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## SCIENTIFIC

wound swabs. Early diagnosis is vital in the prevention and reduction of urinary tract infections.

## CLED Agar

**[REF] PO0120A, PB1248E\* & PB1228E\*\***

\* This instructions for use (IFU) document is intended to be read in conjunction with the IFU for Columbia CAP Agar product code: PB1161A.

\*\* This instructions for use (IFU) document is intended to be read in conjunction with the IFU for Staphylococci- Streptococci Selective Medium product code PB0308A

### Intended Use **[IVD]**

CLED Agar (PO0120A) is a differential medium for the isolation and enumeration of the common microorganisms causing urinary tract infections from urine samples. CLED Agar (PO0120A) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having urinary tract infections. The device is for professional use only, is not automated nor is it a companion diagnostic.

Columbia CAP Agar / CLED Medium (PB1248E) is a biplate for the isolation of *Staphylococcus* and *Streptococcus* species on the Columbia CAP side and the isolation and enumeration of the common microorganisms causing urinary tract infections on the CLED side. Columbia CAP Agar / CLED Medium (PB1248E) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections. The device is for professional use only, is not automated nor is it a companion diagnostic.

CLED Medium / Staphylococci-Streptococci Selective Medium (PB1228E) is a biplate for the isolation and enumeration of the common microorganisms causing urinary tract infections on the CLED side and for the isolation of *Staphylococcus* and *Streptococcus* species on the Staph-Strep side from clinical samples (e.g., wounds, throat, genital, nose, groins etc.). CLED Medium / Staphylococci-Streptococci Selective Medium (PB1228E) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections. The device is for professional use only, is not automated nor is it a companion diagnostic.

### Summary and Explanation

Urinary tract infections, often referred to as UTIs, are common infections that occur when bacteria invade the urinary tract by entering via the urethra. These infections can impact different parts of the urinary tract, but the most prevalent is cystitis (a bladder infection). The symptoms of cystitis can include frequent urination, or needing to urinate whilst having an empty bladder, a burning sensation or pain whilst urinating, blood in the urine and pressure or cramps in the lower abdominal area. The symptoms of kidney infections are very different. These can include chills, a fever, nausea and vomiting and pain in the lower back<sup>1</sup>. There are many species of bacteria that cause UTIs, but most common are *Escherichia coli*, *Staphylococcus aureus* and *Proteus mirabilis*<sup>2,3</sup>.

Due to the severity of UTIs in a vast number of patients, it is very important to be able to isolate and identify common UTI-causing microorganisms from urine samples and

### Principle of the Method

Peptones and Lab Lemco powder are present to supply the materials required for the growth of bacteria and agar in the solidifying agent. Lactose provides a carbohydrate source. Bromothymol blue is a pH indicator which differentiates lactose fermenters (yellow) from non-fermenters. Cystine enhances the growth of cystine-dependent coliforms. Electrolytes are reduced in order to restrict the swarming of *Proteus* spp.

### Typical Formula

	grams per litre
Peptone	4.0
'Lab-Lemco' Powder	3.0
Tryptone	4.0
Lactose	10.0
L-cysteine	0.128
Bromothymol blue	0.02
Agar	15.0

### Physical Appearance

Colour	Blue/ Green
Clarity	Clear
Fill weight	19 ± 2.0g
pH	7.3 ± 0.2g

### Materials Provided

PO0120A: 10 x 90 mm CLED agar plates

PB1248E: 10 x 90 mm Columbia CAP agar/ CLED agar biplates

PB1228E: 10 x 90 mm CLED agar/ Staphylococci-Streptococci Selective agar biplates

Each plate should only be used once.

### Materials Required but Not Supplied

- 1) Inoculating loops
- 2) Swabs
- 3) Collection containers
- 4) Incubators
- 5) Quality control organisms

### Storage

- Store product in its original packaging at 2–10°C until used.
- The product may be used until the expiry date stated on the label.
- Store away from light.
- Allow product to equilibrate to room temperature before use.
- Do not incubate prior to use.

### Warnings and Precautions

- For *in vitro* diagnostic use only.
- For professional use only.
- Inspect the product packaging before first use.
- Do not use the product if there is any visible damage to the packaging or plates.
- Do not use the product beyond the stated expiry date.
- Do not use the device if signs of contamination are present.
- Do not use the device if the colour has changed or there are other signs of deterioration.
- It is the responsibility of each laboratory to manage waste produced according to their nature and degree of hazard and to have them treated or disposed of in accordance with any federal, state and local applicable regulations.

