

# Customer information:

## MASTDISCS® Combi IFU

### Update notification

As part of Mast Group Ltd.'s commitment to quality and continual improvement, a review has been performed on the **MASTDISCS® Combi** Instructions for Use (IFUs). Accordingly, changes have been identified and the IFUs (see Table 1 below) have been updated and standardised across the product range. Details of the changes are outlined afterwards.

**Table 1 – List of products where updates have been made to IFUs.:**

Product code	Product	IFUs no.	Previous version no.	New version no.
171055	ESBL - Set (CPD30) D52C	111	9	10
171622	Cefotaxime ESBL - Set D62C	168	7	8
171632	Cefepime ESBL - Set D63C	169	8	9
171642	Ceftazidime ESBL - Set D64C	170	7	8
171662	Cefpodoxime ESBL - Set D66C	172	7	8
171672	ESBL - Set (CPD10) D67C	185	5	6
171682	AmpC and ESBL - Set D68C	179	12	13
171692	AmpC - Set D69C	187	5	6
171712	Carbapenemase Activity Test (CAT) D71C	189	7	8
171722	AmpC, ESBL & Carbapenemase Set D72C	192	6	7
171732	Carba Plus - Set D73C	190	7	8
171762	ESBL - Set D76C (EUCAST)	194	1	2

### Details of significant changes:

#### 1. D63C intended use

- Intended use for D63C has been changed to the following: “For the detection of Extended spectrum Beta-lactamases in Group 2 *Enterobacterales* (chromosomal AmpC)”. This is for further clarification since cefepime is stable to AmpC hydrolysis.
- *Enterobacter cloacae* NCTC 13464 has been added to the IFU as a recommended ESBL positive Quality Control strain (as this is a Group 2 *Enterobacterales*).



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## 2. Methodology in IFUs

- There are methodological changes for the following products to ensure that these products fit easily in to the workflow of laboratories following CLSI methodology: D52C, D62C, D64C and D67C. The incubation time has been changed to 16 to 18 hours, the incubation temperature changed to 35±2 °C, and Mueller-Hinton agar is now recommended as the susceptibility test medium.
- There are methodological changes for the following products to ensure that these products fit easily in to the workflow of laboratories following EUCAST methodology: D63C, D66C, D68C, D69C, D71C and D73C. The incubation time has been changed to 16 to 18 hours, the incubation temperature changed to 35±2 °C, and Mueller-Hinton agar is now recommended as the susceptibility test medium.
- The following statement has been removed from IFU111 (D52C) and IFU185 (D67C) as these products do not contain the antimicrobial contents recommended in current CLSI guidelines for ESBL detection: “**MASTDISCS® Combi** ESBL Detection Discs are also compatible with Clinical and Laboratory Standards Institute (CLSI) phenotypic confirmatory test method”.

## 3. Limitations

- Addition of limitation that the product is not for use in *Pseudomonas* spp. or *Acinetobacter* spp. for the following products: D52C, D62C, D63C, D64C, D66C, D67C, D68C and D69C.
- Addition of a limitation for D62C and D64C that these products must be used together, and that a positive result using one or both tests indicates an ESBL.
- Addition of a limitation that all discs must be tested on the same plate for all products in the range, with the exception of D71C.

These changes are now live on the (<https://www.mast-group.com/de/products/microbiology/esbl-ampc-and-carbapenemase-detection-kits/>), and there is a transition in place for packs currently being manufactured, with an additional label applied temporarily to highlight the changes. Please ensure you download and use the IFUs from the website as product in the supply chain may contain the previous version of the IFU.

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