Recom: Growth of translucent, purple or black in color. A green sheen may be observed at the edge of the colony. Swarming of Enterobacter cloacae is evident. The characteristics swarming of Proteus vulgaris and Escherichia coli are not observed.

Principles of the procedure

The goal of the procedure is to achieve reliable test results. Procedure:

1. Remove the URICULT® from the protective vial, closing the screw cap. The inoculated CULTURE-PADDLE is protected.
2. Inoculate each bacterial suspension onto a separate URICULT®. Place the plate of this culture on the agar surface. Pour the suspension from the suspension bottle over the agar surfaces. Blot the plate on absorbent paper if desired. Remove URICULT® from the agar surface and incubate at 35°C for 18–24 hours. URICULT® should be transported to a laboratory for incubation and/or interpretation.
3. The laboratory should inspect the inoculated URICULT® specimen at the time of manufacture. Media stability to the expiration date.
4. No growth should be observed at the time of manufacture. Media stability to the expiration date.
5. Each specimen should be inoculated onto one URICULT® and incubated for 18–24 hours. Urine CULTURE-PADDLES are for in vitro use.
6. Inserted colonies on inoculated URICULT® are for in vitro use only. Inoculated URICULT® should be transported to a laboratory for incubation and/or interpretation.
7. The laboratory should inspect the inoculated URICULT® specimen at the time of manufacture. Media stability to the expiration date.
8. Place inoculated URICULT® into incubator. Place the inoculated URICULT® out of reach of children. This EMB lot meets the NCCLS Approved Standard for commercially prepared media, as determined by the American Type Culture Collection.

Quality control

The following table lists the expected growth characteristics for the EMB lot:

<table>
<thead>
<tr>
<th>Bacterial Strain</th>
<th>Growth Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Escherichia coli</td>
<td>Growth</td>
</tr>
<tr>
<td>Enterobacter cloacae</td>
<td>Growth</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>Inhibited</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>Growth</td>
</tr>
<tr>
<td>Enterococcus faecalis</td>
<td>Inhibited</td>
</tr>
<tr>
<td>Salmonella typhimurium</td>
<td>Growth</td>
</tr>
<tr>
<td>Proteus vulgaris</td>
<td>Growth</td>
</tr>
<tr>
<td>Enterococci</td>
<td>Inhibited</td>
</tr>
<tr>
<td>Staphylococcus epidermidis</td>
<td>Inhibited</td>
</tr>
<tr>
<td>Lactose fermentation</td>
<td>Positive</td>
</tr>
<tr>
<td>Dipotassium Erythorhodamin</td>
<td>0.13 g/L</td>
</tr>
<tr>
<td>Dipotassium Erythorhodamin</td>
<td>2.0 g/L</td>
</tr>
<tr>
<td>L-Cystine</td>
<td>0.00157 g/L</td>
</tr>
<tr>
<td>Lactose</td>
<td>5.0 g/L</td>
</tr>
</tbody>
</table>

Certificate of Analysis

Uricult® CLED+Polymyxin® EMB + Product No. 1002

Typical formulas

<table>
<thead>
<tr>
<th>Component</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLED+Polymyxin medium</td>
<td>g/L</td>
</tr>
<tr>
<td>Growth of pin point colonies</td>
<td></td>
</tr>
<tr>
<td>No growth</td>
<td></td>
</tr>
</tbody>
</table>

Storage

Store at 7°C ± 2°C. This product is sterile.

Procedures

1. Prepare separate suspensions of the following organisms:
   - Escherichia coli ATCC 25922
   - Enterococcus faecalis ATCC 29212
   - Salmonella typhimurium ATCC 14028
   - Proteus vulgaris ATCC 27853
   - Staphylococcus aureus ATCC 25923

2. Inoculate each bacterial suspension onto a separate URICULT®. Place the plates of this culture on the agar surface. Pour the suspension from the suspension bottle over the agar surfaces. Blot the plates on absorbent paper if desired. Remove URICULT® from the agar surface and incubate at 35°C for 18–24 hours. URICULT® should be transported to a laboratory for incubation and/or interpretation.

3. The laboratory should inspect the inoculated URICULT® specimen at the time of manufacture. Media stability to the expiration date.

4. No growth should be observed at the time of manufacture. Media stability to the expiration date.

5. Each specimen should be inoculated onto one URICULT® and incubated for 18–24 hours. Urine CULTURE-PADDLES are for in vitro use only.

6. Inserted colonies on inoculated URICULT® are for in vitro use only. Inoculated URICULT® should be transported to a laboratory for incubation and/or interpretation.

7. The laboratory should inspect the inoculated URICULT® specimen at the time of manufacture. Media stability to the expiration date.

8. Place inoculated URICULT® into incubator. Place the inoculated URICULT® out of reach of children. This EMB lot meets the NCCLS Approved Standard for commercially prepared media, as determined by the American Type Culture Collection.

Quality control

The following test procedure is recommended:

1. Prepare separate suspensions of the following organisms:
   - Escherichia coli ATCC 25922
   - Enterococcus faecalis ATCC 29212
   - Salmonella typhimurium ATCC 14028
   - Proteus vulgaris ATCC 27853

2. Inoculate each bacterial suspension onto a separate URICULT®. Place the plates of this culture on the agar surface. Pour suspensions from the suspension bottle over the agar surfaces. Blot the plates on absorbent paper if desired. Remove URICULT® from the agar surface and incubate at 35°C for 18–24 hours. URICULT® should be transported to a laboratory for incubation and/or interpretation.

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8. Place inoculated URICULT® into incubator. Place the inoculated URICULT® out of reach of children. This EMB lot meets the NCCLS Approved Standard for commercially prepared media, as determined by the American Type Culture Collection.
The Colony Density Chart allows the reporting of colony counts of bacteriuria concentrations as low as 1,000 CFU/mL of urine.

At the end of the incubation period, check the agar surfaces of the culture-paddles. If there is a significant difference in the number of colonies on the two sides of each culture-paddle, it is necessary to perform a count-match-up procedure and report the highest colony count.

In instances where the inoculated paddle cannot be incubated up to 48 hours, following initial storage up to 48 hours at elevated temperatures, the paddle should be returned to 45°F...77°F (7°C...25°C) for storage up to an additional 48 hours. Following storage at 45°F...77°F (7°C...25°C) for a total of 96 hours, paddles should be inserted into the device. Paddles stored under these conditions will not contribute to colony count match-up errors or growth.

For the prevention of colony growth, if all visible bacterial colonies are similar in size and appearance, it is necessary to perform a count-match-up procedure and report the highest colony count.

References


Expected values

<table>
<thead>
<tr>
<th>Colony count (CFU/mL)</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 10,000 CFU/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>10,000–100,000 CFU/mL</td>
<td>Doubtful</td>
</tr>
<tr>
<td>Greater than 100,000 CFU/mL</td>
<td>Positive</td>
</tr>
</tbody>
</table>

Explanation of symbols

- E coli
- Bacteriuria
- Culture-Paddle
- Colony count
- Temperature limitation
- Use by

Performance characteristics

URICULT® disposable CULTURE-PADDLES are indicated for the quantitation of colony counts of bacteriuria concentrations as low as 1,000 CFU/mL of urine.
Written by: Jauri Outi, Teir Ann-Marie, Riikonen Tiina

Date dd.mm.yyyy (UTC) Justification Electronically signed by

08.01.2018 15:41:12 Approved Talja Katri (taljka)