

**MASTDISCS® combi - Carba plus - D73C**

**Introduction**

D73C is a five disc test kit for the detection of carbapenemase production in Enterobacteriaceae comprising a penem antibiotic with MBL inhibitor, KPC inhibitor and AmpC inhibitor. The final disc comprises temocillin with an MBL inhibitor. D73C detects MBL positive strains, KPC positive strains and OXA-48 positive strains. D73C can also differentiate KPC positive isolates from isolates expressing *ampC* coupled with porin loss.

**Method**

Surface inoculate a susceptibility test agar plate with a 0.5 McFarland suspension of the test organism. Place one of each type of **MASTDISCS® combi - Carba plus** (D73C) discs on to the inoculated medium. Incubate the plate at 35°C to 37°C for 18 to 24 hours. Measure and record (in millimeters) the diameter of any zones of inhibition that are observed. Results can be interpreted using the D73C calculator, available to download at [www.mastgrp.com](http://www.mastgrp.com). Alternatively, results can be interpreted via manual calculation as detailed below.

**Interpretation**

	B-A	C-A	D-A	E
MBL	≥5mm	<5mm	<5mm	>10mm
KPC	<5mm	≥5mm	<5mm	>10mm
OXA-48	<5mm	<5mm	<5mm	≤10mm
AmpC with porin loss	<4mm	≥5mm	≥5mm	>10mm
Negative	≤2mm	≤2mm	≤2mm	>10mm

**Quality Control**

**Uniformity**

Discs randomly chosen from the batch are placed on an assay medium plate which has been surface inoculated with an organism sensitive to the antibiotic. Plates are incubated at 35°C to 37°C for 18 to 24 hours. All zones produced by the discs should be within 3mm of each other.

**Performance**

Discs are placed on the surface of assay medium plates which have been surface inoculated with recommended QC strains dependent on the method being followed. Plates are incubated at 35°C to 37°C for 18 to 24 hours. Zones of inhibition for each disc should be within the interpretation limits specific for the resistance mechanism present.

**Bioburden**

A sample of discs are aseptically added to the surface of nutrient agar and incubated at 35°C to 37°C for 40 hours. There should be no signs of contamination after 40 hours incubation.

**Stability**

Long term stability tests are undertaken to ensure that the performance of the product remains within specified tolerances, under recommended storage conditions, over the period between manufacture and stated expiry date. Studies are based on "Real Time" testing of retained product samples of the same material formulation, container and closure system as utilized in products supplied to the customer.

## Performance Evaluation Data

Performance tests were carried out as described above on the batches listed below when stored at 2°C to 8°C. Prior to testing each component was allowed to warm to room temperature and tested in the approved manner.

### Performance against *Enterobacter cloacae* Wild type strain – AmpC producer with porin loss

Lot Number	Date of Manufacture	Time from Manufacture (months)	Zone of Inhibition (mm)					Within Specification
			Disc A	Disc B	Disc C	Disc D	Disc E	
16-002	04/02/2016	0	10	11	19	19	20	Yes
16-002	04/02/2016	1	12	12	17	18	20	Yes
16-002	04/02/2016	2	13	14	20	21	20	Yes
16-002	04/02/2016	3	11	13	19	19	20	Yes
16-002	04/02/2016	4	11	13	19	19	20	Yes
16-002	04/02/2016	5	12	12	19	18	19	Yes
16-002	04/02/2016	6	12	12	18	18	18	Yes
16-002	04/02/2016	12	15	15	20	21	16	Yes
16-002	04/02/2016	18	13	14	21	22	18	Yes
16-003	04/02/2016	0	11	11	20	19	21	Yes
16-003	04/02/2016	1	11	12	18	19	21	Yes
16-003	04/02/2016	2	12	12	20	19	19	Yes
16-003	04/02/2016	3	11	13	19	19	20	Yes
16-003	04/02/2016	4	12	14	20	19	20	Yes
16-003	04/02/2016	5	12	12	18	18	19	Yes
16-003	04/02/2016	6	11	13	19	18	18	Yes
16-003	04/02/2016	12	15	16	20	20	18	Yes
16-003	04/02/2016	18	15	15	22	21	18	Yes
16-004	04/02/2016	0	10	12	21	19	20	Yes
16-004	04/02/2016	1	12	12	20	19	22	Yes
16-004	04/02/2016	2	15	16	21	22	20	Yes
16-004	04/02/2016	3	12	13	18	18	20	Yes
16-004	04/02/2016	4	12	12	18	19	19	Yes
16-004	04/02/2016	5	12	13	20	19	20	Yes
16-004	04/02/2016	6	12	12	17	19	19	Yes
16-004	04/02/2016	12	15	15	19	20	17	No (Equivocal result)
16-004	04/02/2016	18	16	16	20	22	20	No (Equivocal result)
370910	20/05/2016	0	12	13	19	18	19	Yes
370910	20/05/2016	1	11	12	19	19	22	Yes
370910	20/05/2016	2	11	13	21	18	18	Yes
370910	20/05/2016	3	12	13	19	18	20	Yes
370910	20/05/2016	4	13	14	19	19	19	Yes
370910	20/05/2016	5	14	15	19	20	16	Yes
370910	20/05/2016	6	16	15	21	21	19	Yes
370910	20/05/2016	12	15	16	21	21	19	Yes

