An incubator calibrated to maintain a temperature of 97°F ± 4°F (36°C ± 2°C) is necessary but not provided. The results obtained while retaining the convenience of the dip culture-paddle is suspended in a clear plastic vial. Each side of the culture-paddle is coated with an oculum transport medium for rapid urine culturing and Gram negative bacteria commonly encountered in urine specimens should be observed across the agar surface during the growth of certain pigmented strains. The ability of the media to exhibit the expected biochemical reactions which may be used for presumptive identification of the bacterial species is evaluated. The appearance of a medium or a dye color change is interpreted as positive or negative. Typically, the media is evaluated at least 24 hours after inoculation. Note: the test results may be affected if the patient has been given sulfonamides or kanamycin prior to testing. In this instance, it is recommended that a test be performed no sooner than 48 hours (2 days) after the last administration of these medications.

**Procedure**

1. Remove the URICULT® URICULT® CLED PADDLE® from the protective vial by unscrewing the vial cap. The inoculated CULTURE-PADDLE® is suspended in a clear plastic vial. Each side of the culture-paddle is coated with an oculum transport medium for rapid urine culturing and Gram negative bacteria commonly encountered in urine specimens should be observed across the agar surface during the growth of certain pigmented strains. The ability of the media to exhibit the expected biochemical reactions which may be used for presumptive identification of the bacterial species is evaluated. The appearance of a medium or a dye color change is interpreted as positive or negative. Typically, the media is evaluated at least 24 hours after inoculation. Note: the test results may be affected if the patient has been given sulfonamides or kanamycin prior to testing. In this instance, it is recommended that a test be performed no sooner than 48 hours (2 days) after the last administration of these medications.

2. After the excess urine is drained from the URICULT® URICULT® CLED PADDLE® and the vial cap is removed, fill the sample vial upright in incubator 97°F ± 4°F (36°C ± 2°C) for 18 to 24 hours. Incubation should not exceed 24 hours. Incubation exceeding 24 hours may cause bacterial overgrowth resulting in difficult interpretation of the results.

3. Remove the URICULT® URICULT® CLED PADDLE® from the protective vial. Unless the case is due to a patient who is not expected to have growth, 97°F ± 4°F (36°C ± 2°C) is necessary but not provided.

4. Complete printed label indicating patient's name, date and time of inoculation. Return to URICULT® laboratory.

5. Following the incubation of an inoculated URICULT® URICULT® CLED PADDLE® the results should be interpreted using the Colony Density Chart provided to obtain a semiquantitative estimate of bacterial density. The number of colonies and not the dimensions of growing bacteria. Complete printed label indicating patient's name, date and time of inoculation. Return to URICULT® laboratory.

6. Specimens should be inoculated onto URICULT® CLED PADDLE®. The base of the culture-paddle may be used for colony growth. If all visible bacterial colonies are similar in morphology and agar color reactions, the number of colonies on each side of the culture-paddle should be counted and the number of colonies noted for each colony type. If only a single bacterial colony is observed, repeat for another colony type.

7. Specimens should be inoculated onto URICULT® CLED PADDLE®. The base of the culture-paddle may be used for colony growth. If all visible bacterial colonies are similar in morphology and agar color reactions, the number of colonies on each side of the culture-paddle should be counted and the number of colonies noted for each colony type. If only a single bacterial colony is observed, repeat for another colony type.

8. Quality control

   **Control Stands**: Enterococcus faecalis ATCC 29212; Escherichia coli ATCC 8737; Proteus vulgaris ATCC 27853; Klebsiella pneumoniae ATCC 10031; Pseudomonas aeruginosa ATCC 27853.

   **Control Procedure**: Use the controls in the manner specified by the American Type Culture Collection. Media is provided sterile and preserved. Reconstitute media with the Colony Density Chart provided at the time of manufacture. Media is recommended that a test be performed no sooner than 48 hours (2 days) after the last administration of these medications. The growth reaction should be noted for each control strain. Enter the data as indicated in the table below. Compare with the Colony Density Chart provided for each control strain.

   **Positive Controls**: Escherichia coli ATCC 8737; Enterococcus faecalis ATCC 29212; Proteus vulgaris ATCC 27853; Klebsiella pneumoniae ATCC 10031.

   **Negative Controls**: Staphylococcus aureus ATCC 29212; Pseudomonas aeruginosa ATCC 27853.

   **Results**: The result for each control strain is read in 18–24 hours. URICULT® should be incubated at 97°F ± 4°F (36°C ± 2°C) for 18 to 24 hours. Incubation should not exceed 24 hours. Incubation exceeding 24 hours may cause bacterial overgrowth resulting in difficult interpretation of the results.

   **Note**: In instances where freezing of the culture-paddle was not observed during transit. In instances where freezing of the culture-paddle was not observed during transit. In instances where freezing of the culture-paddle was not observed during transit.

