

**Intended Use:**

The **URI-ID Dip Paddle** provides a rapid, simple and reliable culture method for urine bacterial semi-quantification. This system aids in differentiating Gram-negative from Gram-positive bacteria. It is also useful for screening asymptomatic and high risk patients as a means of monitoring therapy and 'test-of-cure' during and following chemotherapy. This device is intended to be used at the discretion of each individual laboratory or clinic to meet its specific requirements.

**History / Summary:**

Kass<sup>1</sup> documented that the presence of  $1 \times 10^5$  viable organisms per ml of freshly voided urine was indicative of infection. Since this concentration may be found in the absence of symptoms, many clinicians regard the detection of asymptomatic bacteriuria an important aspect of health screening.

The 'dip-paddle' technique for determining significant bacteriuria is a convenient tool for screening high risk populations such as adolescents and pregnant females. The need for rapid transport of specimens to the laboratory is eliminated by having the test performed on-site by individuals who follow the instructions detailed below. Test paddles that have been inoculated may be transferred to a laboratory for further testing or subculture without affecting the colony count.

**Principles of the procedure:**

Urinary tract infections are primarily caused by Gram-negative, non-sporulating rods of the *Enterobacteriaceae* family, of which *Escherichia coli* accounts for as much as 90%. *Pseudomonas*, *Proteus*, *Staphylococci*, *Enterococci* and other microorganisms account for the remaining 10%<sup>2</sup>.

Semi-quantification is done by comparing the bacterial colony density on the paddle with the standardized diagrams shown below. This method is rapid and accurate for specimens containing  $1 \times 10^3$  to  $1 \times 10^7$  colonies per millimeter. General quantification can be divided into three categories as originally described by Kass<sup>1</sup>:

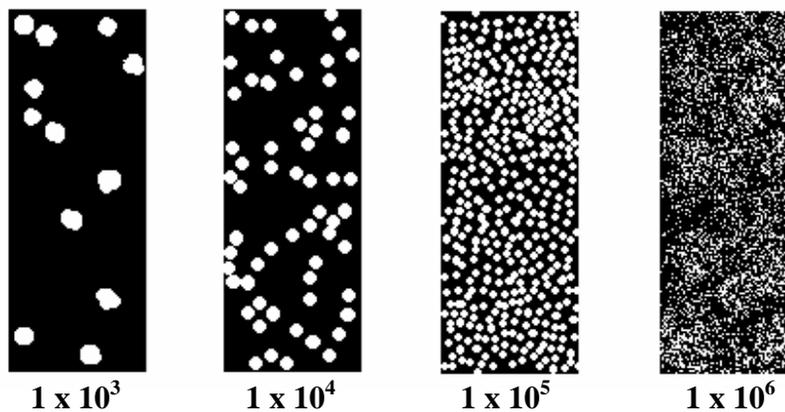
- ▶  $\geq 1 \times 10^5$  organisms/ml indicates infection
- ▶  $1 \times 10^4$  to  $1 \times 10^5$  organisms/ml indicates possible infection or contamination
- ▶  $\leq 1 \times 10^4$  organisms/ml indicates possible contamination

The **URI-ID Dip Paddle** system allows for detection, quantification and differentiation of urinary tract pathogens. Most of the growth on EMB agar (reddish-purple colored side) will represent Gram-negative rods while growth on CLED agar (blue-green) will represent some Gram-negative rods as well as common contaminants such as *Diphtheroids*, *Staphylococci*, and *Streptococci* organisms.

A difference in colony densities on the EMB and CLED agar suggests that the specimen was probably contaminated during collection. Abundant growth on CLED agar and negligible growth on EMB agar suggests infection with organisms other than Gram-negative rods, particularly if the growth is primarily one colony type.

**Reagents:**

Each **URI-ID Dip Paddle** contains EMB agar (reddish-purple) on one side and CLED agar (blue-green) on the other. These media are formulated and tested according to specifications of the National Committee for Clinical Laboratories (NCCLS) and United States Pharmacopoeia (USP).



**Precautions:**

For *in vitro* diagnostic use. Do not use product if vial is damaged or media are contaminated, dehydrated, discolored, dislodged from paddle, or if there is any indication of alteration of product. Do not use after expiration date. Do not reuse paddles. Dispose of paddle into biohazard container (red bag) after use.

Allow the media to come to room temperature before inoculation. Monitor incubator temperature (35-37°C) to avoid separation of cap and container resulting from air expansion during incubation.

**Limitations of Procedure:**

In all suspect cases, the recovery of pathogenic microorganisms cannot be assured. Factors which may adversely affect the recovery rate and colony count from clinical samples are: specimen contamination, un-refrigerated specimens, state of dehydration of the patient, patient's daily voiding pattern (i.e., time of day) and chemotherapy. If further identification of organisms is desired, the culture should be sent to a reference laboratory. If the growth yields several different bacterial morphologies, the mixture may be due to contamination. A new clean catch specimen should be carefully collected and tested.

**Storage and Stability:**

For optimum shelf life, store **URI-ID Dip Paddles** at 2-25°C and avoid temperature fluctuations. Do not freeze. Allow the media to come to room temperature before inoculation. Do not incubate prior to use. Product will remain stable until expiration date if store as recommended.

**Specimen Collection:**

Urine specimen should be collected by clean-catch, mid-stream technique, or other suitable procedure, in a sterile container. Inoculate the **URI-ID Dip paddle** before performing any other urine test or divide the specimen for bacteriology and chemistry to avoid contamination. If unable to inoculate immediately, refrigerate specimen at 2-8°C for up to 24 hours. Note: Antimicrobial therapy prior to specimen collection may reduce colony count and viable organisms, resulting in an inaccurate analysis

**Procedure: (see diagram below)**

1. Remove the **URI-ID Dip Paddle** from the vial and dip into urine making sure the agar is wet on both sides. Avoid contaminating agar.
2. Drain the excess and replace paddle into vial. Label the vial with patient information. Incubate for 16-24 hours at 35 to 37°C.
3. Read paddle for growth and record results.

**Materials required but not provided:**

Sterile specimen container  
Incubator maintaining 35-37°C

**User quality control:**

The following incoming inspection procedures must be performed for each batch (batch = same lot, same shipment) of culture media received in the laboratory:

1. Inspect paddles according to instructions contained on the "Quality Control Log Sheet."
2. Peel off the lower portion of a product box label (Quality Control Certificate) for the lot being accepted into the laboratory and affix it to the Quality Control Log Sheet.
3. Initial and date the Quality Control Log Sheet.

Note: Notify Technical Service immediately if media does not meet the inspection criteria

**Performance:** The media may be tested by inoculating with stock cultures of the organisms listed below and examined for expected results after 16 to 24 hours.

<b>Organism</b>	<b>EMB</b>	<b>CLED</b>
<i>Escherichia coli</i>	Growth (green sheen)	Growth (yellow center)
<i>Proteus vulgaris</i>	Growth (amber)	Growth (bluish)
<i>Staphylococcus aureus</i>	Inhibition	Growth (deep yellow)

References\*

1. Kass, E.H., 1956. Asymptomatic infections of the urinary tract. *Trans. Assn Amer, Physicians* 69: 45-63.
2. Beeson, P.B. 1967; Beeson, P.B. and W. McDermott (Eds.), *Cecil-Loeb Textbook of Medicine*, 12th Ed. Philadelphia, PA: W.B. Saunders, Co., p. 228.

\* References cited herein are per industry standard substantiation of works derived by independent investigation and HealthLink. does not by reference thereto warrant content validity.