Performance against *Escherichia coli* Wild type strain – KPC producer

Lot Number	Date of Manufacture	Time from Manufacture (months)	Zone of Inhibition (mm)					Within Specification
			Disc A	Disc B	Disc C	Disc D	Disc E	
16-002	04/02/2016	0	6	7	15	6	13	Yes
16-002	04/02/2016	1	6	6	13	6	15	Yes
16-002	04/02/2016	2	6	9	15	6	14	Yes
16-002	04/02/2016	3	6	9	15	6	15	Yes
16-002	04/02/2016	4	6	6	16	6	17	Yes
16-002	04/02/2016	5	6	8	14	6	16	Yes
16-002	04/02/2016	6	6	6	14	6	13	Yes
16-002	04/02/2016	12	6	6	11	6	13	Yes
16-002	04/02/2016	18	6	6	15	6	13	Yes
16-003	04/02/2016	0	6	6	15	6	15	Yes
16-003	04/02/2016	1	6	6	13	6	14	Yes
16-003	04/02/2016	2	6	6	16	6	15	Yes
16-003	04/02/2016	3	6	8	15	6	17	Yes
16-003	04/02/2016	4	6	9	16	6	15	Yes
16-003	04/02/2016	5	6	8	12	6	14	Yes
16-003	04/02/2016	6	6	8	15	6	13	Yes
16-003	04/02/2016	12	6	6	14	6	13	Yes
16-003	04/02/2016	18	6	6	15	6	13	Yes
16-004	04/02/2016	0	6	8	16	6	14	Yes
16-004	04/02/2016	1	6	6	16	6	16	Yes
16-004	04/02/2016	2	6	6	15	6	16	Yes
16-004	04/02/2016	3	6	8	14	6	16	Yes
16-004	04/02/2016	4	6	6	17	6	15	Yes
16-004	04/02/2016	5	6	8	14	6	15	Yes
16-004	04/02/2016	6	6	8	15	6	14	Yes
16-004	04/02/2016	12	6	8	15	6	13	Yes
16-004	04/02/2016	18	6	6	14	6	12	Yes
370910	20/05/2016	0	6	8	16	6	15	Yes
370910	20/05/2016	1	6	8	13	6	15	Yes
370910	20/05/2016	2	6	6	14	6	14	Yes
370910	20/05/2016	3	6	8	16	6	14	Yes
370910	20/05/2016	4	6	8	16	6	16	Yes
370910	20/05/2016	5	6	8	15	6	15	Yes
370910	20/05/2016	6	6	8	13	6	15	Yes
370910	20/05/2016	12	6	8	16	6	14	Yes

