Non selective chromogenic medium for the isolation, differentiation and enumeration of urinary tract pathogens

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1. INTENDED USE

Uri Select™4 is a non-selective chromogenic agar medium for the isolation, differentiation and enumeration of urinary tract pathogens. Uri Select™4 allows for the differentiation and immediate identification of Escherichia coli, Enterococci spp. and Proteus mirabilis and presumptive identification of some other urinary pathogens, in particular KESC group Enterobacteria (Klebsiella, Enterobacter, Serratia and Citrobacter) and PMP (Proteus-Morganella-Providencia) group.

2. SUMMARY AND EXPLANATION OF THE TEST

Urinary tract infections (UTIs) are among the most common bacterial infections and account for a significant part of the workload in clinical microbiology laboratories. Escherichia coli, Enterococci, the Klebsiella-Enterobacter-Serratia (KES) and the Proteus-Morganella-Providencia groups are frequently encountered organisms in urinary tract infections (UTI). Staphylococcus saprophyticus and Streptococcus agalactiae may also be isolated from females, although less frequently.

Due to the different antimicrobial susceptibility patterns of the microorganisms involved, identification to the species level is necessary for effective antimicrobial therapy. The laboratory must quantify culture results to determine the clinical relevance of a microbial isolate.

Uri Select™4 is a non-selective chromogenic medium for the isolation and counting of all urinary tract microorganisms:

- **Immediate identification** of the bacteria most often responsible for urinary tract infections, namely Escherichia coli, Proteus mirabilis, and enterococci via demonstration of enzyme activities;
- **Presumptive identification** of some other urinary pathogens, in particular KESC group Enterobacteria (Klebsiella, Enterobacter, Serratia and Citrobacter) and PMP (Proteus-Morganella-Providencia) group.

3. PRINCIPLES OF THE PROCEDURE

Uri Select™4 consists of a rich nutritive base combining different peptones and tryptophan as well as a chromogenic mix which enable the detection of activities of specific enzymes, thus assuring the differentiation of certain species or certain groups of organisms, with only a minimum of confirmatory tests.

The high concentration of agar prevents the swarming of Proteus.

Appearance of the various enzyme activities:

- **Direct examination**
  - After incubation at 35-37°C for 18 to 24 hours, observe the color of the colonies
    - β-galactosidase: Pink colonies,
    - β-glucosidase: Turquoise-blue colonies,
    - Both β-galactosidase and β-glucosidase: Blue-purple colonies,
    - Tryptophan Deaminase (TDA): Brownish halo surrounding orange-brown colonies.

- **After reagent addition**
  - To detect tryptophanase activity (indole production), deposit one drop of Kovac’s (or James or DMACA) reagent directly onto a well-isolated colony (see Section 7. Procedure).

<table>
<thead>
<tr>
<th>Indole test</th>
<th>Positive reaction</th>
<th>Negative reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kovac’s reagent</td>
<td>Reagent turns pink within no more than 15 seconds</td>
<td>No shift in coloration</td>
</tr>
<tr>
<td>James reagent</td>
<td>Colony turns red within no more than 15 seconds</td>
<td></td>
</tr>
<tr>
<td>DMACA reagent</td>
<td>Colony turns blue-purple within no more than 2 minutes</td>
<td></td>
</tr>
</tbody>
</table>

4. REAGENTS

4.1. DESCRIPTION

Uri Select™4 (URI4) is available in 3 presentations:

<table>
<thead>
<tr>
<th>Identification on label</th>
<th>Description</th>
<th>Presentation / Preparation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uri Select™4</td>
<td>Box of agar plates</td>
<td>20 x 90mm / Ready to use</td>
</tr>
<tr>
<td>63726</td>
<td>Box of agar plates</td>
<td>100 x 90mm / Ready to use</td>
</tr>
<tr>
<td>63727</td>
<td>Bottle of 500g</td>
<td>500g / Dehydrated</td>
</tr>
<tr>
<td>64694</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Approximate media formulation (g/L)

- Peptones mix: 21
- Silica: 20
- Chromogenic mix: <1
- Tryptophan: 1
- Agar: 16

4.2. STORAGE AND HANDLING REQUIREMENTS
Reagents can be used until the expiry date mentioned on the packaging.

<table>
<thead>
<tr>
<th>Presentation</th>
<th>Conservation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agar plates</td>
<td>+2-8°C, protected from light</td>
</tr>
<tr>
<td>Dehydrated</td>
<td>+15-25°C, carefully sealed bottle in a dry place</td>
</tr>
</tbody>
</table>

The expiry date and the batch number are indicated on the packaging.

