

## URICULT PROCEDURE MANUAL

### NAME OF TEST:

Uricult® - URICULT is a simple, self-contained urine test method for the detection of various types of bacteria that commonly cause urinary tract infections.

When URICULT is used as recommended, test results can show:

1. The presence or absence of potential urinary pathogens in a tested urine sample;
2. The approximate concentration of bacteria in each milliliter (ml) of urine; and
3. A presumptive identification of the specific bacteria type.

### MEDICAL IMPORTANCE:

Bacteriuria is the presence of bacteria in the urine. Bacteriuria may be due to many causes:

1. A symptomatic bacterial urinary tract infection (UTI).
2. An asymptomatic presence of bacteria within the urinary tract. The presence of bacteria may be transient or may be persistent but does not cause disease symptoms - Asymptomatic bacteriuria.
3. Contamination from skin or other body sites due to improper specimen collection.
4. Contamination contributed by the container in which the specimen is collected.

Urinary tract infections include localized infections in any particular site within the urinary tract. More specific terms include:

1. Pyelonephritis - kidney
2. Cystitis - bladder
3. Prostatitis - Prostate
4. Urethritis - Urethra

Urinary Tract Infections occur when bacteria invade different areas of the urinary tract. Urinary tract infections vary in seriousness. As the infection moves upwards from the urethra to the bladder, then on to the kidney, it becomes more and more serious.

UTI caused by bacteria are considered uncomplicated infections and no surgery is required. Occasionally a UTI will be caused by a blockage such as a kidney stone or a structural abnormality of the urinary tract. This is called a complicated infection. Surgery is required to remove the obstruction or abnormality. Most urinary tract infections are caused by a single bacterial isolate. In unusual circumstances, it is possible that two organisms may be responsible. Should an incubated culture show three or more bacterial growths, the specimen should be considered contaminated and the culture repeated.

### MATERIALS REQUIRED:

URICULT Culture-Paddle and patient identification label. Uricult Culture-Paddles should be stored at 45-77°F (7-25°C) in the package provided. Protect from light and temperature fluctuations.

URICULT Reference Chart

An Incubator calibrated to maintain a temperature of 36°C ± 2°C

Sterile urine collection cup (with lid if specimen is stored in refrigerator)

## **SPECIMEN COLLECTION, PROCESSING AND CRITERIA FOR SPECIMEN REJECTION:**

### SPECIMEN COLLECTION

Ideally, urine for culture analysis should be incubated in the bladder for four hours prior to collection. Urine samples may be obtained by voiding, catheterization or supra-pubic aspiration. If a voided specimen is to be used, a mid-stream, clean catch specimen is recommended. A paper cup labeled with the patient's identification may be used to collect the specimen.

### PATIENT INSTRUCTION FOR MIDSTREAM CLEAN CATCH TECHNIQUE

**Females:** Spread labia and cleanse genital area with wet soapy gauze wiping from front to back. Repeat 2 to 3 times using fresh gauze each time. Rinse by wiping in the same direction with water-soaked gauze and repeat 2 to 3 times with fresh wet gauze. Keeping labia spread, begin to void. Then collect the "midstream" middle portion of the urine in a paper cup. Do not touch the urine or inside of the paper cup.

**Males :** Retract foreskin if necessary. Cleanse the head of the penis with a wet, soapy gauze pad and repeat 2 to 3 times using a fresh gauze pad each time. Rinse with water soaked gauze. Begin to void, then collect the middle portion of the urine in a paper cup. Do not touch the urine or inside edges of the cup.

Specimens that are not received in accordance to the above guidelines should be rejected and a new specimen collected. In addition, if the volume of urine is not sufficient to completely immerse paddle or pour over both agar surfaces, a new specimen should be obtained.