Performance against *Klebsiella pneumoniae* NCTC 13438 – KPC producer

Lot Number	Date of Manufacture	Time from Manufacture (months)	Zone of Inhibition (mm)					Within Specification
			Disc A	Disc B	Disc C	Disc D	Disc E	
16-002	04/02/2016	0	6	6	11	6	13	Yes
16-002	04/02/2016	1	6	6	13	6	15	Yes
16-002	04/02/2016	2	6	6	11	6	14	Yes
16-002	04/02/2016	3	6	6	11	6	14	Yes
16-002	04/02/2016	4	6	6	11	6	15	Yes
16-002	04/02/2016	5	6	6	11	6	14	Yes
16-002	04/02/2016	6	6	6	12	6	13	Yes
16-002	04/02/2016	12	6	6	10	6	13	No (Equivocal result)
16-002	04/02/2016	18	6	6	11	6	12	Yes
16-003	04/02/2016	0	6	6	11	6	15	Yes
16-003	04/02/2016	1	6	6	13	6	15	Yes
16-003	04/02/2016	2	6	6	12	6	14	Yes
16-003	04/02/2016	3	6	6	12	6	15	Yes
16-003	04/02/2016	4	6	6	13	6	16	Yes
16-003	04/02/2016	5	6	6	11	6	13	Yes
16-003	04/02/2016	6	6	6	11	6	13	Yes
16-003	04/02/2016	12	6	6	11	6	14	Yes
16-003	04/02/2016	18	6	6	11	6	12	Yes
16-004	04/02/2016	0	6	6	12	6	15	Yes
16-004	04/02/2016	1	6	6	11	6	14	Yes
16-004	04/02/2016	2	6	6	12	6	15	Yes
16-004	04/02/2016	3	6	6	11	6	14	Yes
16-004	04/02/2016	4	6	6	13	6	16	Yes
16-004	04/02/2016	5	6	6	11	6	12	Yes
16-004	04/02/2016	6	6	6	12	6	13	Yes
16-004	04/02/2016	12	6	6	11	6	14	Yes
16-004	04/02/2016	18	6	6	11	6	13	Yes
370910	20/05/2016	0	6	6	12	6	14	Yes
370910	20/05/2016	1	6	6	11	6	13	Yes
370910	20/05/2016	2	6	6	11	6	14	Yes
370910	20/05/2016	3	6	6	13	6	14	Yes
370910	20/05/2016	4	6	6	12	6	14	Yes
370910	20/05/2016	5	6	6	11	6	13	Yes
370910	20/05/2016	6	6	6	12	6	13	Yes
370910	20/05/2016	12	6	6	12	6	13	Yes

Performance against *Klebsiella pneumoniae* NCTC 13440 – MβL producer

Lot Number	Date of Manufacture	Time from Manufacture (months)	Zone of Inhibition (mm)					Within Specification
			Disc A	Disc B	Disc C	Disc D	Disc E	
16-002	04/02/2016	0	6	15	6	6	17	Yes
16-002	04/02/2016	1	6	17	6	6	20	Yes
16-002	04/02/2016	2	6	16	6	6	20	Yes
16-002	04/02/2016	3	6	16	6	6	17	Yes
16-002	04/02/2016	4	6	21	6	6	22	Yes
16-002	04/02/2016	5	6	16	6	6	18	Yes
16-002	04/02/2016	6	6	16	6	6	17	Yes
16-002	04/02/2016	12	6	22	6	6	24	Yes
16-002	04/02/2016	18	6	20	6	6	22	Yes
16-003	04/02/2016	0	6	15	6	6	18	Yes
16-003	04/02/2016	1	6	17	6	6	20	Yes
16-003	04/02/2016	2	6	16	6	6	21	Yes
16-003	04/02/2016	3	6	16	6	6	18	Yes
16-003	04/02/2016	4	6	22	6	6	23	Yes
16-003	04/02/2016	5	6	16	6	6	18	Yes
16-003	04/02/2016	6	6	16	6	6	18	Yes
16-003	04/02/2016	12	6	23	6	6	26	Yes
16-003	04/02/2016	18	6	20	6	6	24	Yes
16-004	04/02/2016	0	6	15	6	6	18	Yes
16-004	04/02/2016	1	6	16	6	6	18	Yes
16-004	04/02/2016	2	6	15	6	6	19	Yes
16-004	04/02/2016	3	6	16	6	6	18	Yes
16-004	04/02/2016	4	6	21	6	6	24	Yes
16-004	04/02/2016	5	6	16	6	6	17	Yes
16-004	04/02/2016	6	6	16	6	6	16	Yes
16-004	04/02/2016	12	6	23	6	6	25	Yes
16-004	04/02/2016	18	6	20	6	6	22	Yes
370910	20/05/2016	0	6	15	6	6	19	Yes
370910	20/05/2016	1	6	16	6	6	17	Yes
370910	20/05/2016	2	6	16	6	6	17	Yes
370910	20/05/2016	3	6	16	6	6	17	Yes
370910	20/05/2016	4	6	22	6	6	22	Yes
370910	20/05/2016	5	6	21	6	6	21	Yes
370910	20/05/2016	6	6	22	6	6	22	Yes
370910	20/05/2016	12	6	15	6	6	17	Yes

