

Intended use

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

Principles of the procedure

The Uricult Plus dipslide system is based on three agar media. One side of the plastic slide is covered with green CLED medium and the other with both reddish-brown MacConkey medium and a colourless Enterococcus medium.

The CLED medium is intended for determining the total bacterial count. The MacConkey medium is intended for detecting gram-negative organisms. This medium contains bile salts that prevent the growth of gram-positive organisms other than enterococci which may grow as minute colonies. The selective Enterococcus medium is intended especially for detecting enterococci. Certain group B streptococci may also grow on this medium.

Reagents**Contents**

Uricult Plus	Cat. No. 67465
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 Plus 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 Plus 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 Plus 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.

Samples are usually obtained from clean-voided (mid-stream) urine. Samples for culture may also be obtained by catheterisation or suprapubic bladder aspiration.

The sample should be inoculated onto the Uricult Plus slide immediately after collection. The slide should then at once 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.

Medications (especially antibiotics) may affect the result of the Uricult Plus test. Therefore, 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 Plus by the cap, dip the slide into freshly voided mid-stream 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 Plus 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 investigation⁶. 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 Plus dipslides at the time of manufacture. Should the user wish to perform his own quality control, the following procedure is recommended:

- Prepare a 10³–10⁸ bacteria/ml suspension of each of the following bacteria in sterile saline:
 - Staphylococcus aureus* ATCC 25923
 - Escherichia coli* ATCC 25922
 - Proteus mirabilis* ATCC 12453
 - Enterococcus faecalis* ATCC 29212
- Use the suspensions to inoculate the Uricult Plus dip slides, 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. No growth on the Enterococcus medium.

P. mirabilis ATCC 12453:

Growth of translucent colonies on the CLED medium, with a possibility of blue coloration of the medium. Growth of colourless colonies on the MacConkey medium. No growth on the Enterococcus medium.

Ent. faecalis ATCC 29212:

Growth of yellow colonies on the CLED medium, with yellow coloration of the medium. Growth of minute colonies or no growth at all on the MacConkey medium. Growth of reddish colonies on the Enterococcus 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 some enterococci may grow as pinpoint colonies on the medium⁷. Lactose-positive bacteria grow as red and lactose-negative bacteria as translucent colonies on the medium.

Enterococci and some group B streptococci produce colonies in various shades of red on the Enterococcus medium. As the selectivity of this medium is based on the presence of nalidixic acid, polymyxin and crystal violet, the medium will support the growth of organisms resistant to these antibiotics, including Proteus species from the urine of hospitalised patients. The difference in the size of colonies reduces the likelihood of false interpretations, however.

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 Plus is most likely due to contamination of the urine sample.

Limitations of the procedure

Uricult Plus 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 method¹.

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
Asymptomatic bacteriuria	≥ 10 ⁵
Bladder aspiration sample	Any growth

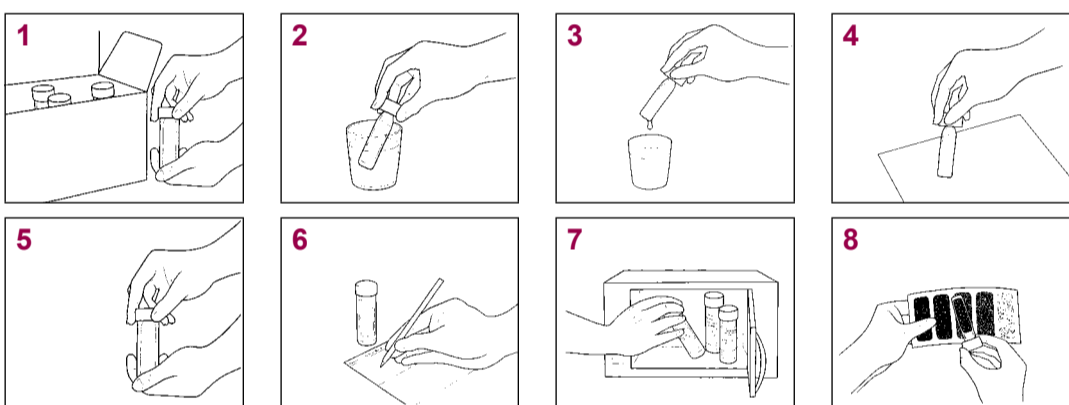
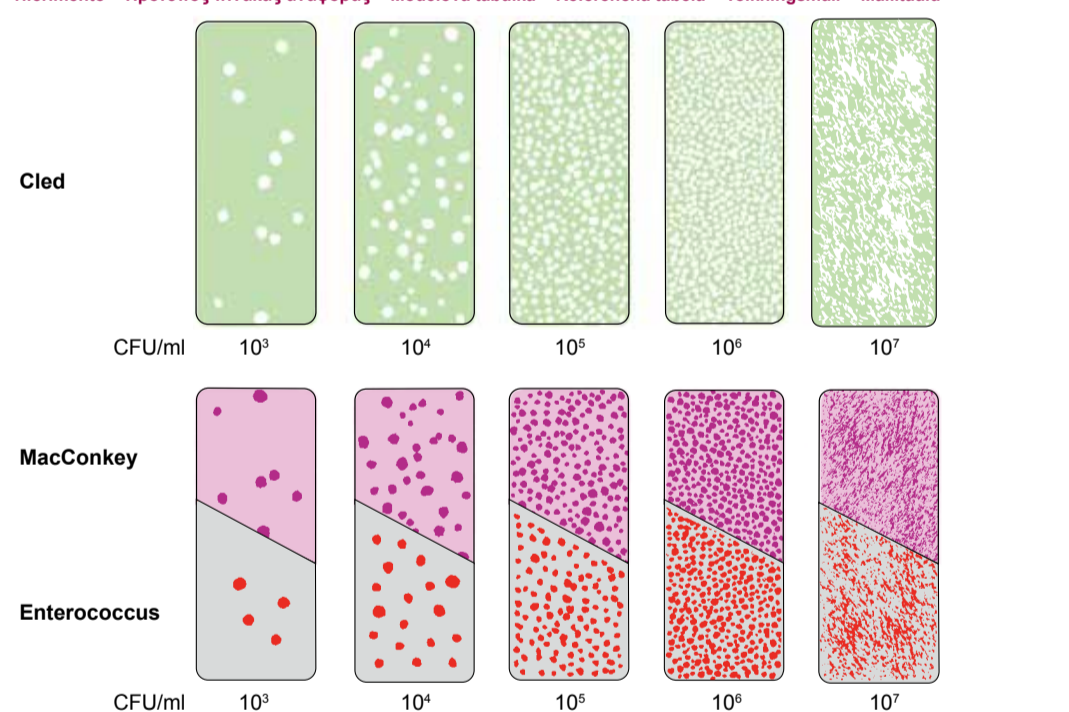
Note: In some cases, bladder urine < 4 hours may express clinically significant colony counts below 10³ CFU/ml.

