

URICULT CONTROL KIT

Catalog #'s: URI-KIT

USE

This kit is utilized as a quality control procedure for processing Urine Culture specimens using URICULT Urine CULTURE-PADDLES®. The kit provides both positive and negative controls for monitoring URICULT Urine CULTURE-PADDLES® procedures.

SUMMARY AND PRINCIPLES

URICULT Urine CULTURE-PADDLES® are used to detect the presence of bacteria in a urinary tract infection, to identify the microorganism(s) present, and to guide treatment.

URICULT Urine CULTURE-PADDLES® provide effective bacterial detection and presumptive identification in a simple and reliable manner. They are attached to a screw cap. Each side of the CULTURE-PADDLE® is coated with an agar medium suitable for the growth of urinary tract bacteria, and the CULTURE-PADDLE® is suspended in a clear plastic vial.

The CULTURE-PADDLES® are safely isolated in this vial during transport, incubation, storage and handling. Because of the uniform application of agar to the URICULT Urine CULTURE-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.

CONTENTS

Positive Control, Escherichia coli ATCC 25922, >100,000 CFU/ml

Negative Control, Sterile Matrix, No Growth

Rehydration Bottles, 2 x 99 mls

PRECAUTIONS

This kit is for IN VITRO DIAGNOSTIC USE only. Precautions should be taken against the dangers of microbiological hazards. Specimens, containers, and controls should be sterilized after use. Wear suitable protective clothing, gloves, and eye/face protection.

STORAGE INSTRUCTIONS

This product should be stored at 2-8°C and remain in the original packaging. If any deficiencies are observed, notify the manufacturer.

OTHER MATERIAL REQUIRED BUT NOT SUPPLIED

The URICULT Urine CULTURE-PADDLE® is needed for procedures involving the use of this product.

PROCEDURE

Note: Use the following procedures for processing both controls.

1. Using the tear slit, open the foil pouch and remove the vial containing the pellet from the foil pouch.
2. Unscrew the cap of the 99 ml PBS diluent.
3. Using aseptic technique, place the pellet in the 99 ml diluent and vortex/mix thoroughly.
4. Remove the URICULT Urine CULTURE-PADDLES® from the protective vial by unscrewing the vial cap.
5. Handling the URICULT Urine CULTURE-PADDLE® by the cap, dip the CULTURE-PADDLE® into the 99 ml diluent containing the rehydrated pellet to fully immerse the agar surfaces.
6. Allow the excess liquid to drain from the URICULT Urine CULTURE-PADDLE®.
7. Replace the inoculated URICULT Urine CULTURE-PADDLE® in its protective vial.
8. Place inoculated URICULT® vial upright in incubator $36^{\circ}\text{C} \pm 2^{\circ}\text{C}$ for 18 to 24 hours. Incubation should not exceed 24 hours. Incubation exceeding 24 hours may cause bacterial overgrowth resulting in difficult interpretation of colony counts and possibly misleading biochemical reactions.
9. Remove URICULT® vial from incubator following incubation period. Compare colony count density on the agar surfaces with the Colony Density Chart provided in the URICULT® kit to obtain a semi-quantitative colony count in CFU/ml of urine. Compare only the number of colonies present, not the size of the colonies or the agar surface area they cover. The colonies on the agar surface may also be observed at this time for morphology and agar color reactions which may be used for presumptive identification of the bacterial growth.
10. Negative cultures may be incubated for an additional 24 hour period, if desired. This will allow for the detection of slow growing bacteria.

EXPECTED RESULTS

Positive Control: The positive control should yield a result of growth of yellow colonies on the CLED medium and growth of purple or metallic green colonies on the EMB medium.

Negative Control: No growth on CLED or EMB mediums.

LIMITATIONS OF THE PROCEDURES

Bacterial identifications based on the biochemical reactions evidenced by URICULT® and colony morphology will result only in a presumptive identification.

Bacterial and colony morphology variation may occur.

Incubation of the inoculated URICULT Urine CULTURE-PADDLE® at $36^{\circ}\text{C} \pm 2^{\circ}\text{C}$ should not exceed 48 hours. Inoculated paddle storage up to 48 hours with caps tightly closed may result in inconclusive agar color reactions and atypical colony morphology, making a presumptive identification not possible.