Performance against *Klebsiella pneumoniae* NCTC 13439 – MβL producer

Lot Number	Date of Manufacture	Time from Manufacture (months)	Zone of Inhibition (mm)					Within Specification
			Disc A	Disc B	Disc C	Disc D	Disc E	
16-002	04/02/2016	0	6	16	6	6	20	Yes
16-002	04/02/2016	1	6	17	6	6	20	Yes
16-002	04/02/2016	2	6	19	6	6	20	Yes
16-002	04/02/2016	3	6	19	6	6	19	Yes
16-002	04/02/2016	4	6	17	6	6	20	Yes
16-002	04/02/2016	5	6	17	6	6	20	Yes
16-002	04/02/2016	6	6	17	6	6	20	Yes
16-002	04/02/2016	12	6	19	6	6	22	Yes
16-002	04/02/2016	18	6	17	6	6	20	Yes
16-003	04/02/2016	0	6	17	6	6	20	Yes
16-003	04/02/2016	1	6	18	6	6	21	Yes
16-003	04/02/2016	2	6	18	6	6	20	Yes
16-003	04/02/2016	3	6	18	6	6	21	Yes
16-003	04/02/2016	4	6	18	6	6	21	Yes
16-003	04/02/2016	5	6	17	6	6	19	Yes
16-003	04/02/2016	6	6	18	6	6	20	Yes
16-003	04/02/2016	12	6	18	6	6	22	Yes
16-003	04/02/2016	18	6	18	6	6	22	Yes
16-004	04/02/2016	0	6	18	6	6	21	Yes
16-004	04/02/2016	1	6	17	6	6	21	Yes
16-004	04/02/2016	2	6	18	6	6	20	Yes
16-004	04/02/2016	3	6	18	6	6	20	Yes
16-004	04/02/2016	4	6	18	6	6	20	Yes
16-004	04/02/2016	5	6	18	6	6	19	Yes
16-004	04/02/2016	6	6	18	6	6	18	Yes
16-004	04/02/2016	12	6	18	6	6	19	Yes
16-004	04/02/2016	18	6	18	6	6	21	Yes
370910	20/05/2016	0	6	18	6	6	19	Yes
370910	20/05/2016	1	6	18	6	6	22	Yes
370910	20/05/2016	2	6	17	6	6	19	Yes
370910	20/05/2016	3	6	19	6	6	21	Yes
370910	20/05/2016	4	6	18	6	6	21	Yes
370910	20/05/2016	5	6	18	6	7	20	Yes
370910	20/05/2016	6	6	19	6	6	21	Yes
370910	20/05/2016	12	6	17	6	6	19	Yes