Minimize exposure to light before and during incubation, as light may decrease the performances of the medium.

5. WARNING AND PRECAUTIONS
For in vitro diagnostic use.
For healthcare professional use only.

5.1. HEALTH AND SAFETY PRECAUTIONS
- This medium should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Wear appropriate protective clothing, gloves and eye/face protection and handle appropriately with the requisite Good Laboratory Practices.
- Observe aseptic technique and established precautions against microbiological hazards throughout all procedures.
- Dispose of all specimens and material used to perform the test as though they contain an infectious agent. Laboratory, chemical or biohazardous wastes must be handled and discarded in accordance with all local, regional and national regulations.
- For hazard and precaution recommendations related to some chemical components in this medium, please refer to the pictogram(s) mentioned on the labels and the information supplied at the end of instruction for use. The Safety Data Sheet (SDS) is available on www.bio-rad.com.

Contains <0.25% N,N-DimethylFormamide (DMF):
Reproductive toxicant 1B

DANGER

5.2. PRECAUTIONS RELATED TO THE PROCEDURE

5.2.1. PREPARING
- Before use, wait for the ready-to-use plates to stabilize at room temperature (18-30°C).
- Do not use expired reagents.
- Do not use ready-to-use plates if they show any evidence of contamination, drying, cracking or any other sign of deterioration.
- Prolonged exposure of UriSelect™ medium to light may result in reduced recovery and/or coloration of the QC organisms or patient isolates.

5.2.2. PROCESSING
- Perform the test at room temperature (18-30°C).
- Do not change the assay procedure.

6. SPECIMENS
Appropriate collection of microbiology urine specimens has an important influence on the usefulness of culture results. Refer to appropriate guidelines or standards for details in specimen/sample collection and handling procedures.

BIO-RAD
7. PROCEDURE

7.1. MATERIAL PROVIDED

- UriSelect™4 medium

7.2. MATERIALS REQUIRED BUT NOT PROVIDED

- 10 µL calibrated loops,
- Indole test reagent: Kovac’s, James or DMACA reagent,
- 35-37°C incubator,
- Waste container (for contaminated waste),
- Blotting paper disc
- Optional materials not provided: Quality control organisms.

7.3. REAGENTS PREPARATION (IF APPLICABLE)

Preparation of the dehydrated medium (64694): Homogenize the powder before use. Suspend 56.8 g in one liter of distilled water, stirring continuously until obtaining a homogeneous suspension (about 10 min.). Bring to boil, stirring frequently, until optimal dissolution of the agar. If necessary, adjust the pH to 7.3. Sterilize by autoclaving at 120°C during 15 min. Pour in 90mm Petri dishes (approximate volume of 18-22 mL/dish).

7.4. ASSAY PROCEDURE

1) Use a standard 10 µL bacteriological loop.
2) Hold the loop vertically and submerge it in the urine.
3) Deliver the urine onto the agar by streaking the loop once along one radius of the dish (a).
4) Starting at the top of the deposit, without reloading the loop, streak at closely spaced intervals over the entire surface of the agar, perpendicularly to the initial streak (b).
5) Incubate the plate in a 35-37°C incubator for 18 to 24 hours.

7.5. QUALITY CONTROL

Quality control testing must be performed in accordance with local, state, and federal regulations or accreditation requirements and your laboratory’s standard quality control procedures. The performances of UriSelect™4 medium can be controlled with the following strains (results obtained after 18 to 24 hours of incubation at 35-37°C):

<table>
<thead>
<tr>
<th>STRAINS</th>
<th>COLONIES COLOR on UriSelect™4</th>
<th>CHARACTERISTICS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>β-GALACTOSIDASE</td>
</tr>
<tr>
<td>Escherichia coli ATCC 25922</td>
<td>PINK</td>
<td>+</td>
</tr>
<tr>
<td>Enterococcus faecalis ATCC 29212</td>
<td>TURQUOISE BLUE</td>
<td>-</td>
</tr>
<tr>
<td>Klebsiella pneumoniae ATCC 13883</td>
<td>BLUE-PURPLE</td>
<td>+</td>
</tr>
<tr>
<td>Proteus mirabilis ATCC 25933</td>
<td>ORANGE-BROWN with a brownish halo</td>
<td>-</td>
</tr>
<tr>
<td>Providencia stuartii ATCC 33672</td>
<td>ORANGE-BROWN with a brownish halo</td>
<td>-</td>
</tr>
<tr>
<td>Staphylococcus aureus ATCC 25923</td>
<td>WHITE</td>
<td>-</td>
</tr>
</tbody>
</table>

