

Intended use

A dipslide culture method for diagnosing urinary tract infections by demonstrating microbes in urine.

Principles of the procedure

The Uricult dipslide system is based on two agar media. One side of the plastic slide is covered with green CLED medium and the other with red-brown MacConkey medium for detection of microbes causing urinary tract infections.

The CLED medium is intended for determining the total bacterial count. On the MacConkey medium, bile salts prevent the growth of gram-positive organisms other than enterococci which may grow as pinpoint colonies. This medium supports the growth of gram-negative organisms.

Reagents**Contents**

| Uricult | Cat. No. 67404 |
|----------------------|----------------|
| Dipslides | 10 |
| Patient labels | 10 |
| Instructions for use | 1 |

Storage

Store Uricult at 7...25°C protected from draught, temperature fluctuations and light sources. Avoid storage near heat-generating appliances. **Do not allow to freeze.** The expiry date is marked on the box.

Warnings and precautions

Uricult is for **in vitro diagnostic use** only.

Do not use the product beyond the expiry date marked on the box. Wear protective clothing and disposable gloves while handling samples or tests, and wash hands thoroughly afterwards.

Do not use the Uricult if you detect discoloration or dehydration of the agar, separation of the growth media from the plastic slide or evidence of bacterial or fungal growth.

Because any colonies growing on Uricult are actual or potential pathogens, do not touch the growth.

Sample collection and preparation

Ideally, urine for bacterial culture should remain in the bladder for four hours prior to sampling. Urine samples may be obtained by voiding (clean-voided midstream urine), catheterisation or suprapubic aspiration. The sample should be inoculated onto the Uricult slide immediately after collection. The slide should then be returned into its protective tube and the cap closed tightly.

If the urine sample needs to be stored prior to inoculation, it should be maintained refrigerated at 2...8°C no longer than 24 hours.

Uricult test results may be affected if the patient has received anti-infective treatment. The test should not be performed until 48 hours after the final dose of medication.

Procedure

- Unscrew the slide from the tube without touching the agar surfaces.
- Holding Uricult by the cap, dip the slide into freshly voided midstream urine so that the agar surfaces are totally immersed. If the volume of urine is too small for this, the agar surfaces can be wetted by pouring urine on them, followed by tilting to ensure complete wetting.
- Allow excess urine to drain from the slide.
- Blot the last drops on absorbent paper.
- Screw the slide tightly back into the tube.
- Fill in the patient label and attach it to the tube.
- Place the tube upright in an incubator (36±2°C) for 16–24 hours. The tube may also be sent to a laboratory for incubation.
- To obtain a colony count (CFU/ml), remove the slide from the tube and compare the colony density with the model chart provided in the kit.

Note:

- Negative cultures and complicated or catheter-associated UTI samples are recommended to always be incubated for an additional 24 hours to ensure that slow-growing bacteria are detected.
- The inoculated slide may be incubated immediately or stored or transported to a laboratory for incubation and interpretation. Storage or transportation should not exceed 48 hours at 7...25°C, after which Uricult should be incubated at 36±2°C for 16–24 hours. If the slide has been stored or transported for up to 48 hours, only the presence of growth and the colony count should be recorded from it; the colour reaction may be atypical.
- The inoculated slide may be incubated at room temperature for 1–3 days, after which positive cultures may be sent to a specialised laboratory for further investigation⁵. Negative cultures may be incubated for additional 24 hours to detect slow-growing bacteria⁶.

Quality control

Quality control tests are performed on each lot of Uricult dip slides at the time of manufacture. Should the user wish to perform his own quality control, the following procedure is recommended:

- Prepare a 10⁵–10⁸ bacteria/ml suspension of each of the following bacteria in sterile saline:
 - Staphylococcus aureus* ATCC 25923
 - Escherichia coli* ATCC 25922
 - Proteus mirabilis* ATCC 124532.

Use the suspensions to inoculate the Uricult dipslides, using the normal procedure.