Performance against *Escherichia coli* Wild type strain – OXA-48 producer

Lot Number	Date of Manufacture	Time from Manufacture (months)	Zone of Inhibition (mm)					Within Specification
			Disc A	Disc B	Disc C	Disc D	Disc E	
16-002	04/02/2016	0	17	18	17	18	6	Yes
16-002	04/02/2016	1	19	19	20	20	6	Yes
16-002	04/02/2016	2	19	20	21	20	9	Yes
16-002	04/02/2016	3	20	21	22	21	10	Yes
16-002	04/02/2016	4	19	19	20	20	6	Yes
16-002	04/02/2016	5	19	19	19	20	8	Yes
16-002	04/02/2016	6	18	18	19	18	6	Yes
16-002	04/02/2016	12	16	16	16	16	6	Yes
16-002	04/02/2016	18	18	18	20	19	6	Yes
16-003	04/02/2016	0	18	19	19	20	6	Yes
16-003	04/02/2016	1	19	20	21	20	6	Yes
16-003	04/02/2016	2	19	19	20	20	6	Yes
16-003	04/02/2016	3	20	21	21	21	9	Yes
16-003	04/02/2016	4	20	21	21	21	6	Yes
16-003	04/02/2016	5	18	19	20	19	6	Yes
16-003	04/02/2016	6	17	18	19	19	6	Yes
16-003	04/02/2016	12	16	17	19	18	6	Yes
16-003	04/02/2016	18	18	19	19	19	6	Yes
16-004	04/02/2016	0	19	19	18	20	6	Yes
16-004	04/02/2016	1	19	19	20	20	9	Yes
16-004	04/02/2016	2	19	19	21	21	6	Yes
16-004	04/02/2016	3	20	20	21	20	9	Yes
16-004	04/02/2016	4	20	21	21	21	6	Yes
16-004	04/02/2016	5	19	19	20	20	6	Yes
16-004	04/02/2016	6	19	19	19	18	6	Yes
16-004	04/02/2016	12	15	16	17	17	6	Yes
16-004	04/02/2016	18	19	19	21	20	6	Yes
370910	20/05/2016	0	19	19	19	20	6	Yes
370910	20/05/2016	1	18	19	20	19	6	Yes
370910	20/05/2016	2	18	20	20	19	6	Yes
370910	20/05/2016	3	18	19	19	19	6	Yes
370910	20/05/2016	4	19	19	21	20	8	Yes
370910	20/05/2016	5	18	19	21	19	6	Yes
370910	20/05/2016	6	20	20	22	21	6	Yes
370910	20/05/2016	12	19	19	21	19	6	Yes

Performance against *Klebsiella pneumoniae* NCTC 13442 – OXA-48 producer

Lot Number	Date of Manufacture	Time from Manufacture (months)	Zone of Inhibition (mm)					Within Specification	
			Disc A	Disc B	Disc C	Disc D	Disc E		
16-002	04/02/2016	0	13	12	12	15	7	Yes	
16-002	04/02/2016	1	14	14	13	15	6	Yes	
16-002	04/02/2016	2	15	15	15	15	6	Yes	
16-002	04/02/2016	3	14	15	12	16	9	Yes	
16-002	04/02/2016	4	15	15	14	16	6	Yes	
16-002	04/02/2016	5	13	13	11	15	6	Yes	
16-002	04/02/2016	6	13	13	11	14	6	Yes	
16-002	04/02/2016	12	26	26	25	26	6	Yes	
16-002	04/02/2016	18	13	12	11	13	6	Yes	
16-003	04/02/2016	0	14	14	13	14	8	Yes	
16-003	04/02/2016	1	14	14	14	15	6	Yes	
16-003	04/02/2016	2	15	14	14	16	9	Yes	
16-003	04/02/2016	3	14	14	13	16	9	Yes	
16-003	04/02/2016	4	15	16	14	16	6	Yes	
16-003	04/02/2016	5	13	12	12	14	6	Yes	
16-003	04/02/2016	6	13	13	11	14	6	Yes	
16-003	04/02/2016	12	6	6	9	6	6	Yes	
16-003	04/02/2016	18	13	13	6	15	6	Yes	
16-004	04/02/2016	0	13	14	13	15	6	Yes	
16-004	04/02/2016	1	14	14	13	15	6	Yes	
16-004	04/02/2016	2	15	15	14	16	8	Yes	
16-004	04/02/2016	3	14	14	13	15	9	Yes	
16-004	04/02/2016	4	16	15	14	16	6	Yes	
16-004	04/02/2016	5	13	14	11	14	6	Yes	
16-004	04/02/2016	6	14	14	12	15	6	Yes	
16-004	04/02/2016	12	No result available						
16-004	04/02/2016	18	14	13	11	13	6	Yes	
370910	20/05/2016	0	14	14	12	15	6	Yes	
370910	20/05/2016	1	13	14	12	14	6	Yes	
370910	20/05/2016	2	14	14	12	15	6	Yes	
370910	20/05/2016	3	13	13	10	14	6	Yes	
370910	20/05/2016	4	14	14	11	14	8	Yes	
370910	20/05/2016	5	13	13	11	14	6	Yes	
370910	20/05/2016	6	14	14	12	16	6	Yes	
370910	20/05/2016	12	12	13	11	14	6	Yes	



