lifeSign

Product Name: **Uricult**	Moderately Complex
Item Number: 1000	

Intuition:	
Prepared By:	Date:
Title:	

Accepted By:	Date:
Title:	

Accepted By:	Date:

Discontinued By	Date:

SECTION 1 - TEST NAME

Uricult

SECTION 2 - INTENDED USAGE

For the detection of bacteriuria and the presumptive identification of uropathogens

SECTION 3 - SUMMARY AND EXPLANATION OF TEST

In the mid 1960's Mackey and Sandy's developed a dip inoculums transport media for rapid urine culturing. Subsequent improvements have been made which increase the accuracy of the results obtained while retaining the convenience of the inoculum technique.

Uricult urine culture paddles provide effective bacterial detection and presumptive identification in a simple and reliable manner.
Uricult urine culture paddles are attached to a screw cap. Each side of the culture paddle is coated with an agar medium suitable for the growth of urinary bacteria and the culture paddle is suspended in a clear plastic vial. Uricult cuture paddles are safely isolated in this vial during transport, incubation, storage and handling. Because of the uniform application of agar to the **Uricult** paddle, it is possible to obtain semi-quantitative results when the device is used as directed. This is determined by a simple visual comparison of bacterial growth on the agar surface with the Colony Density Chart provided. No actual colony counting is necessary

SECTION 4 - PRINCIPLE OF TEST

CLED Agar (Cystine-Lactose-Electolyte-Deficient) media was the first described by Mackey and Sandy's specifically for the use in dip inoculums procedures for urinary bacteriology. This agar supports the growth of both gram negative and gram positive bacteria commonly encountered in urine specimens. The electrolyte deficient nature of the media prevents the

characteristics swarming of Proteus. The inclusion of lactose and the indicator dye, Brom-Thymol Blue, allows differentiation of lactose fermenting bacteria, since the by-products of lactose fermentation cause the color of the agar to change from its original pale green color towards yellow.

EMB Agar (Eosin Methylene Blue) is a selective reddish-brown colored media recommended for the detection and isolation of gram negative intestinal pathogenic bacteria. The balanced combination of the two dyes (Eosin and Methylene Blue) contained in the EMB agar makes it possible to distinguish lactose fermenting bacteria from non-lactose fermenting bacteria. Those bacteria which ferment lactose will have dark colonies, purple or back in color. A green sheen may be observed across the agar surface during the growth of certain lactose fermenting bacteria.

SECTION 5 - KIT CONTENTS AND STORAGE

Uricult paddles are provided in packages of 10 culture paddles each in individual vials. Included in the package are 10 self-adhesive patient identification labels and instructions for use, which includes a Colony Density Chart.

- Store at 45….77°F in the package provided.
- Protection from light and temperature fluctuations will ensure product stability to the expiration date.
- Avoid drafts and do not store near heat generating appliances
- DO NOT FREEZE

SECTION 6 - MATERIALS REQUIRED BUT NOT PROVIDED

- An incubator calibrated to maintain a temperature of 97° F ± 4° (36° C ± 2°) is necessary but not provided
- Latex gloves
- External positive and negative control set item# 200030

SECTION 7 - WARNINGS AND PRECAUTIONS

- **Uricult** urine culture paddles are for *in vitro diagnostic use*.
- Do not use the product beyond expiration date

- Do not use the **Uricult** culture paddles exhibiting discoloration, dehydration, of the agar, media separating from the sides of the paddle or evidence of mold or bacterial growth.
- Because bacterial colonies on inoculated **Uricult** paddles are actual or potential pathogens, a potential biohazard may exist and the culture paddles should not be touched or unduly exposed.
- High concentrations of E. coli may cause variations in the degree of metallic sheen.

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

SECTION 8 - PATIENT PREPARATIONS AND SPECIMEN COLLECTION

Follow instruction for patient collection of midstream-clean catch urine

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, being to void. Then collect the "midstream" middle portion of the urine in a sterile cup. Do not touch the urine or inside of the 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, and then collect the middle portion of the urine in a sterile 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.

SECTION 9 - QUALITY CONTROL AND ASSURANCE

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.

Mix urine specimen thoroughly immediately before inoculating the **Uricult paddle.**

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.)

Perform a visual inspection of each new shipment of Uricult

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
* Unequal filling of paddles
* Cracked Media
* Excessive number of bubbles
* Freezing
* Contamination
* Discoloration
* Media separating from paddle
* Dehydration
* 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.