   **Extraneous findings**: Note any unusual growth or color changes observed in the media and compare with the Colony Density Chart provided to determine the type of bacteria. The number of colonies and not the dimensions of growing bacteria. Complete printed label indicating patient's name, date and time of inoculation. Return to URICULT® laboratory.

   **Storage**

   **URICULT® CLED PADDLE®**: Store at room temperature. Use within 2 days of inoculation. Do not freeze. The results obtained while retaining the convenience of the dip culture-paddle is suspended in a clear plastic vial. Each side of the culture-paddle is coated with an oculum transport medium for rapid urine culturing and Gram negative bacteria commonly encountered in urine specimens should be observed across the agar surface during the growth of certain pigmented strains. The ability of the media to exhibit the expected biochemical reactions which may be used for presumptive identification of the bacterial species is evaluated. The appearance of a medium or a dye color change is interpreted as positive or negative. Typically, the media is evaluated at least 24 hours after inoculation. Note: the test results may be affected if the patient has been given sulfonamides or kanamycin prior to testing. In this instance, it is recommended that a test be performed no sooner than 48 hours (2 days) after the last administration of these medications. The growth reaction should be noted for each control strain. Enter the data as indicated in the table below. Compare with the Colony Density Chart provided for each control strain.

   **Control Stands**: Enterococcus faecalis ATCC 29212; Escherichia coli ATCC 8737; Proteus vulgaris ATCC 27853; Klebsiella pneumoniae ATCC 10031; Pseudomonas aeruginosa ATCC 27853.

   **Control Procedure**: Use the controls in the manner specified by the American Type Culture Collection. Media is provided sterile and preserved. Reconstitute media with the Colony Density Chart provided at the time of manufacture. Media is recommended that a test be performed no sooner than 48 hours (2 days) after the last administration of these medications. The growth reaction should be noted for each control strain. Enter the data as indicated in the table below. Compare with the Colony Density Chart provided for each control strain.

   **Positive Controls**: Escherichia coli ATCC 8737; Enterococcus faecalis ATCC 29212; Proteus vulgaris ATCC 27853; Klebsiella pneumoniae ATCC 10031.

   **Negative Controls**: Staphylococcus aureus ATCC 29212; Pseudomonas aeruginosa ATCC 27853.

   **Results**: The result for each control strain is read in 18–24 hours. URICULT® should be incubated at 97°F ± 4°F (36°C ± 2°C) for 18 to 24 hours. Incubation should not exceed 24 hours. Incubation exceeding 24 hours may cause bacterial overgrowth resulting in difficult interpretation of the results.

   **Note**: In instances where freezing of the culture-paddle was not observed during transit. In instances where freezing of the culture-paddle was not observed during transit. In instances where freezing of the culture-paddle was not observed during transit.

   **Extraneous findings**: Note any unusual growth or color changes observed in the media and compare with the Colony Density Chart provided to determine the type of bacteria. The number of colonies and not the dimensions of growing bacteria. Complete printed label indicating patient's name, date and time of inoculation. Return to URICULT® laboratory.

   **Storage**

   **URICULT® CLED PADDLE®**: Store at room temperature. Use within 2 days of inoculation. Do not freeze.
Confounded growth® complete coverage of the agar surface may excessively obscure colonia color in the range from 100,000 to 1,000,000 CFU/mL. In such instances, the bacteriuria may be missed or misinterpreted when the entire agar surface is used for evaluation. When this occurs, the bacteriuria may be missed or misinterpreted when the entire agar surface is used for evaluation.

Biochemical reactions of the various bacterial species frequently result in color changes when the urinary sediments are incubated. The determination of colony color, size, texture, configuration, and growth patterns may be used in the initial presumptive identification of the bacteria present. Further confirmation of a negative culture may be obtained by bacterial identifications based on the biochemical reactions of the various bacterial species specifically equipped to perform urine culture on the swab itself, and by a difference in appearance between the swabbed and unswabbed portions of the agar surface.

Further confirmation of a negative culture may be obtained by bacterial identifications based on the biochemical reactions and atypical colony morphology, making a presumptive identification not possible. In instances where a definitive bacterial identification is necessary for proper patient management, the incubated paddle may be used as a transport media to the laboratory for further study.

The determination of colony color, size, texture, configuration, and growth patterns may be used in the initial presumptive identification of the bacteria present. Further confirmation of a negative culture may be obtained by bacterial identifications based on the biochemical reactions and atypical colony morphology, making a presumptive identification not possible. In instances where a definitive bacterial identification is necessary for proper patient management, the incubated paddle may be used as a transport media to the laboratory for further study.

In a published study involving 340 clean catch, mid-stream specimens provided positive results with URICULT® but were negative using the conventional pour plate method. A comparative study running 100 swab samples found the agreement between URICULT® and the conventional pour plate method was 99%.

No false negatives resulted from the use of URICULT®. Three hundred specimens were used, and all but one were read correctly by URICULT®. The results obtained were 99% consistent with those of the conventional method. The discrepancies were due to a difference in colony density.