Performance against *Escherichia coli* ATCC®25922 – Negative for carbapenemase production

Lot Number	Date of Manufacture	Time from Manufacture (months)	Zone of Inhibition (mm)					Within Specification
			Disc A	Disc B	Disc C	Disc D	Disc E	
16-002	04/02/2016	0	22	22	23	24	24	Yes
16-002	04/02/2016	1	24	23	25	25	26	Yes
16-002	04/02/2016	2	25	26	26	27	26	Yes
16-002	04/02/2016	3	23	24	24	24	25	Yes
16-002	04/02/2016	4	25	26	26	27	25	Yes
16-002	04/02/2016	5	23	23	23	24	23	Yes
16-002	04/02/2016	6	22	23	23	23	22	Yes
16-002	04/02/2016	12	26	27	26	26	26	Yes
16-002	04/02/2016	18	25	24	26	26	26	Yes
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16-003	04/02/2016	0	23	24	24	26	25	No (Equivocal Result)
16-003	04/02/2016	1	22	23	23	23	26	Yes
16-003	04/02/2016	2	25	25	26	27	25	Yes
16-003	04/02/2016	3	24	23	24	25	25	Yes
16-003	04/02/2016	4	26	26	26	27	26	Yes
16-003	04/02/2016	5	23	23	24	25	23	Yes
16-003	04/02/2016	6	23	23	22	23	25	Yes
16-003	04/02/2016	12	24	26	25	27	28	No (Equivocal Result)
16-003	04/02/2016	18	25	25	27	27	27	Yes
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16-004	04/02/2016	0	25	25	25	26	25	Yes
16-004	04/02/2016	1	24	24	24	26	24	Yes
16-004	04/02/2016	2	26	26	26	27	26	Yes
16-004	04/02/2016	3	23	24	24	24	24	Yes
16-004	04/02/2016	4	26	26	26	26	26	Yes
16-004	04/02/2016	5	23	23	23	24	22	Yes
16-004	04/02/2016	6	23	23	22	23	23	Yes
16-004	04/02/2016	12	25	25	27	28	26	No (Equivocal Result)
16-004	04/02/2016	18	25	25	26	26	26	Yes
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370910	20/05/2016	0	23	24	24	24	24	Yes
370910	20/05/2016	1	24	25	26	26	24	Yes
370910	20/05/2016	2	24	23	24	24	23	Yes
370910	20/05/2016	3	24	24	25	25	25	Yes
370910	20/05/2016	4	25	25	25	26	25	Yes
370910	20/05/2016	5	24	24	24	24	24	Yes
370910	20/05/2016	6	25	26	25	26	25	Yes
370910	20/05/2016	12	15	15	21	21	19	Yes

### Repeatability

Nine discs of each disc type from several batches of D73C were tested against a freshly cultured strain of the negative control *Escherichia coli* ATCC® 25922.