ADDITIONAL NOTES:

### SPECIMEN PROCESSING

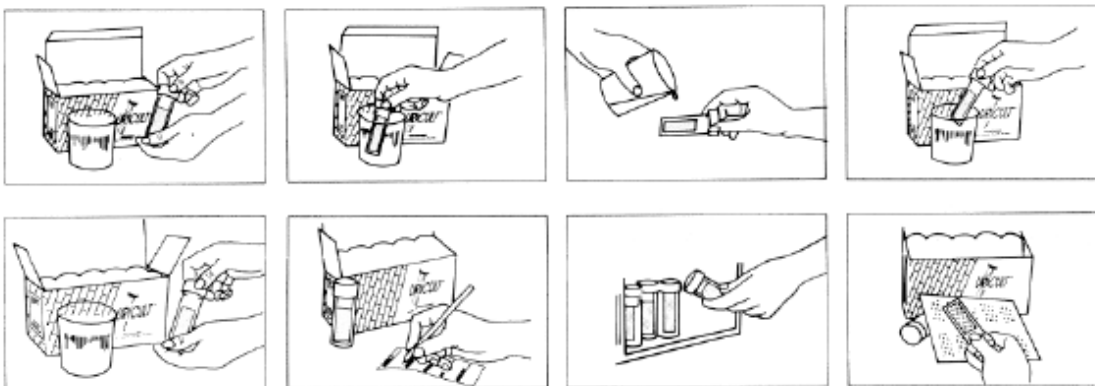
Specimens should be inoculated within 30 minutes following collection. If specimen cannot be inoculated within 30 minutes, the specimen should be maintained at refrigerated temperatures (2°-8°C/36°-°46F) in a closed sterile container labeled with patient identification information. Storage should not exceed 24 hours.

ADDITIONAL NOTES:

### SPECIMEN REJECTION

Do not use urine preservative systems. Do not accept specimens that have remained at room temperature for longer than 30 minutes. Do not allow specimens in home made type containers (glass jars, etc.)

ADDITIONAL NOTES:



1. Unscrew and remove the URICULT paddle from its protective vial. Handle the paddle only by its cap and do not touch its exposed agar culture surfaces.
2. Dip the URICULT paddle into the urine sample to totally immerse the agar surfaces, *OR*:
3. If the volume of urine sample is insufficient for total immersion of the paddle, the urine can be poured onto the agar surfaces.
4. Allow excess to drain from the paddle; you may blot any residual drops from the plastic paddle tip on absorbent paper. Do not allow the agar surfaces to come in contact with the absorbent paper.
5. Insert the paddle into its protective vial and screw down *lightly* to allow air to circulate inside vial.
6. Write patient's name, specimen date, as well as date and time of inoculation on a self-adhesive label, and attach it to the URICULT vial.
7. Preferably immediately after inoculation, place the URICULT in an upright position (cap side up) in an incubator for 18 to 24 hours at approximately 34°-38°C (93°-100°F). *Note*: Incubation for more than 24 hours may allow reactions to occur which may then cause a misinterpretation of test results.
8. Interpret URICULT test results for colony counts and presumptive identification of bacteria according to the recommendations and guidelines described in the "Interpretation of Results" section. Negative cultures may be incubated for an additional 24 hour period if desired. This will allow for the detection of slow growing bacteria.

### INTERPRETATION OF RESULTS:

Following the incubation of an inoculated URICULT Urine CULTURE-PADDLE, the presence of bacteria may be evidenced by visible signs of colony growth on the agar surface. Separate, distinct areas of bacterial growth on the agar surface are called "colonies". Since the formation of a colony results from the natural multiplication of a single bacterial cell, and since the agar surface on URICULT Urine Culture-Paddles are uniform in dimension, the number of colonies can indicate the "colony count" which is the approximate number of CFU/ml of urine.

