Laboratory Report

Transit Studies

Introduction

Mast Group Limited supplies a range of microbiological reagents to over 70 countries worldwide by direct means or via distributors. To establish the effect exposure to adverse, or extreme, temperature has on the product range, transit validation studies on representative samples has been undertaken on Mast Dehydrated Culture Media (DCM), Mast antibiotic susceptibility products (**mast**discs™ and MASTRING-S™) and antisera products.

Based on our knowledge of transport conditions that these products may be exposed to, packs of Mast DCM, Mast antibiotic susceptibility products (**mast**discs™ and MASTRING-S™), 1 antisera product were subjected to controlled temperature extremes ranging from -20°C to 60°C for a period of 14 days (2 weeks) and then tested according to relevant standard quality control tests to determine the effect of simulated transit on their quality.

Additionally, a 2 week stability study was set up to examine the performance of Mast Occutest reagents under various storage conditions. Mast Occutest reagents were stored at the following temperatures: 4°C, RT (approx 25°C), 37°C and 60°C.

A further 2 week stability study was set up to examine the performance of Mast ID Intralactam strips (ETO/1) under various storage conditions. A batch of ETO/1 strips was obtained and stored at the following temperatures: -20°C, 4°C, RT (approx 25°C), 37°C and 60°C.

Methods

The test method for each product was conducted as per the product Instructions for Use, and following recommended test methods e.g. for **mast**discs™ products CLSI Antimicrobial Susceptibility Test Methods. Mast DCM, Mast antibiotic susceptibility products (**mast**discs™ and MASTRING-S™) and antisera were subjected to -20°C, 4°C, RT (room temperature), 37°C and 60°C. All products were tested in triplicate and on 6 different occasions, typically day 0, 1, 5,7,10 and 14 days, over a 14 day period.

Mast Occutest reagents were tested at 7 and 14 days using the performance methods described on the product IFU.

Mast ID Intralactam strips (ETO/1) were tested at 0, 1, 3, 8, 11 and 14 days using the performance methods described in the product IFU.

Discussion

Results are shown in table 2, 3 and 4.

All dehydrated culture medium tested showed no change in performance over the 14 day test period at all temperature ranges. Egg Yolk Telurite Emulsion showed a decline in performance when stored at -20°C and had reduced performance following 12 days storage at 60°C.

Antibiotic susceptibility discs when stored at -20°C, 4°C and RT showed no change in performance over the 14 day period, with the exception of Caspofungin which demonstrated reduced performance (smaller zone diameter than CLSI acceptance limits) when stored at RT for 7 days or more. At the other temperature ranges tested products showed changes in performance. Four products gave results outside the acceptance range following storage at 37°C between 8-11 days. These products were SAM20 (11 days), CTX30 (8 days), CAS5 (7 days) and D68C (10 days). At 60°C, 23 products

showed no deterioration in performance over the 14 day period. 16 products showed diminished performance at 60°C following ≤7 days storage and 4 products (D68C, D69C, OX1 and NA30) gave decreased performance following 8-14 days storage.

ETO/1 strips when stored at -20°C, 4°C, RT and 37°C showed no change in performance over the 14 day period. At 60°C, the strips demonstrated reduced performance after 11 day storage.

A total of ten Mastring products were tested and all showed no change in performance at 4°C and RT over 14 day period, 1 product (SGH5) showed decline in performance after 9 days at -20°C. Four products (SGH3, SGH4, SGH7 and SGH10) showed decline in performance between 1-10 days at 37°C and all products tested gave decline in performance between 1-10days at 60°C.

Antisera showed decline in performance when subjected to 60°C for greater than 7 days. At all other temperature ranges no change in product performance was found over the 14 day trial period.

Mast Occutest reagents 'A' and 'B' showed decline in performance when subjected to 60°C over a 7 and 14 day period, respectively. Mast Occutest reagent 'C' showed no change in product performance over the 14 day period.

Table 1 – Products tested in transit study

Dehydrated Culture Medium	
Product	**Code**
CLED	DM110
Cooked meat medium	DM120
XLD Agar	DM230
Mueller Hinton	DM170
Sabaroud Dextrose Agar	DM200
TCBS Cholera medium	DM218
Nutrient Agar	DM179
Columbia Agar	DM115
Baird Parker Medium	DM096
Egg Yolk Telurite Emulsion	DM097S
Burkholderia cepacia	DM253
Buffered RV Broth	DM269
Islams Agar	DM137
MacConkey Agar No.3	DM143
Legionella BCYE Agar	DM258
MacConkey Broth	DM150
C.E.M.O Agar	DM470
Wilkins Chalgren Agar	DM235
Tryptone Soy Broth	DM226
Antibiotic Susceptibility Discs	
Product	**Code**
Gentamicin	GM10
Rifampicin	RP5
Cotrimoxazole	TS25

Product	Code
Metronidazole	MZ5
Vancomycin	VA30
Teicoplanin	TEC30
Telithromycin	TEL15
Clindamycin	CD2
Colistin	CO10
Erythromycin	E15
Cefepime	CPM30
Ampicillin	AP10
Penicillin G	PG10
Piperacillin	PRL100
Ticarcillin	TC75
Oxacillin	OX1
Mecillinam	MEC10
Augmentin	AUG30
Sulbactam/ampicillin mixture	SAM20
Piperacillin/tazobactam	PTZ110
Cefotaxime	CTX30
Fluconazole	FCN25
Cefoxitin	FOX30
Chloramphenicol	C30
Mupirocin	MUP20
Nalidixic acid	NA30
Ciprofloxacin	CIP5
Synercid	SYN15
Tetracycline	T30
Aztreonam	ATM30
Imipenem	IMI10
Caspofungin	CAS5
ESβL & AmpC detection (D68C)	D68C
AmpC detection (D69C)	D69C
Antibiotic Susceptibility Rings	
Product	**Code**
Mastring	SGH3
Mastring	SGH4
Mastring	SGH5
Mastring	SGH6
Mastring	SGH7
Mastring	SGH8
Mastring	SGH9
Mastring	SGH10
Mastring	MID8