Product Code	Lot Number	Time from Manufacture (months)	Zone diameter variation of 9 discs (mm)									
			Disc A		Disc B		Disc C		Disc D		Disc E	
			Min	Max	Min	Max	Min	Max	Min	Max	Min	Max
D73C	16-002	0	25	27	25	27	26	28	27	28	25	26
	16-003		25	27	26	27	26	27	25	26	25	26
	16-004		24	25	26	27	27	28	26	28	25	27
	370910		25	26	25	26	26	27	26	27	24	26
D73C	16-002	3	24	26	24	26	24	25	25	27	24	26
	16-003		24	25	24	25	25	26	26	27	25	26
	16-004		24	26	24	26	24	26	25	26	24	25
	370910		26	26	26	27	27	27	27	28	25	27
D73C	16-002	6	27	27	27	28	28	29	29	29	23	24
	16-003		27	27	24	24	26	27	26	27	24	25
	16-004		24	25	24	25	25	25	27	28	24	26
	370910		26	27	26	27	26	27	27	28	26	27
D73C	16-002	12	27	27	26	28	26	28	27	28	26	27
	16-003		26	28	27	28	27	29	28	29	28	28
	16-004		26	28	28	29	28	29	27	29	28	30
	370910		25	26	26	27	26	28	27	27	24	25
D73C	16-002	18	26	28	25	27	26	28	27	29	26	28
	16-003		26	27	27	29	28	29	29	30	26	28
	16-004		25	26	26	28	28	29	28	30	26	28
	370910											

**Reproducibility**

4 different batches of D73C (16-002, 16-003, 16-004 and 370910) were tested at weekly intervals against freshly cultured isolates of carbapenemase producers, non-carbapenemase producers and OXA-48 producers. The following results were obtained:

Batch: 16-002					
Organism	Strain Information	Interpretation of results			
		Week 1	Week 2	Week 3	Week 4
<i>Enterobacter cloacae</i>	Wild type – AmpC producer with porin loss	AmpC with porin loss	AmpC with porin loss	AmpC with porin loss	AmpC with porin loss
<i>Escherichia coli</i>	Wild type – KPC producer	KPC	KPC	KPC	KPC
<i>Klebsiella pneumoniae</i>	NCTC 13438 – KPC producer	KPC	KPC	KPC	KPC
<i>Klebsiella pneumoniae</i>	NCTC 13440 – MβL producer	MβL	MβL	MβL	MβL
<i>Klebsiella pneumoniae</i>	NCTC 13439 – MβL producer	MβL	MβL	MβL	MβL
<i>Escherichia coli</i>	Wild type – OXA-48 producer	OXA-48	OXA-48	OXA-48	OXA-48
<i>Klebsiella pneumoniae</i>	NCTC 13442 – OXA-48 producer	OXA-48	OXA-48	OXA-48	OXA-48
<i>Escherichia coli</i>	ATCC®25922 – Negative for carbapenemase production	Negative	Negative	Negative	Negative

Batch: 16-003					
Organism	Strain Information	Interpretation of results			
		Week 1	Week 2	Week 3	Week 4
<i>Enterobacter cloacae</i>	Wild type – AmpC producer with porin loss	AmpC with porin loss	AmpC with porin loss	AmpC with porin loss	AmpC with porin loss
<i>Escherichia coli</i>	Wild type – KPC producer	KPC	KPC	KPC	KPC
<i>Klebsiella pneumoniae</i>	NCTC 13438 – KPC producer	KPC	KPC	KPC	KPC
<i>Klebsiella pneumoniae</i>	NCTC 13440 – MβL producer	MβL	MβL	MβL	MβL
<i>Klebsiella pneumoniae</i>	NCTC 13439 – MβL producer	MβL	MβL	MβL	MβL
<i>Escherichia coli</i>	Wild type – OXA-48 producer	OXA-48	OXA-48	OXA-48	OXA-48
<i>Klebsiella pneumoniae</i>	NCTC 13442 – OXA-48 producer	OXA-48	OXA-48	OXA-48	OXA-48
<i>Escherichia coli</i>	ATCC®25922 – Negative for carbapenemase production	Negative	Negative	Negative	Equivocal