7.6. INTERPRETATION OF THE RESULTS

7.6.1. COUNTING

After incubation for 18 to 24 hours at 35-37°C, interpretation of the results should be performed in the light of the patient’s history, source of the specimen, clinical manifestations, urinary leukocytes count, microorganism identification and colony counts.

Counting of well-isolated colonies on UriSelect™4 should be possible up to 10⁴ CFU/mL of urine. Above that concentration, presence of confluent colonies does not result in accurate counts.
7.6.2. IDENTIFICATION

Identify the microorganism based on the color of the colonies as described on the following diagram:

- **PINK COLONIES**
  - ß-Galactosidase activity suggests presence of *E. coli*, to be confirmed by testing for indole production.
  - Deposit one drop of an indole test reagent on a well-isolated pink colony and interpret as described in paragraph 3.
  - For mixed cultures: deposit 1 to 3 morphologically homogeneous colonies on a blotting paper disc. Then, add one drop of an indole test reagent, interpret for indole production accordingly.
  - Indole production indicates the microorganism is *E. coli* (However, a small proportion of *E. coli* strains are indole Θ).
  - In absence of indole production, identify the microorganism using a conventional method.
  - More than 99% of *E. coli* strains produce a ß-galactosidase activity.
  - A small proportion of microorganisms other than *E. coli* produces ß-galactosidase and can yield pink colonies on UriSelect™4.
  - Some of these microorganisms are rarely responsible for UTIs (*Salmonella, Shigella*); the others can cause UTIs but are indole Θ (*Citrobacter freundii*) and produce smaller colonies (*S. saprophyticus*).

- **TURQUOISE BLUE COLONIES**
  - ß-Glucosidase activity: small bright turquoise blue colonies (0.5 to 1.5 mm in diameter) determined as Gram positive cocci by examining under a microscope are enterococci. If any of these characteristics are not exhibited, identify the microorganism using a conventional method.
  - Among streptococci, only enterococci express ß-glucosidase positivity by producing colonies exhibiting a bright turquoise blue color.
  - Very pale blue colonies of cocci are not necessarily enterococci and should be studied using a conventional identification method (they can correspond to group A or B streptococci).
• **BLUE-PURPLE COLONIES**
  Both β-galactosidase and β-glucosidase activities generate large blue-purple colored colonies (2.0 to 3.0 mm in diameter). Determined as Gram negative bacilli, it suggests a microorganism which probably belongs to the KESC group (Klebsiella, Enterobacter, Serratia, or Citrobacter). Identify the microorganism using a conventional method.
  In general, bacteria from KESC group present both β-galactosidase and β-glucosidase activities and produce blue-purple colonies. However, some strains of this group may have a weak β-galactosidase activity: the color of the colonies is then intermediary between blue-purple and turquoise blue.
  *Citrobacter diversus* produces blue-purple, indole + colonies.

• **ORANGE-BROWN COLONIES (with a brownish halo)**
  Tryptophan deaminase activity (TDA) indicates a microorganism of the PMP group (Proteus-Providencia-Morganella). Testing for indole production allows differentiating the *Proteus mirabilis* from the rest of the group.
 Deposit one drop of an indole test reagent directly onto a well-isolated orange-brown colony with a brownish halo, as described in Section 3. “Principle of the procedure”.
  For mixed cultures, deposit 1 to 3 morphologically homogeneous colonies on a blotting paper disc. Then, add one drop of an indole test reagent and interpret for indole production accordingly.
  Indole production indicates *Proteus* spp. (other than *P. mirabilis*), *Providencia* spp. or *Morganella* spp. Identification of the microorganism should be performed using a conventional method.
  Absence of indole production indicates the microorganism is *Proteus mirabilis* (*Proteus penneri*, which is rarely found, is also indole ⊕ and TDA ⊕).
  Some *Proteus vulgaris* and *Providencia rettgeri*, having a β-glucosidase activity, produce blue-green or green colonies with a brownish halo. They can be identified by a positive indole test.