- Interpret the results after a 16–48 hour incubation as follows:
 - S. aureus ATCC 25923:** Growth of colonies on the CLED medium only. Colonies ferment lactose, as indicated by the yellow colour of the colonies and the shift towards yellow of the medium.
 - E. coli ATCC 25922:** Growth of yellow colonies with a shift towards yellow of the CLED medium and growth of pink-red colonies on the MacConkey medium.
 - P. mirabilis ATCC 12453:** Growth of translucent colonies with a shift towards blue of the CLED medium and growth of colourless colonies on the MacConkey medium.

Results' interpretation

After incubation of the inoculated slide, the presence of bacteria is evidenced by colonies on the agar surface. Because a colony is the result of the multiplication of a single bacterial cell, the number of colonies indicates the concentration of colony-forming units (CFUs/ml) in the urine sample. The colony count should be determined from the originally green CLED medium by matching the colony density with the model chart it most closely resembles. It is important to compare the number of colonies, not their size.

The low electrolyte concentration of the CLED medium prevents spreading of *Proteus* strains. Bromthymol blue and lactose in the medium allow the detection of lactose-fermenting bacteria. Such lactose-positive strains grow as yellow colonies and turn the medium yellow, whereas lactose-negative strains grow as translucent colonies with no colour change of the medium.

The originally brownish-red, selective MacConkey medium supports the growth of gram-negative bacteria, but even enterococci may grow as pinpoint colonies on the medium⁷. The selectivity is accomplished by bile salts. Lactose-positive bacteria grow as red and lactose-negative bacteria as translucent colonies on the medium.

When the urinary bacterial content is high (≥ 10⁷ CFU/ml), the agar surfaces may become totally covered by confluent growth. This can be misinterpreted as a negative result. Therefore, any surfaces that appear negative should be examined under a reflecting light; absence of reflection indicates confluent growth. A bright light also allows very small colonies to be detected.

A mixture of different bacterial strains on the Uricult is most likely due to contamination of the urine sample.

Limitations of the procedure

Uricult is capable of detecting bacterial concentrations between 10³ and 10⁷ CFU/ml. The model chart allows the determination of colony counts to the nearest power of 10. When the chart is used according to instructions, colony counts show a 99% correlation with the conventional pour plate method⁸.

Expected values

The following values are based on the ECLM-EUG European Urinalysis Guidelines (2000).

| Method of sampling clinical status | Significant colony count (CFU/ml) |
|--|-----------------------------------|
| Midstream, bladder time < 4 hours, symptomatic patient | ≥ 10 ³ |
| Midstream, bladder time > 4 hours | ≥ 10 ⁴⁻⁵ |
| Catheter sample from man | ≥ 10 ³ |
| Catheter sample from woman | ≥ 10 ⁴ |
| Nonsymptomatic bacteriuria | ≥ 10 ⁵ |
| Puncture sample | Any growth |

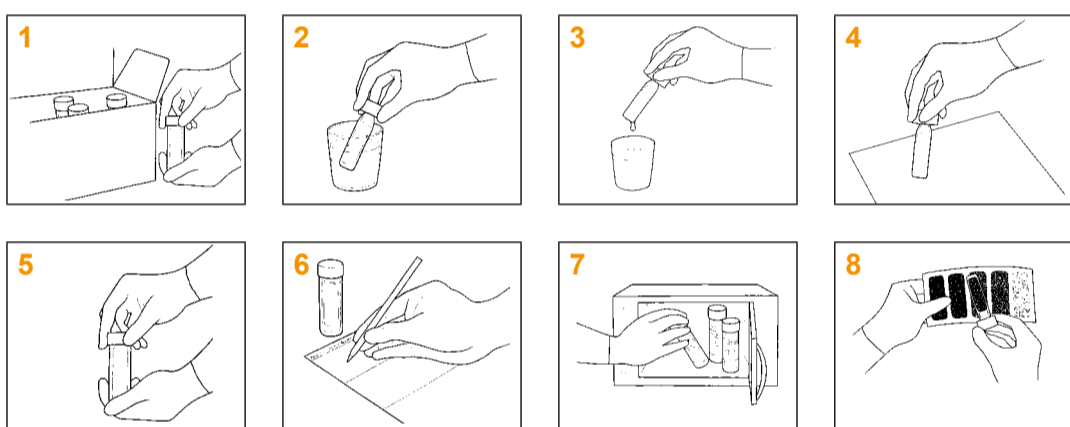
Note: In some cases, bladder urine < 4 hours may express clinically significant colony counts below 10³ CFU/ml.