External QC should be performed with every new shipment and every new lot number. Or, an IQCP document can be written documenting risk assessment associated with this product. Be sure to check with your laboratory, State and Federal regulatory agencies for compliance guidelines.

SECTION 10 - TEST PROCEDURE

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.

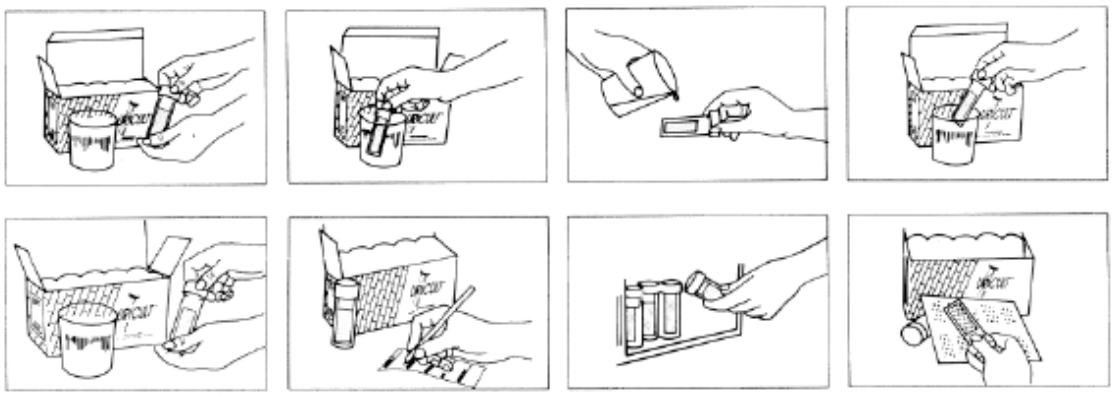
5. Insert the paddle into its protective vial and screw down *lightly* to allow air to circulate inside vial.

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 count of bacteria according to the recommendations and guidelines described in the "Interpretation of Results" section

9. Negative cultures may be incubated for an additional 24 hour period if desired. This will allow for the detection of slow growing bacteria.



SECTION 11 - 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 *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. when a colony count is more than 100,000 (10^5) CFU/ml, and may be *misinterpreted as*

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.

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 investigation.

SECTION 12 RESULT REPORTING

When the recommended procedure for a clean catch midstream specimen collection is followed, contamination of the specimen is minimized. Kass[2] 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.

SECTION 13 LIMITATIONS

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.

SECTION 14 EXPECTED RESULTS

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

SECTION 15 REFERENCECES

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.

SECTION 16 TECHNICAL ASSISTANCE

For technical assistance, contact LifeSign Technical Service Department at 1-800-526-2125

Certification of Training

This is to verify that personnel responsible for running _____ test at

_____ have been thoroughly in-serviced on the test and the test procedure(s).

This has included:

Review of the package insert

Demonstration of the product assay

Successful performance of the test and interpretation of results

Names of the personnel who have been trained with the above test and are responsible for reporting patient results:

Print Name	Signature	Date

Signature(s) of those responsible for personnel and testing:

_____ _____

Signature Date

_____ _____

Signature Date

_____ _____

Signature Date

URICULT QUALITY CONTROL RECORD*

*This quality control record is to be used by our customers who are reporting **COLONY COUNT**.

Additional documentation and QC is required if you are reporting growth, no growth, or presumptive ID. Refer to our CLIA compliance reference guide.

VISUAL INSPECTION PROCEDURE:

Upon arrival, examine **2 paddles** per box for:

- ✳ Cracked Vials
- ✳ Cracked Media
- ✳ Excessive number of bubbles
- ✳ Unequal filling of paddles
- ✳ Freezing
- ✳ Contamination
- ✳ Discoloration
- ✳ Media separating from paddle
- ✳ Dehydration
- ✳ Excess moisture

Notify **LifeSign** @ 1-800-526-2125 if any of these deficiencies are noted and document the action taken on the reverse side of this QC record. Record the visual inspection

Record the visual inspection results on the form below.

Remove the Certificate of Analysis form from the package insert and attach it to this QC record.

Date Uricults Received	Lot Number	Expiration Date	Visual Inspection Results. Pass or Fail	Removed and attached Certificate of Analysis	Initials and date