At the end of the incubation period, check the agar surfaces on both sides of the URICULT Urine Culture-Paddle for colony growth. If all visible bacterial colonies are similar in characteristics, compare the number of colonies on each side of the culture-paddle. If there is a significant difference in the number of colonies on each side, the side with the greater number should be used for determining the "colony count". In making the determination, the number of colonies and not the dimensions of the individual colonies should be considered. Match the "colony density" on the agar surface with the printed example it most closely resembles on the Colony Density Chart. If the characteristics of visible colonies on either side of the culture-paddle differ enough to indicate more than one type of bacteria, the colony count match-up procedure should be performed and reported on each organism.

"Confluent growth" (complete coverage of the agar surfaces) may occasionally occur when a colony count is more than 100,000 ( $10^5$ ) CFU/ml, and may be *misinterpreted as a negative culture* because there is not clear definition between colonies. To avoid misinterpretation, it is recommended, therefore, that cultures which appear to have no clearly defined colonies be scanned under a bright light. The light will be reflected from the agar surface when there are no bacterial colonies. An agar surface completely coated with confluent bacterial growth will not reflect the light. The use of bright light will also allow relatively small colonies to be seen.

Further confirmation of a negative culture may be obtained by gently swabbing part of the agar surface. Bacterial growth will be evident on the swab itself, and by a difference in appearance between the swabbed and unswabbed portions of the agar surface.

Most urinary tract infections are caused by a single strain of bacteria, with the most common being E. coli. If there are three or more different colony types, the urine is probably contaminated and a repeat sample should be obtained.

The determination of colony color, size, texture, configuration, and observation of the agar media for color changes induced by bacterial growth, can provide information useful in making a presumptive identification of the bacteria present.

The Uricult Reference Chart should be consulted for expected colony count, colony morphology and biochemical reactions of the various bacterial species frequently encountered in urine specimens.

Bacterial identifications based on the biochemical reactions evidenced by URICULT and colony morphology will result only in a presumptive identification. Bacterial variation may occur and atypical strains may be isolated. In instances where a definitive bacterial identification is necessary for proper patient management, the inoculated paddle may be used as a transport media to forward the bacterial specimen to a laboratory for further study.

**ADDITIONAL NOTES:**

### **REPORTABLE RANGES:**

URICULT® CULTURE-PADDLES® are capable of detecting bacteriuria in the range of  $10^3$  (1,000) to  $10^7$  (10,000,000) CFU/ml.

### **QUALITY CONTROL PROCEDURES:**

1. Upon arrival, a representative sample (2 vials per box) of Uricult paddles should be examined for the following characteristics with results recorded in the Quality Control Record:

- |                               |                                |
|-------------------------------|--------------------------------|
| * Cracked Vials               | * Contamination                |
| * Unequal filling of paddles  | * Discoloration                |
| * Cracked Media               | * Media separating from paddle |
| * Excessive number of bubbles | * Dehydration                  |
| * Freezing                    | * Excess Moisture              |

2. Remove the Certificate of Analysis from the package insert and attach to QC record. Record date received, lot number and Pass/Fail visual inspection results, tech initials in QC log.

3. Monitor incubator temperature and record temperature (36 +/- 2 degrees C) daily in QC log.

### **QUALITY CONTROL REMEDIAL ACTION:**

The presence of any deficiencies listed in the Quality Control Procedure section should result in notification of the LifeSign Technical Services Department (1-800-526-2125). Documentation of resulting action should be recorded in the Quality Control Records. Do not test patient samples if the media exhibit these deficiencies. Do not use product beyond expiration date.

### **LIMITATIONS IN METHODOLOGY:**

Bacterial identifications based on the biochemical reactions evidenced by URICULT and colony morphology will result only in a presumptive identification. Bacterial variation may occur and atypical strains may be isolated. In instances where a definitive bacterial identification is necessary for proper patient management, the inoculated paddle may be used as a transport media to forward the bacterial specimen to a laboratory for further study.

