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# Polymyxin B Supplement EN

REF **SR0099E**

This instructions for use (IFU) document is intended to be read in conjunction with the IFU for Bacillus cereus Selective Agar Base (CM0617B) and MYP Agar Base (CM0929B).

## Intended Use

Polymyxin B Supplement (SR0099E) is a selective supplement that may be used in the preparation of PEMBA medium for the isolation and enumeration of *Bacillus cereus* from faecal samples. Can also be used in the preparation of MYP agar for testing food samples.

The device is for professional use only, is not automated and nor is it a companion diagnostic.

## Summary and Explanation

*Bacillus cereus* is a Gram-positive bacterium that is widely distributed environmentally[1]. It can be found in soil, water, and both fresh and decaying organic matter[2] with spores that germinate when in contact with organic matter or when inside a host.

*B. cereus* is a common cause of food-borne gastrointestinal illnesses[3] and is more prevalent in warmer months[4]. Two different enteric diseases may be caused by *B. cereus*: emetic syndrome and diarrhoeal syndrome[4]. The presence of the peptide cereulide causes emetic syndrome, while diarrhoeal syndrome is caused by the enterotoxins haemolysin BL, non-haemolytic enterotoxin, and cytotoxin K. Symptoms of enteric *B. cereus* infection are usually mild and subside within 24 hours. However, *B. cereus* can also cause severe opportunistic extraintestinal infections, particularly in immunocompromised individuals[5].

Moreover, *B. cereus* is capable of forming biofilms[2,5] and shows resistance to most β-lactam antibiotics[5,6], with resistance to penicillin being an identifying feature of *B. cereus*[1]. *B. cereus* is also capable of resisting pasteurization and cleaning processes in hospital settings due to its capacity to sporulate[7].

## Principle of Method

The formulation for Polymyxin B Supplement (SR0099E) contains Polymyxin B, which is an antibiotic that disrupts the outer cell membrane of Gram-negative bacteria. Polymyxin B binds to the cell membrane and alters its structure making it more permeable resulting in cell death.

## Typical Formula

| | IU/500ml |
|---|---|
| Polymyxin B | 50000IU |

## Materials Provided

SR0099E: 10x freeze dried vials, each for supplementing 500ml of medium.

## Materials Required but Not Supplied

- Bacillus cereus Selective Agar Base (CM0617B)
- MYP Agar Base (CM0929B).
- Inoculating loops
- Swabs
- Collection containers.
- Petri dishes.

## Storage

- Store product in its original packaging between 2°C and 8°C.
- Keep container tightly closed.
- The product may be used until the expiry date stated on the label.
- Protect from moisture.
- Store away from light.
- Allow reconstituted product to equilibrate to room temperature before use.

## Warnings and Precautions

Each vial is for single use. Do not re-use.
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 vials.
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).

**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** There are no specimen collection and/or transport materials provided with this device. Specimens should be collected and handled following local recommended guidelines, such as the UK Standards for Microbiology Investigations (UK SMI) ID 9, S 7 and Q 5.

**Procedure**
To one vial aseptically add 2ml of sterile distilled water and mix gently to dissolve the contents completely. Avoid frothing. Add the contents to sterile Bacillus Cereus Selective Agar Base (CM0617B) or MYP Agar Base (CM0929B) cooled to 50°C to which sterile Egg Yolk Emulsion (SR0047) has been added. Mix gently and pour into sterile containers.

**Bibliography**

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3. Acosta Pedemonte, N.B. *et al.* (2020) "Bacillus cereus bacteremia in a patient with an abdominal stab wound," *Revista Argentina de Microbiología*, 52(2), pp. 115–117. doi:10.1016/j.ram.2019.07.003.
4. Public Health England (2020) *UK Standards for Microbiology Investigations. Gastroenteritis. S 7 Issue 2.*
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6. Turnbull, P.C. and Kramer, J.M. (1983) "Non- gastrointestinal Bacillus cereus infections: an analysis of exotoxin production by strains isolated over a two-year period.," *Journal of Clinical Pathology*, 36(10), pp. 1091–1096. doi:10.1136/jcp.36.10.1091.
7. Lewin, A. *et al.* (2019) "*Bacillus cereus* infection in neonates and the absence of evidence for the role of banked human milk: Case reports and literature review," *Infection Control & Hospital Epidemiology*, 40(7), pp. 787–793. doi:10.1017/ice.2019.110.


**Symbol Legend**

| Symbol | Definition |
|---|---|
| REF | Catalogue number |
| IVD | In Vitro Diagnostic Medical Device |
| LOT | Batch code |
|  | Temperature limit |
|  | Use-by date |
|  | Keep away from sunlight |
|  | Do not re-use |
|  | Consult instructions for use or consult electronic instructions for use |

| | |
|---|---|
|  | Contains sufficient for <n> tests |
|  | Do not use if packaging damaged and consult instructions for use |
|  | Manufacturer |
| EC REP | Authorized representative in the European Community/ European Union |
| CE | European Conformity Assessment |
| UK CA | UK Conformity Assessment |
| UDI | Unique device identifier |
|  | Importer - To indicate the entity importing the medical device into the locale. Applicable to the European Union |
| 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 | Modifications introduced |
|---|---|
| 2.0 | 2023-12-15 |