

**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 Plus 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.

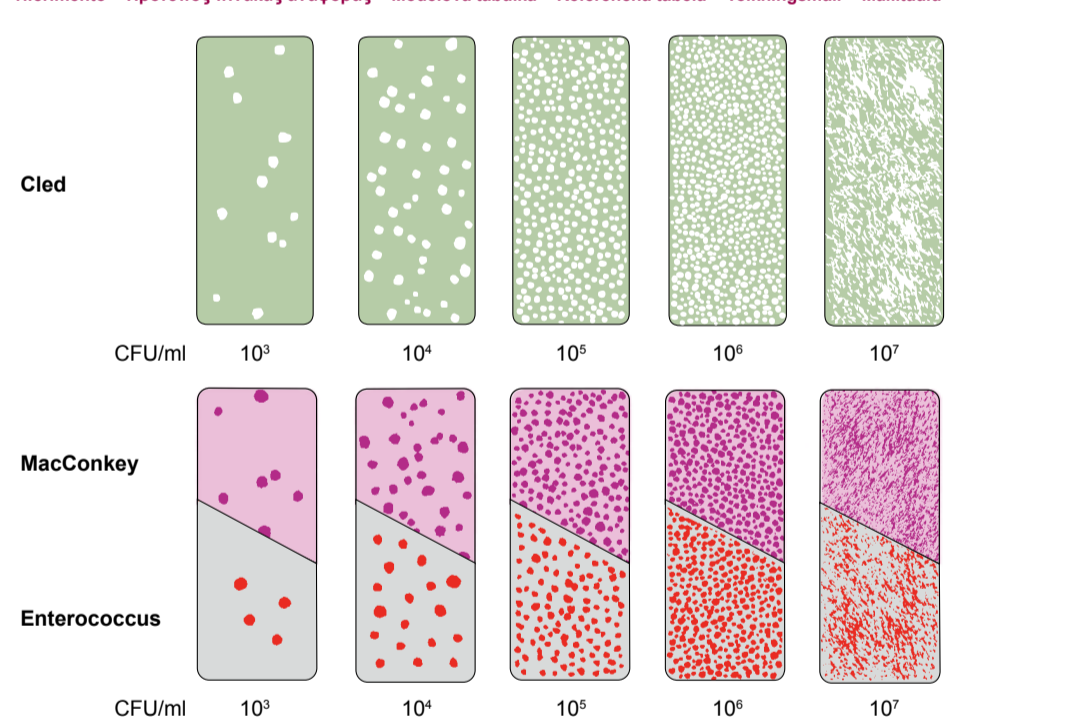
**Note:**

- 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 investigation<sup>6</sup>. Negative cultures may be incubated for additional 24 hours to detect slow-growing bacteria<sup>6</sup>.

**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 10<sup>3</sup>–10<sup>6</sup> 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:

**Model Chart • Tableau de référence • Standardbildkarte • Tablas de referencia • Tabela de Referência • Tavola di riferimento • Πρότυπος πίνακας αναφοράς • Modelová tabulka • Referenčná tabela • Tolkningsmall • Mallitaulu****Typical formulation • Formules • Typische Formulierung • Fórmula típica • Fórmula típica • Formulazione típica • Τυπική Σύσταση • Typické 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 <sub>2</sub> HPO <sub>4</sub> 4.0 g/l
L-Cystine 0.13 g/l	Bile salts 0.8 g/l	Triphenyl 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 • Bibliografía • Referências Bibliográficas • Bibliografia • Βιβλιογραφία • Literatura • Litteratur • Kirjallisuus**

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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. Aesculapulus 11–12, 1985.
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**Explanation of symbols • Explication des symboles • Zeichenerklärung • Explicación de los símbolos • Explicação de símbolos • Spiegazione dei simboli • Ερμηνεία 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> ιατροβιολογικό βοήθημα που χρησιμοποιείται για διάγνωση <i>in vitro</i> Diagnostický zdravotnický prostředek <i>in vitro</i> Diagnostická zdravotnícka pomôcka <i>in vitro</i> Medicinteknisk produkt avsedd för <i>in vitro</i> -diagnostik <i>In vitro</i> -diagnostikkana tarkoitettu lääkinällinen laite	Catalogue number Référénc du catalogue Bestellnummer Número de catálogo Número de catálogo (n°) Riferimento di Catalogo Αριθμός καταλόγου Katalošká číslo Kataloška številka Listnummer Tuotenumero	Batch code Code du lot Loscode Código de lote Código de lote Codice di lotto Κωδικός Παρτίδας Kód sarže Steilvika serien Satsnummer Eräkoodi	Temperature limitation Limites de température Temperaturbegrenzung Limitación de temperatura Limites de temperatura Limiti di temperatura Περιορισμοί θερμοκρασίας Τεplotní omezení Templotné omezié Temperaturbegrænsning Lämpötilarajat	Use by A utiliser jusqu'à Verwendbar bis Fecha de caducidad Utilizar até Utilizzare entro/Scadenza Χρησιμοποιήστε έως Poružitelné do Uporabno do Används före Käytettävä ennen	Manufacturer Fabricant Hersteller Representante autorizzato in Svizzera Representante autorizado en Suiza Representante autorizado na Suíça Εξουσιοδοτημένος αντιπρόσωπος στην Ελλάδα Autorizovaný zástupník v Slovensku Pooblaščený zastopnik v Šviciji Autoriseret representant i Schweiz Autoriseret representant i Sveits Auktoriserad representant i Schweiz Valtuutettu edustaja Sveitsissä

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