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MASTDISCS® *Combi*
AmpC Detection Set

D69C

Intended use
For the detection of AmpC β-lactamase enzyme production in Enterobacterales.

FOR IN VITRO DIAGNOSTIC USE ONLY

Contents and Formulation*
3 cartridges per pack, each cartridge containing approximately 50 discs.

Cartridge A	Cefpodoxime 10 μg + AmpC inducer
Cartridge B	Cefpodoxime 10 μg + AmpC inducer + ESβL inhibitor
Cartridge C	Cefpodoxime 10 μg + AmpC inducer + ESβL inhibitor + AmpC inhibitors

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
1. Using a pure, fresh culture of the test organism, prepare a suspension equivalent in density to a 0.5 McFarland standard in physiological saline.
2. 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.
3. Using a MAST® DISCMASTER Dispenser, or alternatively a sterile needle or forceps, place one of each disc onto the plate of inoculated medium, ensuring sufficient space between the discs to allow formation of clearly defined zones of inhibition.
4. Incubate at 35 ± 1°C for 18 ± 2 hours.
5. 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
Interpret results by comparing inhibition zone diameters in the sequence described below:

Step 1 - Compare the zone of inhibition of the cefpodoxime plus AmpC inducer disc (**A**) to the zones of inhibition of each of the cefpodoxime plus inducer and inhibitor discs (**B, and C**).
If all zones are within 3 mm of each other, record the organism as negative for AmpC production.

Step 2 - Subtract **A** from **C**, **A** from **B** and **B** from **C.**

If **C** – **A** and **C** – **B** is ≥5 mm the organism is demonstrating AmpC activity. This should be considered as a positive result

If **C** – **A** and **B** – **A** is ≥5 mm and zones of Discs **B** and **C** have a maximum difference of 4 mm then the organism may be demonstrating another resistance mechanism.

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 against a negative control organism *E. coli* ATCC® 25922, should be equal or show no greater difference in diameter than ±3 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
Escherichia coli ATCC® 25922	Negative
Escherichia coli DSMZ 22316 (Plasmid AmpC)	Positive
Enterobacter cloacae NCTC 13406 (Derepressed AmpC)	Positive
Enterobacter cloacae NCTC 13405 (Inducible AmpC)	Positive

Limitations
D69C is not suitable for use with *Pseudomonas* spp. or *Acinetobacter* spp. To avoid potentially erroneous results do not mix cartridges from different batches of D69C and ensure all discs in the set are tested on the same plate.

The formulation is designed to detect all types of AmpC production. The ESβL inhibitor is present to prevent this enzyme affecting results when an isolate contains both AmpC and ESβL enzymes. Although ESβL inhibitor is contained in discs B and C, this product **cannot** be used for ESBL detection.

References
Bibliography is available on request.

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*Formulation may change to meet performance criteria