

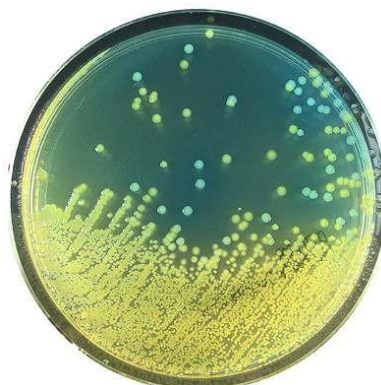
AG – CLED AGAR - INSTRUCTIONS FOR USE

(Ready Plated Media)

• INTENDED USE:

In vitro diagnostic. Differential culture medium for isolation, enumeration and presumptive identification of microorganisms from urine.

• PRINCIPLE:



Lactose fermenting *E.coli* (yellow colonies) and
Lactose non-fermenting *Salmonella* (blue colonies)

The Cystine - Lactose - Electrolyte – Deficient (C.L.E.D.) medium is found to be ideal for the dip-slide inoculation and for urinary bacteriology in general, good colonial differentiation and easy recognition being particular features. It supports the growth of all urinary potential pathogens. It also supports the growth of a number of essential contaminants such as diphtheroids, lactobacilli, and micrococci, which gives an indication of the extent of the contamination, and whilst being non-inhibitory it prevents the swarming of *Proteus* sp.

• MATERIALS PROVIDED:

PRODUCT	TYPE	REF	PACK
AG – CLED Agar Plates	Ready Plated Media	AG/CLED/22/01	10 plates in a pack

• MATERIALS REQUIRED BUT NOT PROVIDED:

Sterile loops, incubator, and laboratory equipment as required.

• SPECIMENS:

CLED Agar is intended for the microbiological processing of clinical specimens such as urine. Collect specimens before antimicrobial therapy where possible. Good laboratory practices for collection, transport and storage of clinical specimens should be applied.

• TEST PROCEDURE, READING AND INTERPRETATION:

- Allow plates to come to room temperature.
- Inoculate and streak the specimen with a loop over the four quadrants of the plate. Alternatively, if the material is being cultured directly from a swab sample, roll the swab over a small area of the surface at the edge; then streak from this inoculated area.
- Incubate inoculated CLED Agar plates with the specimen or with a specimen enriched in liquid medium, in aerobic conditions at 35-37°C for 18-24 hours.

• USER QUALITY CONTROL:

All manufactured lots of the product are released for sale after Quality Control has been performed to check the compliance with the specifications. However, the end user can perform its own Quality Control in accordance with the local applicable regulations, in compliance with accreditation requirements and the experience of the Laboratory. Here below are listed some test strains useful for quality control.

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CONTROL STRAINS	INCUBATION	EXPECTED RESULTS
<i>E. coli</i> ATCC 8739	37°C /18-24H-Aerobic	Yellow, opaque colonies, centre slightly deeper yellow
<i>P. mirabilis</i> ATCC 12453	37°C /18-24H- Aerobic	Blue, translucent colonies
<i>S. aureus</i> ATCC 25923	37°C /18-24H-Aerobic	good growth, yellow colonies
<i>K. pneumoniae</i> ATCC 700603	37°C /18-24H-Aerobic	Yellow to whitish-blue colonies, mucoid

Key: ATCC is a trademark of American Type Culture Collection

• LIMITATIONS OF THE METHOD:

- CLED medium is basically non-selective but, due to electrolyte exclusion, *Shigella* spp. usually do not grow on the medium.
- If in the specimen the presence of genitourinary pathogens such as *Neisseria gonorrhoeae*, *Gardnerella vaginalis*, *Ureaplasma* is suspected, specific culture media must be inoculated.
- Even if the microbial colonies on the plates are differentiated on the basis of their morphological and chromatic characteristics, it is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on isolates, from pure culture, for complete identification. If required and relevant, perform antimicrobial susceptibility testing.
- This culture medium is intended as an aid in the diagnosis of infectious diseases; the interpretation of the results must be made considering the patient's clinical history, the origin of the sample and the results of other diagnostic tests.

• PRECAUTIONS AND WARNINGS:

- This product is for microbiological control and for professional use only; it is to be used by adequately trained and qualified laboratory personnel, observing approved biohazard precautions and aseptic techniques.
- All laboratory specimens should be considered infectious.
- The laboratory area must be controlled to avoid contaminants such as culture medium or microbial agents.
- Sterilize all biohazard waste before disposal. Dispose of the unused medium and the sterilized plates inoculated with samples or microbial strains in accordance with current local legislation.
- The Certificates of Analysis and the Safety Data Sheet of the product are available with AstraGene and can be provided on request.

• STORAGE CONDITIONS AND SHELF LIFE:

- Upon receipt, store at +2 - 8°C away from direct light in a cool, dry place. Storage below 2°C may lead to crystallization of media components due to near freezing temperature. The user is responsible for the storage method (temperature) of the medium.
- For optimal usage, it is advisable to utilize the entire pack of 10 plates once they have been taken out of the packaging.
- If properly stored, the product may be used up to the expiration date. Do not use it beyond the mentioned expiry date.

• SYMBOLS:



Date of manufacture



Use-by-date



Do not use if package is damaged



Manufacturer



Batch Code



Refer to the instructions



ISO



GMP



In-Vitro diagnostic Medical devices



Mark of conformity



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