Antisera	
Product	**Code**
Salmonella O Factor O9	M10314
ID Strips	
Product	**Code**
Intralactam strips	ETO/1
Faecal Occult Blood Test	
Product	**Code**
Mast Occutest	OCCU1

Table 2 – Results of transit study

		Transit shelf (Number of days product was subjected to temperature and maintained performance)				
Product	**Code**	**-20°C**	**4°C**	**RT**	**37°C**	**60°C**
CLED	DM110	14	14	14	14	14
Cooked meat medium	DM120	14	14	14	14	14
XLD Agar	DM230	14	14	14	14	14
Mueller Hinton	DM170	REPEAT				
Sabaroud Dextrose Agar	DM200	14	14	14	14	14
TCBS Cholera medium	DM218	14	14	14	14	14
Nutrient Agar	DM179	14	14	14	14	14
Columbia Agar	DM115	14	14	14	14	14
Baird Parker Medium	DM096	14	14	14	14	14
Egg Yolk Telurite Emulsion	DM097S	0	14	14	14	<14 (12)
Burkholderia cepacia	DM253	14	14	14	14	14
Buffered RV Broth	DM269	14	14	14	14	14
Islams Agar	DM137	14	14	14	14	14
Tryptone Soy Broth	DM226	14	14	14	14	14
MacConkey Agar No.3	DM143	14	14	14	14	14
Legionella BCYE Agar	DM258	14	14	14	14	14
MacConkey Broth	DM150	14	14	14	14	14
C.E.M.O Agar	DM470	14	14	14	14	14
Wilkins Chalgren Agar	DM235	14	14	14	14	14
Product	**Code**					
Mastring	SGH3	14	14	14	<7	<1
Mastring	SGH4	14	14	14	<9 (6)	<6 (2)
Mastring	SGH5	<14 (9)	14	14	14	<6 (2)
Mastring	SGH6	14	14	14	14	<1
Mastring	SGH7	14	14	14	<10 (7)	<7 (3)
Mastring	SGH8	14	14	14	14	<3 (1)
Mastring	SGH9	14	14	14	14	14
Mastring	SGH10	14	14	14	10	<3

Product	Code					
Mastring	MID 8	14	14	14	14	<14 (10)
Product	**Code**					
Salmonella O Factor O9	M10314	14	14	14	14	<10 (7)
Product	**Code**					
Gentamicin	GM10	14	14	14	14	14
Rifampicin	RP5	14	14	14	14	14
Cotrimoxazole	TS25	14	14	14	14	14
Vancomycin	VA30	14	14	14	14	14
Teicoplanin	TEC30	14	14	14	14	14
Telithromycin	TEL15	14	14	14	14	14
Clindamycin	CD2	14	14	14	14	14
Colistin	CO10	14	14	14	14	14
Erythromycin	E15	14	14	14	14	14
Metronidazole	MZ5	14	14	14	14	14
Chloramphenicol	C30	14	14	14	14	14
Mupirocin	MUP20	14	14	14	14	14
Nalidixic acid	NA30	14	14	14	14	<14 (13)
Ciprofloxacin	CIP5	14	14	14	14	14
Synercid	SYN15	14	14	14	14	14
Tetracycline	T30	14	14	14	14	14
Ampicillin	AP10	14	14	14	14	<8 (4)
Penicillin G	PG10	14	14	14	14	14
Piperacillin	PRL100	14	14	14	14	14
Ticarcillin	TC75	14	14	14	14	<5
Oxacillin	OX1	14	14	14	14	<14 (13)
Mecillinam	MEC10	14	14	14	14	<7 (3)
Augmentin	AUG30	14	14	14	14	14
Sulbactam/ampicillin mixture	SAM20	14	14	14	<14 (11)	<8 (4)
Piperacillin/tazobactam	PTZ110	14	14	14	14	14
Cefotaxime	CTX30	14	14	14	<11 (8)	<4 (1)
Cefepime	CPM30	14	14	14	14	<5 (1)
Cefoxitin	FOX30	14	14	14	14	<4 (1)
Aztreonam	ATM30	14	14	14	14	14
Imipenem	IMI10	14	14	14	14	14
Caspofungin	CAS5	14	14	<9 (7)	<9 (7)	<5 (1)
Fluconazole	FCN25	14	14	14	14	14
ESβL & AmpC detection (D68C)	D68C	14	14	14	<14 (10)	<14 (10)
AmpC detection (D69C)	D69C	14	14	14	14	<14 (10)
Product	**Code**					
Intralactam strips	ETO/1	14	14	14	14	<14 (11)
Product	**Code**					
Mast Occutest reagent 'A'	OCCU1	N/A	14	14	14	<7

Product	Code					
Mast Occutest reagent 'B'	OCCU1	N/A	14	14	14	<14
Mast Occutest reagent 'C'	OCCU1	N/A	14	14	14	14