• **WHITE, OTHER COLOR or COLORLESS colonies**
  Identify the microorganism using a conventional method.

7.6.3. Comments
  i. Tests for catalase, oxidase and latex agglutination, can be performed directly on colonies isolated on **UriSelect™4**.
  ii. Conventional identification procedures and antibiotic susceptibility tests can be performed directly on colonies harvested from **UriSelect™4**.
  iii. During the reconstitution of the dehydrated medium, some residual grains can sometimes remain insoluble. The presence of such grains does not affect the cultural performances of the medium.

8. **TEST LIMITATIONS**
  • A small proportion of staphylococci strains may not grow on **UriSelect™4** within 24 hours.
  • A limited number of yeast strains may not grow on **UriSelect™4**.
  • When the concentration of organisms is suspected to be more than 10⁷/mL, and in order to obtain well-isolated colonies, it is recommended to inoculate two **UriSelect™4** plates consecutively without reloading the loop, or to dilute urine sample before inoculating.
  • **UriSelect™4** prepared from the dehydrated medium: when the incubation of the agar plates lasts more than 24 hours, a bluish sheen can appear on some strains of *Staphylococcus aureus*.

9. **EXPECTED VALUES**
  UTIs are among the most common bacterial infections. Moreover UTIs have become the most common hospital-acquired infection, accounting for 35% of nosocomial infections, and they are the second most common cause of bacteremia in hospitalized patients (2-3).
  In many clinical laboratories, urine cultures are the most common type of culture, accounting for 24%-40% of submitted cultures and 80% of these urine cultures are submitted from the outpatient setting.
  The bacteria observed vary depending on factors such as prior hospital stay and/or the associated pathologies (see table).
  For example, in the external clinical evaluation of **UriSelect™4**, the overall prevalence of UTIs found by both routine and chromogenic methods was 75.8% (589/777). Among the isolates, a predominance of *E.coli* strains were detected (43.3% (351/811)), followed by *Enterococcus faecalis* strains which were detected at 19.2% (156/811).
10. PERFORMANCE CHARACTERISTICS

10.1. PRECISION STUDY
A panel of nine strains was tested in duplicate by two different operators. Three different batches of UriSelect™ 4 were tested for repeatability on cultural performances (growth and coloration of colonies). All tests conformed to expected results.

10.2. CLINICAL PERFORMANCES
A prospective clinical study [10] has been conducted on 777 fresh urine samples, including both midstream urines and catheter specimens of urine: 405 urine samples (52.1%) were from hospital patients and 372 (47.9%) were referred from general practitioners. They were selected if organisms were observed or if samples contained >200 white blood cell/mm³ as determined by routine microscopy.

1µL of each sample was cultured in duplicate using a semi quantitative culture method, on UriSelect™ 4 and CLED (Cystine Lactose Electrolyte Deficient) media in parallel. The reading and interpretation of the results have been done following manufacturer’s instructions.

Of the 777 samples tested, 589 urine samples yielded potentially significant growth (≥50 colonies) were studied according their morphology and colony color and identified using biochemical methods.

Overall performances

<table>
<thead>
<tr>
<th></th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
<th>% Overall Agreement with 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>UriSelect™ 4</td>
<td>733</td>
<td>64</td>
<td>797</td>
<td>91.6% [89.5% - 93.4%]</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>10</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>737</td>
<td>74</td>
<td>811</td>
<td></td>
</tr>
</tbody>
</table>

10.3. SPECIFICITY
This study demonstrated that UriSelect™ 4 is useful for the preliminary identification of the most common urinary tract pathogens, helped with a better differentiation of mixed cultures.

<table>
<thead>
<tr>
<th>Species or group</th>
<th>Basis of presumptive ID</th>
<th>Sensitivity of detection</th>
<th>Specificity of coloration</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Escherichia coli</em></td>
<td>Red/pink colonies</td>
<td>97.1%</td>
<td>98%</td>
</tr>
<tr>
<td></td>
<td>Red/pink colonies, indole ⊕</td>
<td>97.1%</td>
<td>100%</td>
</tr>
<tr>
<td><em>Enterococci</em></td>
<td>Small turquoise blue colonies</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><em>PMP group</em></td>
<td>Orange-brown colonies</td>
<td>82.4%</td>
<td>100%</td>
</tr>
<tr>
<td><em>KESC group</em></td>
<td>Blue-purple colonies</td>
<td>100%</td>
<td>92%</td>
</tr>
<tr>
<td><em>S. saprophyticus</em></td>
<td>Small pink colonies</td>
<td>100%</td>
<td>88.9%</td>
</tr>
</tbody>
</table>
The data demonstrate that *UriSelect™4* media allowed for:

1) **The immediate identification** of:
   - *Escherichia coli* with a high degree of specificity (98%). The remainder generated white colonies as a result of the absence of ß-galactosidase activity. Inclusion of an indole test increased the specificity to 100% for *E. coli*, and reliably differentiated *E. coli* strain from *Citrobacter freundii* strain.
   - All enterococci (100%) generated small turquoise blue colonies, easily distinguished from staphylococci (generating also small colonies with other distinguished colorations).
   - All *Proteae* generated a diffuse brown coloration (100%). A negative indole test also proved to be useful for the specific identification of *P. mirabilis*.

2) **The presumptive identification** of:
   - All *Enterobacteriaceae* from the KESC group (100%) generated blue-purple colonies.
   - All *S. saprophyticus* grew well on *UriSelect™4* (100%) generating small pink colonies easily distinguished from other staphylococci strains, which generated white colonies. Only one strain of *Staphylococcus simulans* appeared with similar color decreasing the specificity of identification for *S. saprophyticus* to 88.9%.

10.4. **SENSITIVITY**

Sensitivity of detection of the microorganisms on the *UriSelect™4* and CLED media was evaluated on 589 positive urine samples (yielding a significant growth of ≥50 colonies). The results are shown below. The limitations previously indicated (Section 8.) must be taken into consideration.

<table>
<thead>
<tr>
<th>Organism</th>
<th>Total / Isolation medium</th>
<th>Total strains CLED</th>
<th>UriSelect™4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>737 (90.9%)</td>
<td>797 (98.3%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>74 (9.1%)</td>
<td>14 (1.7%)</td>
</tr>
<tr>
<td><strong>Total strains recovered</strong></td>
<td>811 obtained from different media</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total strains not recovered</strong></td>
<td>-</td>
<td>74 (9.1%)</td>
<td>14 (1.7%)</td>
</tr>
<tr>
<td>Acinetobacter spp</td>
<td>8</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>Aerococcus viridans</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Candida spp</td>
<td>6</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Citrobacter diversus</td>
<td>6</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Citrobacter freundii</td>
<td>11</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>Enterobacter aerogenes</td>
<td>5</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Enterobacter cloacae</td>
<td>14</td>
<td>14</td>
<td>13</td>
</tr>
<tr>
<td>Enterococcus faecalis</td>
<td>156</td>
<td>119</td>
<td>155</td>
</tr>
<tr>
<td>Enterococcus faecium</td>
<td>22</td>
<td>20</td>
<td>21</td>
</tr>
<tr>
<td><em>Escherichia coli</em></td>
<td>351</td>
<td>344</td>
<td>347</td>
</tr>
<tr>
<td>Klebsiella oxytoca</td>
<td>24</td>
<td>21</td>
<td>24</td>
</tr>
<tr>
<td>Klebsiella pneumoniae</td>
<td>68</td>
<td>61</td>
<td>68</td>
</tr>
<tr>
<td>Morganella morganii</td>
<td>12</td>
<td>9</td>
<td>12</td>
</tr>
<tr>
<td>Proteus mirabilis</td>
<td>54</td>
<td>49</td>
<td>53</td>
</tr>
<tr>
<td>Proteus penneri</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Proteus vulgaris</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Providencia stuartii</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>20</td>
<td>17</td>
<td>19</td>
</tr>
<tr>
<td>Serratia spp</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>8</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>Staphylococcus epidermidis</td>
<td>10</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>Staphylococcus saprophyticus</td>
<td>8</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>Other coagulase negative staphylococci</td>
<td>9</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>Stenotrophomonas maltophilia</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Streptococcus agalactae</td>
<td>8</td>
<td>8</td>
<td>8</td>
</tr>
</tbody>
</table>

(1) The sensitivity of *UriSelect™4* medium was high with 98.3% when CLED recovered only 90.9% of the strains. The principal reason for the poor performances of CLED was the difficulty to sometimes detect several strains in mixed cultures.

Distribution of isolated species was characterized by a predominance of *Enterobacteriaceae* strains, with a large majority of *E. coli* (43%).