- Directions should be read and followed carefully. This includes the disposal of used or unused reagents as well as any other contaminated disposable material following procedures for infectious or potentially infectious products.

Refer to the Safety Data Sheet (SDS) for safe handling and disposal of the product ([www.thermofisher.com](http://www.thermofisher.com)).

### Serious Incidents

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the relevant regulatory authority in which the user and/or the patient is established.

### Specimen Collection, Handling and Storage

Specimens should be collected and handled following local recommended guidelines, such as the UK Standards for Microbiology Investigations (UK SMI) B 59, B 60, ID 4 and Q 5.

### Procedure

Refer to any local guidelines and protocols. The method used will depend upon the specimen type.

For urine samples:

- 1) Inoculate the specimen as soon as possible after it is received in the laboratory.
- 2) The use of a calibrated loop is recommended to facilitate counting colonies and estimate the colony forming units (cfu)/ mL
- 3) Incubate aerobically at 37°C for 18 to 24 hours.
- 4) Determine colony count and observe colonial characteristics and morphology.

For swabs:

- 1) Roll the swab over a small surface area of the plate and streak to obtain single colonies.
- 2) Incubate aerobically at 37°C for 18 to 24 hours

### Interpretation

- Yellow colonies indicate *Staphylococcus aureus*
- Light yellow colonies indicate *Escherichia coli*
- Transparent blue colonies indicate *Proteus mirabilis*

### Quality Control

It is the responsibility of the user to perform Quality Control testing, taking into account the intended use of the medium, and in accordance with applicable, local regulations (frequency, number of strains, incubation temperature etc.).

The performance of this medium can be verified by testing the following reference strains.

Incubation Conditions: 18 - 24 h @ 37° ± 2°C

Positive Controls	
Inoculum level 10-100 cfu Colony counts should be ≥ 50% of the control medium	
<i>Staphylococcus aureus</i> ATCC® 25923™	Yellow shiny colonies (acid)
<i>Proteus mirabilis</i> NCTC 10975	Translucent blue colonies, no swarming
<i>Escherichia coli</i> ATCC® 25922™	Light yellow shiny colonies (acid)

### Limitations

This medium is for laboratory use only and is not intended for the diagnosis of disease or other conditions. Identifications are presumptive and colonies should be

identified using appropriate methods. A small number of atypical strains may give a weak reaction or fail to grow, especially when low numbers are present in the sample, for example due to a lack of electrolytes *Shigella* spp. do not usually grow.

### Performance Characteristics

Accuracy has been demonstrated through review of the QC data. Correct detection of common UTI-causing microorganism strains is confirmed by the inclusion of a well-characterised isolate in the QC processes performed as part of the manufacture of each batch of the device. The precision of CLED Agar (PO0120A, PB1228E and PB1248E) was demonstrated by an overall pass rate of 100% obtained for the products over several months of testing: December 2021 – February 2022 for CLED Agar (PO0120A), November 2021 – February 2022 for Columbia CAP Agar / CLED Medium (PB1248E), October 2021 – January 2022 for CLED Medium / Staphylococci-Streptococci Selective Medium (PB1228E), with 10 batches tested for each. This shows that the performance is reproducible.

The devices are tested in-house as part of the QC process. For target organisms, when using 10-100 cfu inoculum of *Staphylococcus aureus*, *Proteus mirabilis* and *Escherichia coli* and incubating the device at 37°C ± 2°C for 18-24 hours, the user can recover organisms with the appropriate morphology as listed in this document.

### Bibliography

- 1) Centres for Disease Control and Prevention. 2021. 'Urinary Tract Infection'. <https://www.cdc.gov/antibiotic-use/uti.html>
- 2) Centres for Disease Control and Prevention. 2021. 'E. coli Prevention'. <https://www.cdc.gov/ecoli/ecoli-prevention.html>
- 3) Centres for Disease Control and Prevention. 2021. 'Staphylococcus aureus in Healthcare Settings'. <https://www.cdc.gov/hai/organisms/staph.html>

### Symbol Legend

Symbol	Definition
	Catalogue number
	In Vitro Diagnostic Medical Device
	Batch code
	Temperature limitation (storage temp.)
	Use by (expiration date) YYYY-MM
	Keep away from sunlight
	Do not re-use
	Consult Instructions for Use
	Contains sufficient for <n> tests

	Do not use if packaging damaged
	Manufacturer
	Authorized representative in the European Community
	European Conformity Assessment
	UK Conformity Assessment
Made in the United Kingdom	Made in the United Kingdom



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For technical assistance please contact your local distributor.

### Revision Information

Version	Date of issue and modifications introduced
1.0	2022-10-25. New document. (LIVE)