Performance characteristics**Uricult • CLED medium**

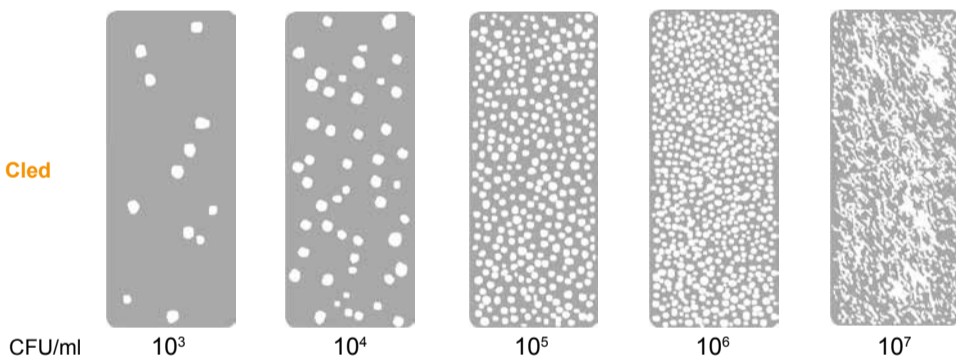
| | | |
|--|-------|---|
| Arnell, G.C. 1970: Detection of bacteriuria at room temperature. Lancet, January 17, pp 119–121 ⁹ | | |
| Number of samples | 140 | Reference method: Pour plate (Nutrient agar) |
| Sensitivity | 100 % | |
| Specificity | 99 % | |
| PPV | 98 % | |
| NPV | 100 % | |

Disposal

- Dispose of contents according to national and local law.
- All patient samples and used components should be handled and disposed of as potentially infectious material.
- Materials of the components:
 - Paper: Instructions for use, patient labels
 - Cardboard: Kit box
 - Plastic: Tubes, caps and dipslides
- When used in accordance with Good Laboratory Practice, good occupational hygiene and the instructions for use, the reagents supplied should not present a hazard to health.



Model Chart • Tableau de référence • Standardbildkarte • Tablas de referencia • Tabela de Referência • Tavola di riferimento • Πρότυπος πίνακας αναφοράς • Modelová tabulka • Referenčna tabela • Modelkort • Avlesningsmal • Tolkningsmall • Mallitaulu



Typical formulation • Formules • Typische Formulierung • Fórmula típica • Fómula típica • Formulazione típica • Τυπική Σύσταση • Typické složení • Sestava gojišč • Agar indhold • Agar sammensetning • Sammansättning • Koostumus

| CLED medium | MacConkey medium |
|--------------------------|-----------------------|
| Peptone 10.0 g/l | Peptone 20.0 g/l |
| Meat extract 3.0 g/l | Lactose 10.0 g/l |
| Lactose 10.0 g/l | Neutral red 0.075 g/l |
| L-Cystine 0.13 g/l | Bile salts 0.8 g/l |
| Bromthymol blue 0.03 g/l | |

Literature • Bibliographie • Literatur • Bibliografía • Referências Bibliográficas • Bibliografia • Βιβλιογραφία • Literatura • Referenser • Litteratur • Kirjallisuus

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- Kass EH: Bacteriuria and the diagnosis of infections of the urinary tract. Archives of Internal Medicine 100: 709–714, 1957.
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- NCCLS Publication M22-A: Quality Assurance Standards for Commercially Prepared Microbiological Culture Media; Approved standard. Volume 10: 14, 1990.
- Ekman et al.: Streptocult- ja Uricult-levyjen käyttö päivystysaikaana. Aesculapius 11–12, 1985.
- Arnell GC: Detection of bacteriuria at room temperature. Lancet, January 17: 119–121, 1970.
- Granato PA: Evaluation of a dip slide device for enumeration of bacteria in urine. Laboratory Medicine Vol. 11, No 4: 246–250, 1980.

