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mastdiscs VALIDATION DATA

Mast® ICT D74C

External Evaluation

Pre-development External Evaluations

Study1, UK:

D74C was tested against a panel of clinical isolates (n= 26) that included Enterobacteriaceae, Pseudomonas aeruginosa and Acinetobacter baumanii. Some of the isolates had known resistance mechanisms, and the remainder were identified through routine screening for carbapenem susceptibility (imipenem, ertapenem or meropenem). These were a mixture of carbapenem susceptible and carbapenem intermediate/ resistant organisms. Isolates displaying reduced susceptibility were sent to a reference laboratory for confirmation of the resistance mechanism.

Results

Resistance Mechanism		Total					
		Positive	Negative	Equivocal	Correctly Identified	Incorrectly Identified	
Carbapenemase Producing Organisms (<i>n</i> =11)	KPC (<i>n</i> =3)	3	0	0	3	0	
	MBL (unspecified, n=3)	3	0	0	3	0	
	MBL (NDM, <i>n</i> =1)	1	0	0	1	0	
	MBL (IMP, n=1)	1	0	0	1	0	
	OXA (<i>n</i> =3)	3	0	0	3	0	
	Total	11	0	0	11	0	
Non- Carbapenemase Producing Organisms (<i>n</i> =15)	ESBL (n=1)	0	1	0	1	0	
	Negative (n=12)	2	10	0	10	2	
	OprD porin loss (<i>n</i> =2)	0	2	0	2	0	
	Total	2	13	0	13	2	



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Sensitivity = 100% Specificity = **87%**

Positive predictive value = 85% Negative predictive value = **100**%

Study 2, UK:

D74C was tested against a large panel of organisms with a diverse range of resistance mechanisms (carbapenemase producers n=39, carbapenemase negative n=14)

Results

Resistance Mechanism		Total					
		Positive	Negative	Equivocal	Correctly Identified	Incorrectly Identified	
Carbapenemase Producing Organisms	KPC (n=6)	6	0	0	6	0	
	MBL (VIM, n=6)	6	0	0	6	0	
	MBL (IMP, n=5)	5	0	0	5	0	
	MBL (NDM, n=5)	5	0	0	5	0	
	MBL/ ESBL co-producer (VIM-10 + VEB-1)	1	0	0	1	0	
	OXA-48 (n=6)	6	0	0	6	0	
	OXA-40 (n=1)	1	0	0	1	0	
	OXA-23 (n=1)	1	0	0	1	0	
	OXA-23 and OXA-51 (n=1)	0	1	0	0	1	
	OXA-like (n=6)	6	0	0	6	0	
	OXA-like/ TEM co- producer (n=1)	1	0	0	1	0	



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	Total	38	1	0	38	1
Non- Carbapenemase Producing Organisms	ESBL (n=5)	2 (we ak)	3	0	3	2
	AmpC (n=6)	0	6	0	6	0
	AmpC + impermeabilit y (n=1)	0	1	0	1	0
	AmpC + porin loss (n=2)	0	2	0	2	0
	Total	2	12	0	12	2

Sensitivity = **97.4%** Specificity = **85.7%**

Positive predictive value = **95.2%**

Negative predictive value = 92.3%