

THERE ARE NO NORMAL VALUES IN MICROBIOLOGY!  
AN IMPROPERLY COLLECTED SPECIMEN MEANS UNINTERPRETABLE RESULTS!

## Evaluation of the CORAL UTI Screen™ System for Rapid Automated Detection of Significant Bacteriuria in Children

Urinary tract infections are one of the most common types of infection in humans, and bacteriuria is caused by a limited number of bacterial species. Urine specimens are therefore the most frequent type of specimen submitted for culture to most clinical microbiology laboratories. Although urine culture remains an essential test for confirmation of a urinary tract infection and identification of the causative uropathogen(s), it is a time consuming procedure that has a high negative rate. Urine cultures in ambulatory patients have a high negative rate, and due to the nature of the collection procedure, urine that is voided over the peri-urethral skin surface is a highly contaminated substance resulting in many cultures that grow mixed Gram-positive organisms that are often skin contaminants. At Calgary laboratory Services (CLS) between 75 -80% of 600 urine samples submitted daily are either culture negative or grow insignificant amounts of bacteria and this is consistent with the experience of other large microbiology laboratories.

CLS initially evaluated the performance of the Coral UTI Screen™ (Coral Biotechnology, San Diego, CA, USA) to reliably detect urine samples that did not have significant bacteriuria (i.e., Would be culture negative) 2-years ago. Based on the results of that study (1), routine urine screening of all samples submitted for urine culture was implemented in June 2001. Although 113 children were included in the original evaluation, it was of interest to perform a much larger paediatric study using different cut-offs on the instrument to optimise use of the screening test for children. As a result of this recently completed study, CLS has changed its urine culture protocol for children as outlined below.

### How Does the CORAL UTI Screen™ Work?

The Coral UTI screen™ system uses a somatic cell release™ agent to release and destroy the adenosine triphosphate (ATP) present in somatic cells (bacterial ATP is protected within bacterial cells). A reduced form of luciferin reacts with bacterial or yeast ATP in the presence of the enzyme luciferase to produce oxidized luciferin, AMP and light. The light produced by this reaction is measured by a photo-multiplier tube detector luminometer and the signal is converted to Relative Light Units (RLU). The RLU produced is proportional to the amount of bacterial ATP present in the urine sample.

### What Were the Results of the CLS Paediatric Urine Evaluation?

Since the initial study only included 113 paediatric patients (i.e. children  $\leq$  14 years) from which only 24 samples were positive, a separate study of paediatric urine specimens has recently been completed. A total of 676 urine specimens from paediatric patients were tested using the Coral UTI screen™ and the results compared to urine culture. A total of 563 (83.3%) of the urine samples were negative by both methods while 75 (11.1%) were positive. A total of 28 (4.1%) urine samples were culture positive for a

potential uropathogen but negative according to the Coral UTI Screen™ using a 4% cutoff. Another 10 (1.5%) urine specimens were considered to be culture negative but positive according to the UTI screen™. Overall the Coral UTI screen™ was 72.8% sensitive (95% CI 63.2-81.1) with a negative predictive value of 95.3% in pediatric patients. Although the performance of the Coral UTI Screen™ was not statistically significantly different than that in adults, there was a trend to lower sensitivity and high specificity in children. The effects of lowering the Wave 180 luminometer cutoff from 4% to >1% (i.e. 2% or more) was also studied. Using a lower instrument cutoff (i.e. 1%) for pediatric urine samples would increase the sensitivity and negative predictive value to 83.5% and 97% respectively which are equivalent to those for adults using a 4% cutoff.

### **Change in Protocol for Paediatric Urine Cultures:**

In order for the CLS microbiology laboratory to continue to use the Coral UTI Screen™ on all urine samples submitted for culture, a 4% instrument cutoff for adults but a lower cutoff of <1% should be used when testing pediatric urine samples in order to have equivalent performance. However, implementation of a different test cutoff for adults versus children would substantially decrease the workflow efficiency and in some cases urine culture turnaround times for pediatric urines since a much smaller number of samples are submitted compared to adults. As of November 1 2003, all paediatric urine culture samples have therefore been directly plated for culture and no longer initially screened using the Coral UTI Screen™. All urine culture results must be correlated with the clinical picture (i.e. symptoms) since urine is a highly contaminated specimen.

### **What Does CLS Consider to be a Significant Urine Colony Count?**

Quantitative urine cultures are inoculated onto Columbia blood agar and Maconkey agar plates using a 10µL loop. A separate plate is added if a yeast culture is requested since routine bacterial media may not support the growth of *Candida* spp. Urine colony counts for each morphological type of bacteria or yeast per plate are determined according to the following guidelines:

- No growth (no colonies)
- Insignificant growth (<10<sup>6</sup> colony forming units/L)
- Significant bacturiuria (≥10<sup>7</sup> colony forming units/L) for up to two uropathogens

### **Potential Uropathogens in Children:**

The following types of microorganisms are considered to be potential uropathogens in children (i.e. ≤14 years of age):

- Enterobacteriaceae (*E. coli*, *Klebsiella* spp. etc.)
- Non-fermentative gram-negative bacilli (i.e. *Pseudomonas* spp.)
- *Staphylococcus saprophyticus* (i.e. children and women)
- *Enterococcus* spp.
- *Staphylococcus aureus*
- Group A, B, C or G Streptococci
- Yeasts

**IF YOU HAVE ANY QUESTIONS OR COMMENTS ABOUT HOW THE LABORATORY WORKS,  
PLEASE CALL US AT 209-5396 (Brenda Kirkham, Manager, Microbiology) or  
209-5281 (Dr. Church, Division Head, Microbiology)**

The Microbiology Newsletter is also available on the Internet and may be accessed at:  
<http://www.crha-health.ab.ca/clin/cme/microbio.htm>