Batch: 16-004					
Organism	Strain Information	Interpretation of results			
		Week 1	Week 2	Week 3	Week 4
<i>Enterobacter cloacae</i>	Wild type – AmpC producer with porin loss	AmpC with porin loss	AmpC with porin loss	AmpC with porin loss	AmpC with porin loss
<i>Escherichia coli</i>	Wild type – KPC producer	KPC	KPC	KPC	KPC
<i>Klebsiella pneumoniae</i>	NCTC 13438 – KPC producer	KPC	KPC	KPC	KPC
<i>Klebsiella pneumoniae</i>	NCTC 13440 – MβL producer	MβL	MβL	MβL	MβL
<i>Klebsiella pneumoniae</i>	NCTC 13439 – MβL producer	MβL	MβL	MβL	MβL
<i>Escherichia coli</i>	Wild type – OXA-48 producer	OXA-48	OXA-48	OXA-48	OXA-48
<i>Klebsiella pneumoniae</i>	NCTC 13442 – OXA-48 producer	OXA-48	OXA-48	OXA-48	OXA-48
<i>Escherichia coli</i>	ATCC®25922 – Negative for carbapenemase production	Negative	Negative	Negative	Negative

Batch: 370910					
Organism	Strain Information	Interpretation of results			
		Week 1	Week 2	Week 3	Week 4
<i>Enterobacter cloacae</i>	Wild type – AmpC producer with porin loss	AmpC with Porin Loss	AmpC with Porin Loss	AmpC with Porin Loss	AmpC with Porin Loss
<i>Escherichia coli</i>	Wild type – KPC producer	KPC	KPC	KPC	KPC
<i>Klebsiella pneumoniae</i>	NCTC 13438 – KPC producer	KPC	KPC	KPC	KPC
<i>Klebsiella pneumoniae</i>	NCTC 13440 – MBL producer	MBL	MBL	MBL	MBL
<i>Klebsiella pneumoniae</i>	NCTC 13439 – MBL producer	MBL	MBL	MBL	MBL
<i>Escherichia coli</i>	Wild type – OXA-48 producer	OXA-48	OXA-48	OXA-48	OXA-48
<i>Klebsiella pneumoniae</i>	NCTC 13442 – OXA-48 producer	OXA-48	OXA-48	OXA-48	OXA-48
<i>Escherichia coli</i>	ATCC®25922 – Negative for carbapenemase production	Negative	Negative	Negative	Negative

**Internal Evaluation**

Resistance Mechanisms		Result						Total	
		KPC	MBL	OXA-48	AmpC/PL	Negative	Equivocal	Correctly Identified	Incorrectly Identified
Carbapenemase Producing Organisms	KPC	11						11	0
	MBL		12					12	0
	OXA-48			11				11	0
	<b>Total</b>	11	12	11				34	0
Non-Carbapenemase Producing Organisms	ESBL					4	11	15	0
	ESBL/AmpC						1	1	0
	AmpC				3	1	11	15	0
	<b>Total</b>				3	5	23	31	0
<b>Sensitivity</b>	<b>100%</b>								
<b>Specificity</b>	<b>100%</b>								

**External Evaluation**

Third party evaluation: Sweden

Resistance Mechanisms		Result						Total	
		KPC	MBL	OXA-48	AmpC/PL	Negative	Equivocal	Correctly Identified	Incorrectly Identified
Carbapenemase Producing Organisms	KPC	3				1		3	1
	MBL	1	11					11	1
	OXA-48			9				9	0
	<b>Total</b>	4	11	9		1		23	2
Non-Carbapenemase Producing Organisms	ESBL	1				1		1	1
	AmpC					1	1	2	0
	Negative				2	3	1	6	0
	<b>Total</b>	1			2	5	2	9	1
<b>Sensitivity</b>	<b>95.83%</b>								
<b>Specificity</b>	<b>81.82%</b>								

Third party evaluation: Japan

Resistance Mechanisms		Result						Total	
		KPC	MBL	OXA-48	AmpC/PL	Negative	Equivocal	Correctly Identified	Incorrectly Identified
Carbapenemase Producing Organisms	KPC	2						2	0
	MBL		11		1		1	11	2
	OXA-48			4			1	4	1
	Negative		1		1		1	2	1
	<b>Total</b>	2	12	4	2		3	17	5
Non-Carbapenemase Producing Organisms	ESBL						1	1	0
	ESBL/AmpC							0	0
	AmpC				1		1	2	0
	<b>Total</b>				1		2	3	0
<b>Sensitivity</b>	<b>85%</b>								
<b>Specificity</b>	<b>83.33%</b>								