

MASTDISCS® *Combi* Cefepime ESβL ID Disc Set

D63C

Intended use

For the detection of extended spectrum beta-lactamases (ESβLs) in Enterobacterales with chromosomal AmpC.

FOR IN VITRO DIAGNOSTIC USE ONLY

Contents and Formulation*

3 x paired sets of cartridges per pack, each cartridge containing approximately 50 discs:

CPM30	Cefepime 30 µg discs (x3)
CPMCV	Cefepime 30 µg + clavulanic acid 10 µg discs (x3)

Storage and shelf life

Store at 2 to 8°C in the containers provided until the expiry date shown on the pack label. Allow to equilibrate to room temperature before opening.

Precautions

For *in vitro* diagnostic use only. Observe approved biohazard precautions and aseptic techniques. To be used only by adequately trained and qualified laboratory personnel. Sterilise all biohazard waste before disposal. Refer to Product Safety Data sheet.

Materials required but not provided

Standard microbiological supplies and equipment such as loops, MAST® culture media, Mueller-Hinton agar, swabs, forceps, callipers etc., as well as an incubator capable of maintaining 35 ± 1°C.

Procedure

- Using a pure, fresh culture of the test organism, prepare a suspension equivalent in density to a 0.5 McFarland standard in physiological saline.
- Using a sterile swab, spread the suspension uniformly across the surface of a single Mueller Hinton Agar plate in accordance with the European Committee on Antimicrobial Susceptibility Testing (EUCAST) procedure.
- Using a MAST® DISCMASTER Dispenser, or alternatively a sterile needle or forceps, place one of each type of disc onto the plate of inoculated medium, ensuring sufficient space between the discs to allow formation of clearly defined zones of inhibition.
- Incubate at 35 ± 1°C for 18 ± 2 hours.
- Measure and record the diameter of any zones of inhibition, to the nearest whole millimetre. Discs showing no zone of inhibition should be recorded as 6 mm.

Interpretation of results

Compare the zone of inhibition for the cefepime disc to that of the cefepime plus clavulanic acid combination disc. An increase in zone diameter of ≥5 mm in the presence of clavulanic acid indicates the presence of ESβL in the test organism.

Quality control

Check for signs of deterioration. Quality control must be performed with at least one organism to demonstrate a positive reaction and at least one organism to demonstrate a negative reaction. Zones of inhibition obtained using the combination disc plus clavulanic acid and corresponding cefepime only disc against ESβL-negative control organism *E. coli* ATCC® 25922, should be equal or show no greater difference in diameter than ±2 mm. Any greater difference implies malfunction or deterioration. Do not use the product if the reactions with the control organisms are incorrect. The list below illustrates a range of performance control strains which the end user can easily obtain:

Test Organism	Result
<i>Enterobacter cloacae</i> NCTC 13464	Positive
<i>Escherichia coli</i> NCTC 13351	Positive
<i>Escherichia coli</i> NCTC 13352	Positive
<i>Escherichia coli</i> NCTC 13353	Positive
<i>Escherichia coli</i> ATCC® 25922	Negative

Limitations

D63C is not suitable for testing *Pseudomonas* spp. or *Acinetobacter* spp. To optimise ESBL detection it is recommended that these discs are used in combination with other products in the MASTDISCS® *Combi* range. To avoid potentially erroneous results do not mix cartridges from different batches of D63C and ensure both discs in the set are tested on the same plate.

References

Bibliography available on request.