Explanation of symbols • Explication des symboles • Zeichenerklärung • Explicación de los símbolos • Explicação de símbolos • Spiegazione dei simboli • Επεξήγηση των συμβόλων • Vysvětlení symbolů • Pojasnila simbolov • Symbolforklaring • Symbolforklaringer • Symbolforklaringer • Symbolien selitykset

| | | | | | |
|---|--|--|---|---|--|
| IVD <i>In vitro</i> diagnostic medical device Dispositif médical de diagnostic <i>in vitro</i> In-vitro-Diagnostikum Producto sanitario para diagnóstico <i>in vitro</i> Dispositivo médico para diagnóstico <i>in vitro</i> Dispositivo medico-diagnostico <i>in vitro</i> Ιατροτεχνολογικό προϊόν που χρησιμοποιείται για διάγνωση <i>in vitro</i> Diagnostický zdravotnícký prostředek <i>in vitro</i> Diagnostická zdravotnícká pomůcka <i>in vitro</i> Medicinsk utstyr til <i>in vitro</i> -diagnostikk Medicinsk utstyr for <i>in vitro</i> -diagnostikk Medicinteknisk produkt avsedd för <i>in vitro</i> -diagnostik In vitro -diagnostiikkaan tarkoitettu lääkinällinen laite | REF Catalogue number Référence du catalogue Bestellnummer Número de catálogo Número de catálogo (n°) Riferimento di Catalogo Αριθμός καταλόγου Katalogovέ číslo Kataloška številka Bestellingsnummer Beställingsnummer Listunumero Tuotenumero | LOT Batch code Code du lot Loscode Código de lote Código de lote Codice di lotto Код партии Stevilka serije Batchkode Lotnummer Satsnummer Eräkoodi | Temperature limitation Limites de température Temperaturbegrenzung Limitación de temperatura Limites de temperatura Limiti di temperatura Περιορισμοί θερμοκρασίας Τεplotné omezení Teplotné rozmedzie Temperaturbegrensning Temperaturbegrensning Temperaturbegrensning Lämpötilarajat | Use by A utiliser jusqu'à Verwendbar bis Fecha de caducidad Utilizar até Utilizzare entro/Scadenza Χρησιμοποιήστε έως Použítelné do Uporabno do Brukes innen Används före Käytettävä ennen | Manufacturer Fabricant Hersteller Fabricante Fabricante Fabricante Κατασκευαστής Vyrobce Proizvajalec Fabrikant Produzent Tillverkare Valmistaja |
| Consult instructions for use Consulter la notice d'utilisation Gebrauchsanweisung lesen Consultense las instrucciones de uso Consultar as instruções de utilização Consultare le istruzioni per l'uso Συμβουλευτείτε τις οδηγίες χρήσης Viz návod k použití Sledi navodilu za uporabo Se bruksanvisningen Se bruksanvisningen Läs bruksanvisningen Katso käyttöohjeita | Sufficient for Suffisant pour Ausreichend für Válido para Suficiente para Sufficiente per Επαρκές για Dostatočné pro Zadovoljivo za Tilstrækkelig til Räckert till Lukumäärä | Protect from draught and temperature fluctuations Conserver à l'abri des courants d'air et des fluctuations de température Vor Zug und Temperatur schwankungen geschützt Proteger de las corrientes de aire y cambios de temperatura Proteger das correntes de ar e variações de temperatura Proteggere da correnti d'aria e variazioni di temperatura Προστατέψτε από ήφραση και μεγάλες μεταβολές θερμοκρασίας Chraňte pred vysišením a kolísaním teploty Zavarujte pred prepihom in temperaturnimi nihanjem Beskyttes mot trekk og temperatursvingninger Undvik drag og temperatursvingninger Suojittava vedolta ja lämpötilan vaihtelulta | | | |

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