the colony count in the urine specimen was significant but low (in the range of  $10<sup>5</sup>$  to  $10<sup>6</sup>$ CFU/ml), the organisms were damaged by antibiotics, or the overall metabolic activity of the organisms was reduced. The incidence of Bac-T-Screen false-negatives has been found to be highest with specimens containing gram-positive cocci (11).

The percentage of false-positive screens for both the Lumac (20.6%) and the Bac-T-Screen (22.3%) was acceptable, considering that both instruments were designed for the optimal detection of negative, not positive, urine specimens. The number of negative specimens that would be processed for culture as a result of false-positive screen results is not so great as to prohibit the use of the instruments for the rapid and more accurate detection of culturenegative urine specimens. The predictive values for a positive culture at  $\geq 10^5$  CFU/ml, however, were low; 55.0% for Bac-T-Screen and 60.3% for Lumac ( $P > 0.1$ ). Because of these low predictive values, positive screen results should be reported with caution and clinicians should be advised not to start therapy on the sole basis of a positive urine screen. In contrast, the predictive value for <sup>a</sup> positive AMS result  $(91.5%)$  was significantly higher than that for the Lumac (P)  $< 0.01$ ) or the Bac-T-Screen ( $P < 0.001$ ).

False-positive screens may be due to a variety of causes. Organisms such as anaerobes, lactobacilli, diphtheroids, or slow-growing yeasts or bacteria may be present in the urine but grow poorly or not at all on conventional media. Data collected by Thore et al. (33) showed that 20% of Lumac false-positive urine specimens grew  $\geq 10^5$  CFU/ml on prolonged incubation. The presence of antibiotics in the urine may inhibit bacterial growth on conventional media. Johnston et al. (12) reported that 42 of 116 Lumac false-positives came from patients who were receiving antimicrobial therapy at the time of specimen collection. Excessive leukocytes or proteinaceous material may be trapped on the Bac-T-Screen filter and be stained by the Safranin O dye. In the Lumac procedure, if the Somase reagent cannot destroy all the somatic cell ATP, a falsely elevated relative light unit value is obtained. This is considered the reason why all visibly bloody urine specimens were positive by Lumac in our study.

The Lumac was the easiest instrument to operate. Because the bioluminescence assay requires only 25  $\mu$ l of sample, all urine specimens were of sufficient quantity for testing. The major disadvantage of the Lumac is reagent instability. Once reconstituted, Somase must be used within 3 h or aliquoted and frozen at  $-20^{\circ}$ C. Lumit PM (luciferinluciferase) maintains sufficient reactivity for only 10 to 12 h after rehydration at room temperature. If frozen at  $-20^{\circ}$ C, Lumit PM is stable for up to <sup>4</sup> weeks. Owing to the instability of the reagents and the required 25-min incubation period, the Lumac is most efficient when urine specimens are screened in batches of 10 to 20.

Interpretation of Bac-T-Screen filters after complete drying was found to offer no advantage over wet readings. When filters were read after drying, accuracy in detecting culturenegative urine specimens was slightly improved (the increase was not statistically significant). However, as expected, this not only delayed reporting of test results but also resulted in decreased sensitivity as a result of an increase in the number of false-negative screens.

Bac-T-Screen reagents are stable at room temperature and require no special preparation. Urine specimens are processed one at a time. This system could therefore be easily adopted in a laboratory handling a low volume of specimens or in a physician's office. Problems with the Bac-T-Screen included an excessively noisy instrument pump mechanism and an inability to predict which urine specimens will clog the filter. A large number of specimens (77 [9.1%]) produced screen results with the Bac-T-Screen which could not be considered either positive or negative. These included a significant number of urine specimens which were bloody or colored and therefore produced uninterpretable pigmented filters and urine specimens which clogged the filter. Specimens uninterpretable by the Bac-T-Screen require plating for culture, and therefore the report times are greatly increased. An additional problem caused by cloggers was a slight disruption in work flow, as the instrument had to be manually cleaned and rinsed before the next urine specimen could be tested.

Of the specimens which clogged the filter, the majority (78.1%) were culture positive at the  $\geq 10^5$ -CFU/ml level. These findings are consistent with a study by Pezzlo et al. (24), in which 69.4% of the specimens clogging the filter contained  $\geq 10^5$  CFU/ml. These authors also demonstrated that the majority of clogging specimens contained large amounts of protein and leukocytes. Since a culture would still be necessary to determine whether a urine specimen which clogs the Bac-T-Screen filter contains significant numbers of organisms, clogging cannot be considered a positive screen but rather an uninterpretable result.

The cost of screening specimens which produce uninterpretable results as well as the cost of all screen-positives must be added to the cost of determining a screen-negative urine specimen. This cost is offset by the savings in materials and technologist labor gained by obviating the need for culture of screen-negative urine specimens. Thus, at any given reagent and labor cost per specimen, the higher the percentage of reliable screen-negatives, the more cost-effective the screening method. Less easily determined is the potential saving to the patient in terms of hospitalization and treatment costs which may follow faster negative urine result turnaround times.

The initial instrument costs for the Lumac or Bac-T-Screen are comparatively low, whereas the AMS is the most expensive of the systems studied. In addition to the large initial capital outlay for instrumentation, the cost per AMS urine identification card is approximately double the reagent cost per specimen with either the Lumac or the Bac-T-Screen. The AMS does, however, produce final identifications faster than does the conventional culture method. Since the negative predictive value of an AMS result is lower and the positive predictive value is significantly higher than those of the other screening methods evaluated, the systems complement one another. Urine specimens can be screened by using either the Lumac or Bac-T-Screen, and only screenpositive specimens are processed on the AMS. In this way, results can be available within 14 h for the majority of urine specimens.

The three screening methods evaluated in this study were most accurate in detecting organisms at the  $\geq 10^5$ -CFU/ml level. When comparing published results and considering urine screen tests for a specific laboratory, one should take into account the demographic patient information and the prevalence of UTIs. Recent literature by Stamm et al. (30)

suggests that colony counts as low as  $10^2$  CFU/ml may be significant in certain patients, particularly symptomatic females. Until urine screening procedures can be made more precise, they may not be appropriate for the specimens from some patients. In cases in which there is a need for special culture techniques, the physician must communicate this need to laboratory personnel.

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