(2) It was notable that the biggest difference between most of strains isolated on *UriSelect™4* medium was due to the detection of enterococci. *UriSelect™4* promoted the additional growth of 30.3% of these strains of enterococci. On this medium, small colonies, with a turquoise blue color were easily distinguished within mixed culture, whereas they were frequently masked on CLED medium by larger colonies of Gram Θ species.

(3) The unidentified *E. coli* strains were β-galactosidase negative and produced white colonies.
Three strains of *Staphylococcus epidermidis* were not recovered on UriSelect™4. In contrast, all *S. saprophyticus* and *S. aureus* grew well. UriSelect™4 was useful for the detection of *S. saprophyticus* because they generated small pink colonies (other staphylococci produce white colonies, except one strain of *S. simulans*).

As previously noticed, the poor performances of CLED in detecting strains when present in mixed culture were observed: only 131 strains (78%) out of the 168 (28.5%) urine samples yielded a mixture of at least 2 strains were detected, whereas 166 strains (99%) were recovered on UriSelect™4.

Moreover, of from 51 samples yielding a growth of at least 3 distinct strains, only 22 cultures (43%) showed the 3 strains on CLED medium, when 47 cultures (92%) easily distinguished 3 types of colonies on UriSelect™4.

<table>
<thead>
<tr>
<th>Number of strains isolated</th>
<th>CLED</th>
<th>UriSelect™4</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>453</td>
<td>418</td>
</tr>
<tr>
<td>2</td>
<td>109</td>
<td>119</td>
</tr>
<tr>
<td>3</td>
<td>22 (43%)</td>
<td>47 (92%)</td>
</tr>
<tr>
<td>Mixed culture</td>
<td>131 (78%)</td>
<td>166 (99%)</td>
</tr>
</tbody>
</table>

### 10.5. RECOVERY STUDY

To determine the percent recovery for the UriSelect™4 medium, a panel of the most common urinary tract pathogens - *E. coli*, *Enterococcus*, *P. mirabilis*, *S. aureus* and *K. pneumoniae* - was tested at varying dilutions. For each strain, a 0.5 McFarland suspension was prepared. Series of 10-fold serial dilutions in saline were carried out and inoculated onto UriSelect™4. The plates were incubated at 35-37°C in ambient air and read at 18-24 hours. The color and number of colonies were recorded. Data showed that the minimum concentration of most urinary tract pathogens reliably detected by UriSelect™4 is $10^3$ CFU/mL.

### 10.6. ENUMERATION

A panel of the most common urinary tract pathogens was tested at varying dilutions from $10^3$ to $10^7$ CFU/mL of urine to cover the possible range of concentration found in routine testing. For each strain to be tested, a 0.5 McFarland suspension was prepared. A series of 10-fold serial dilutions in saline were carried out and inoculated 10 times onto UriSelect™4. The plates were incubated at 35-37°C ambient air and read at 18-24 hours. The color and number of colonies were recorded: it was possible to count isolated colonies up to the concentration of $10^4$ CFU/mL of urine. Above that concentration, presence of confluent colonies does not result in accurate counts.

### 11. BIBLIOGRAPHY REFERENCES


Dispose of contents/container in accordance with local/regional/national/international regulations.

(P) Peligro
Puede perjudicar la fertilidad o dañar al feto.
Llevar guantes/prendas/gafas/máscara de protección.
EN CASO DE exposición manifiesta o presunta: Consultar a un médico. Eliminar el contenido o el recipiente conforme a la reglamentación local/regional/nacional/internacional.

(FI) Vaara
Saatavaa heikentää hedelmällisyyttä tai vauroittaa sikiötä.

(FR) Danger
Peut nuire à la fertilité ou au foetus.
Utiliser l’équipement de protection individuel requis.
EN CAS d’exposition prouvée ou suspectée: consulter un médecin. Eliminer le contenu/recipient conformément à la réglementation locale/régionale/nationale/internationale.

(GR) Κινδύνος
Μπορεί να βλάψει τη γονιμότητα ή το έμβρυο.
Χρησιμοποιήστε μέσα ατομικής προστασίας όταν απαιτείται. ΣΕ ΠΕΡΙΠΤΩΣΗ έκθεσης ή πειθαρχίας έκθεσης Συμβουλευτείτε/Επικοινωνήστε για πρώτο. Απορρίψτε τα περιεχόμενα/σύμβια σύμφωνα με τους τοπικούς/εθνικούς/διεθνείς κανόνες.