Performance characteristics**Uricult Plus • CLED medium**

Arnell, G.C. 1970: Detection of bacteriuria at room temperature. Lancet, January 17, pp 119–121 ⁴ .		
Number of samples	140	Reference method:
Sensitivity	100 %	Pour plate (Nutrient agar)
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 • Tolkningsmall • Mallitaulu****Typical formulation • Formules • Typische Formulierung • Fórmula típica • Fórmula típica • Formulazione típica • Τυπική Σύσταση • Τυπické složení • Sestava gojišč • Agar indhold • Agar sammensetning • Sammansättning • Koostumus**

CLED medium	MacConkey medium	Enterococcus medium
Peptone 10.0 g/l	Peptone 20.0 g/l	Peptone 25.0 g/l
Meat extract 3.0 g/l	Lactose 10.0 g/l	Glucose 2.0 g/l
Lactose 10.0 g/l	Neutral red 0.075 g/l	K ₂ HPO ₄ 4.0 g/l
L-Cystine 0.13 g/l	Bile salts 0.8 g/l	Triphēnyl tetrazoliumchloride 0.1 g/l
Bromthymol blue 0.03 g/l		Crystal violet 0.001 g/l
		Polymyxin B q.s.
		Nalidixic acid q.s.

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

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

IVD	REF	LOT	Temperature limitation	Use by	Manufacturer
<i>In vitro</i> diagnostic medical device Dispositif médical de diagnostic <i>in vitro</i> <i>In-vitro</i> -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 βοήθημα που χρησιμοποιείται για διάγνωση <i>in vitro</i> Diagnosticski zdravotvniški prostredki <i>in vitro</i> Diagnostická zdravotnícka pomôcka <i>in vitro</i> Medicinteknisk produkt avsedd för <i>in vitro</i> -diagnostik <i>In vitro</i> -diagnostiikkaan tarkoitettu lääkinällinen laite	Catalogue number Référence du catalogue Bestellnummer Número de catálogo Número de catálogo (n°) Riferimento di Catalogo Αριθμός καταλόγου Katalogové číslo Kataloška številka Listnummer Tuotenumero	Batch code Code du lot Loscode Código de lote Código de lote Codice di lotto Κωδικός Παρτίδας Kód száze Številka serije Satsnummer Eräkoodi	Temperature limitation Limites de température Temperaturbegrenzung Limitación de temperatura Limites de temperatura Limiti di temperatura Περιορισμοί θερμοκρασίας Teplotní omezení Templotn rozmezje Temperaturbegränsning Lämpötilarajat	Use by A utiliser jusqu'à Verwendbar bis Fecha de caducidad Utilizar até Utilizzare entro/Scadenza Χρησιμοποιήστε έως Použiteľné do Uporabno do Används före Käytettävä ennen	Manufacturer Fabricant Herstellter Fabricante Fabricante Fabbricante Κατασκευαστής Výrobca Proizvajalec Tillverkare Valmistaja
Consult instructions for use Consulter la notice d'utilisation Gebrauchsanweisung beachten Consulte las instrucciones de uso Consultar as instruções de utilização Consultare le istruzioni per l'uso Συμβουλευτείτε τις οδηγίες χρήσης Viz návody k použití Läs bruksanvisningen Katso käyttöohjetta	Sufficient pour Adequado para Ausreichend für Válido para Suficiente para Suficiente per Επαρκές για Dostatečné pro Zadovoljivo za Räcker till Lukumäärä	Protect from draught and temperature fluctuations Conservar à l'abri des courants d'air et des fluctuations de température Vor Zug und Temperaturschwankungen geschützt lagern 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 έρπυσία και μετεβολές θερμοκρασίας Chránite pred prúhom a kolísaním teploty Zavarujte pred prepihom in temperaturnimi nihanjami Undvik drag och temperaturvariationer Suojattava vedolta ja lämpötilan vaihteluilta			