**REFERENCE RANGES:**

When the recommended procedure for a clean catch midstream specimen collection is followed, contamination of the specimen is minimized. Kass<sup>2</sup> has recommended the following guidelines for the interpretation of urinary colony counts on voided specimens:

NORMAL - Less than 10,000 CFU/ml urine

DOUBTFUL - 10,000 to 100,000 CFU/ml urine

POSITIVE - Greater than 100,000 CFU/ml urine

Many factors may influence the colony count obtained. Patients on antibiotics may have a "lowered" or negative colony count as a result of antibiotic interference. Urine which has not incubated in the bladder for four hours could also cause a falsely low colony count. A first morning voided specimen is recommended whenever possible. Specimens that have remained at room temperature for more than 30 minutes may cause a falsely high colony count. In all cases, the physician must be the final judge of the proper interpretation of the Uricult results.

**ADDITIONAL NOTES:****PANIC VALUES**

There are no imminent life-threatening laboratory results or panic values for urine cultures.

**LITERATURE REFERENCES**

1. Mackey, J.P., Sandys, G.H., Laboratory Diagnosis of Infections of the Urinary Tract in General Practice by Means of a Dip-Inoculum Transport Medium, *British Medical Journal* 2:1286-1288, 1965.
2. Kass, E.H., Bacteriuria and the Diagnosis of Infections of the Urinary Tract, *Arch. Int. Med.* 100:709-714, 1957.
3. McAllister, T.A., Arneil, G.C., Barr, W., Kay, P., Assessment of Plain Dipslide Quantitation of Bacteriuria, *Nephron*, 11:111-122, 1973.
4. Ellner, P.D., Papachristos, M.S., *Amer. J. Clin. Path.* 63(4):521, 1975.

**SPECIMEN STORAGE AND PRESERVATION:**

If specimens cannot be inoculated within 30 minutes, the specimen should be maintained at refrigerated temperatures (2°-8°C/36°-46°F) in a closed sterile container labeled with patient identification information and the time and date specimen was collected.

**PROCEDURE FOR REPORTING PATIENT RESULTS:****INSTRUCTIONS FOR COMPLETION OF THIS SECTION**

This section should be approved by the lab director and provide specific information on how patient results are reported in your lab. A copy of patient report forms should be included and explained here, as well as indicating where reports go when they leave the lab. Other information may include:

- Is sensitivity testing performed? On what colony count? With pure cultures? With two organisms?
- When are cultures referred out? What reference lab are they referred to for identification?

**ALTERNATIVE METHOD:**

List the method to be used for urine cultures if the Uricult product is unavailable. If alternate procedures are not employed, list the name and address of the reference laboratory where your specimens would be sent.

Alternative Method:

OR

Reference Lab Name and Address:

**CRITERIA FOR REFERRAL OF SPECIMENS:**

List the criteria for specimen referral to a reference lab, inclusive of procedures for specimen collection, specimen labeling, specimen preservation, and conditions for specimen transportation.

- \* When are specimens or paddles referred out?
- \* What types of collection devices are used?
- \* How are they labeled?
- \* Is the Uricult paddle sent or a urine specimen?
- \* Are urine specimens refrigerated until picked up by reference lab?

**CULTURE DISPOSAL:**

Because the bacterial colonies inoculated on the Uricult culture paddles are actual or potential pathogens, the media should not be touched and should not be exposed to other office personnel or patients. It is recommended for testing personnel to wear gloves and/or other personal protective equipment when handling all biohazard material.

It is advised that the procedure for disposing inoculated culture media be in accordance with your existing federal, State and/or local regulations.

To avoid any risk of contamination after a culture has been interpreted, it is also recommended that the used Uricult paddle be promptly and completely immersed in a cup of bactericidal solution.

**TECHNICAL ASSISTANCE:**

Technical assistance is available from LifeSign, Somerset, New Jersey, between the hours of 8:30 a.m. and 4:45 p.m. EST.

1-800-526-2125

**PROCEDURE APPROVAL**


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 Lab Director

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 Date

NOTE: Procedures must be approved, signed and dated if the directorship of laboratory changes.  
 Each change in a procedure must be approved, signed and dated by the current director.  
 Discontinued procedures should be retained for two years.