(HR) Opasnost
Može štetno djelovati na plodnost ili naškoditi nerodenom djetu.

(HU) Veszély
Károsíthatja a termékenységet vagy a születendő gyermeket.
(IT)
Pericolo
Può nuocere alla fertilità o al feto.
Utilizzare il dispositivo di protezione individuale richiesto. IN CASO di esposizione o di possibile esposizione, consultare un medico. Smaltire il prodotto/recipiente in conformità con le disposizioni locali / regionali / nazionali / internazionali.

(LT)
Pavojinga
Gali pakenkti vaisingumui arba negimusiam vaikui.

(NL)
Gevaar
Kan de vruchtbaarheid of het ongeborne kind schaden.
De nodige persoonlijke beschermingsuitrusting gebruiken. NA (mogelijke) blootstelling: een arts raadplegen. De inhoud en de verpakkning verwerken volgens de plaatselijke/regionale/nationale/internationale voorschriften.

(NO)
Fare

(PL)
Niebezpieczeństwo
Może działać szkodliwie na płodność lub na dziecko wIonie matki.

(PT)
Perigo
Pode afectar a fertilidade ou o nascituro.
Usar o equipamento de protecção individual exigido. EM CASO DE exposição ou suspeita de exposição: consulte um médico. Eliminar o conteúdo/recipiente de acordo com a legislação local/regional/nacional/internacional.

(RO)
Pericol
Poate dăuna fertilității sau fătului.
Utilizați echipamentul de protecție individuală conform cerințelor. ÎN CAZ DE expunere sau de posibilă expunere: consultați medicul. Aruncăți conținutul / containerul în acord cu regulamentele locale / regionale/nationala/internationale.

(SE)
Fara
Kan skada fertiliteten eller det ofödda barnet.

(SI)
Nevarno
Lahko škoduje plodnosti ali nerojenemu otroku.

(SK)
Nebezpečenstvo
Môže spôsobiť poškodenie plodnosti alebo nenarozeného dieťaťa.
Používajte predpísané osobné ochranné prostriedky. Po expozícii alebo podezreli z nej: Vyťažte lekársku pomoc/storistlovc. Zneškodnite obsahu / obalu v súlade s miestnymi/oblasťnými/národnými/medzinárodnými nariadeniami.
Warning
May cause damage to organs through prolonged or repeated exposure.
Do not breathe dust. Get medical advice/attention if you feel unwell. Dispose of contents/container in accordance with local/regional/national/international regulations.
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(LT)
Atsargiai
Geli pakenkti organams, jeigu medžiaga velkia ilgai arba kartotinai.
Nežvelkite dulkių, pasijutus blogelė, kreiptis į gydytoją.
Turinčius iššitą išsikišti - šaltinti pagal vietines / regionines / nacionalines / tarptautines taisykles.

(NL)
Waarschuwing
Kan schade aan organen veroorzaken bij langdurige of herhaalde blootstelling.

(NO)
Advarsel
Kan forårsake organskader ved lengre eller gjentatte eksponering.

(PL)
Uwaga
Może powodować uszkodzenie narządz poprzez długotrwałe lub narażenie powtarzane.

(PT)
Atenção
Pode affectar os órgãos após exposição prolongada ou repetida.
Não respirar as poeiras. Em caso de indisposição, consulte um médico. Eliminar o conteúdo/recipient de acordo com a legislação local/regional/nacional/internacional.

(RO)
Atenție
Poate provoca leziuni ale organelor în caz de expunere prelungită sau repetată.

(SE)
Warning
Kan orsaka organskador genom lång eller upprepad exponering.
Inandas inte damm. Sök läkarjälp vid obehag.
Innehälet / behållaren avfallshanteras enligt lokala / regionala / nationella / internationella föreskrifter.

(SI)
Pozor
Lahko škoduje organom pri dolgotrajni ali ponavljajoči se izpostavljenosti.

(SK)
Pozor
Môže spôsobiť poškodenie orgánov pri dlhšej alebo opakovanej expozícií.
Nevďchajte prach. Ak pocitáte zdravotné problémy, vyhľadajte lekársku pomoc/starostlivosť.
Zneškodnite obsah/obal v súlade s miestnymi/ oblasťnymi/národnými/medzinárodnými nariadeniami.
Plates must be stored protected from light.

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