



SRL SANMEDICO
A. Corobceanu Street 7A, apt. 9,
Chişinău MD-2012,
Moldova

Mast Group Ltd.
Mast House
Derby Road
Bootle
Merseyside L20 1EA
United Kingdom

Tel: +44 (0) 151 933 7277

www.mast-group.com

TO WHOM IT MAY CONCERN

LETTER OF AUTHORISATION

This letter is to confirm, SRL SANMEDICO of address A. Corobceanu Street 7A, apt. 9, Chişinău MD-2012, Moldova is authorised to register products, present proposals, offer quotations and accept orders and to participate in tenders as required for Mast Group Limited products.

The undersigned herewith states that the above is true and correct.

Yours faithfully,

Susan Thomson

Bootle UK

January 11th 2024

International business Manager, on behalf of Mast Group

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Mast Group Ltd
Mast House, Derby Road
Bootle
Liverpool
L20 1EA
United Kingdom

Holds Certificate Number:

FM 724380

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Design, manufacture and supply of in-vitro diagnostic devices and associated services.

For and on behalf of BSI:



Matt Page, Managing Director Assurance - UK & Ireland

Original Registration Date: 1994-06-14

Latest Revision Date: 2021-12-03

Effective Date: 2021-11-11

Expiry Date: 2024-05-31



Page: 1 of 2

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Certificate No: FM 724380

Location	Registered Activities
Mast Group Ltd Mast House, Derby Road Bootle Liverpool L20 1EA United Kingdom	Design, manufacture and supply of in-vitro diagnostic devices and associated services.
Mast Group Ltd Atlantic House, Derby Road Bootle Liverpool L20 1EA United Kingdom	Manufacturing, QC and warehousing of IVD kits and reagents, bacteriological media and other kits and reagents for the life sciences industry.



Original Registration Date: 1994-06-14
Latest Revision Date: 2021-12-03

Effective Date: 2021-11-11
Expiry Date: 2024-05-31

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Mast Group Ltd
Mast House, Derby Road
Bootle
Liverpool
L20 1EA
United Kingdom

Holds Certificate Number:

MD 724379

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, manufacture and supply of in-vitro diagnostic devices for clinical microbiology and molecular biology and bacteriological media.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-10-07

Latest Revision Date: 2021-11-28

Effective Date: 2021-06-01

Expiry Date: 2024-05-31

Page: 1 of 2



...making excellence a habit.™

Certificate No: **MD 724379**

Location	Registered Activities
Mast Group Ltd Mast House, Derby Road Bootle Liverpool L20 1EA United Kingdom	Design, manufacture and supply of in-vitro diagnostic devices for clinical microbiology and molecular biology and bacteriological media
Mast Group Ltd Atlantic House, Derby Road Bootle Liverpool L20 1EA United Kingdom	Manufacture of IVD kits and reagents for clinical microbiology and molecular biology, bacteriological media.



Original Registration Date: 2020-10-07

Latest Revision Date: 2021-11-28

Effective Date: 2021-06-01

Expiry Date: 2024-05-31



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EC DECLARATION OF CONFORMITY

We hereby declare that the devices described below comply with those provisions which apply to them of the European Directive 98/79/EC 'on *in vitro* diagnostic medical devices', and are placed on the European market by Mast Group UK through our appointed EC Authorised Representative Mast Diagnostica GmbH, Feldstrasse 20, 23858 Reinfeld, Germany.

This declaration is valid for the IVD medical devices described below on or after the date hereof, and which bear the CE mark. It is also valid for all IVD medical devices described below which are manufactured by Mast and placed on the market on or after the date hereof by third parties with our consent and which bear the CE mark. All supporting documents relating to this declaration are retained at the manufacturer's premises.

Product code	Product description	IVD Directive classification	EDMS code
Various	MAST® ID identification test paper products - discs, rings and strips. Products for presumptive identification of biochemical reactions or detection of a specific reaction profiles in microbes.	Self certification Annex III excluding section 6	1402020100, 1402020200, 1402020400, 1402020800, 1402029000. (codes registered - 24/03/2003)

Standards applied: EN ISO 13485:2016, ISO 9001:2015, EN ISO 14971:2019, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2016, EN ISO 15223-2:2010.

Declaration made by Date: 22 March 2022

D N Hogben, Quality Assurance and Regulatory Affairs Manager – Mast Group Ltd.

Document valid till: 26th May 2025



European In Vitro Diagnostic Medical Directive 98/79/EC, Annex III – General IVD
EC DECLARATION OF CONFORMITY - Self-Certification (Annex III excluding section 6) – General IVD

Annex – list of MAST® ID identification test paper products

Serial No.	Device ID Number	Product Description	Pack Size	Brand Name	Intended purpose of the medical device type
1	D40C	Bacitracin Discs 0.04 units	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Group A streptococci.
2	D40	Bacitracin Discs 0.04 units	100 Discs	MASTDISCS® ID	For presumptive Identification of Group A streptococci.
3	D41C	Bacitracin Discs 0.1 Unit	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Group A streptococci.
4	D41	Bacitracin Discs 0.1 Unit	100 Discs	MASTDISCS® ID	For presumptive Identification of Group A streptococci.
5	D42C	Optochin Discs 5ug	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Strep. pneumoniae.
6	D42	Optochin Discs 5ug	100 Discs	MASTDISCS® ID	For presumptive Identification of Strep. pneumoniae.
7	D43C	X Factor Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.
8	D43	X Factor Discs	100 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.
9	D44C	V Factor Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.
10	D44	V Factor Discs	100 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.
11	D45C	X+V Factor Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.
12	D45	X+V Factor Discs	100 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.



Serial No.	Device ID Number	Product Description	Pack Size	Brand Name	Intended purpose of the medical device type
13	D46C	Metronidazole Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Gardnerella vaginalis.
14	D46	Metronidazole Discs 50ug	100 Discs	MASTDISCS® ID	For presumptive Identification of Gardnerella vaginalis.
15	D47C	Sulphathiazole Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Gardnerella vaginalis.
16	D47	Sulphathiazole Discs 1ug	100 Discs	MASTDISCS® ID	For presumptive Identification of Gardnerella vaginalis.
17	D48	Lysostaphin Discs 20ug	50 Discs	MASTDISCS® ID	For presumptive Identification of Staphylococci/micrococci.
18	D49	ALA Discs 75ug	100 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.
19	D51C	Nitrate Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Nitrate Reductase in anaerobes.
20	D52C	Extended Spectrum β Lactamase Set	6 x 50 Discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
21	D55	SPS Discs 1000ug	100 Discs	MASTDISCS® ID	For presumptive Identification of P. anaerobius
22	D57C	Oxidase Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Nitrate Reductase in Pseudomonas spp.
23	D57	Oxidase Discs	100 Discs	MASTDISCS® ID	For presumptive Identification of Pseudomonas spp.
24	D59	Nitrocefin Discs (B)	50 Discs	MASTDISCS® ID	For presumptive Identification of Beta lactamase activity.
25	D62C	Cefotaxime 30 & Cefotaxime 30/Clavulanic Acid 10	6 x 50 Discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
26	D63C	Cefepime 30 & Cefepime 30/Clavulanic Acid 10	6 x 50 Discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.in Enterobacteriales.
27	D64C	Ceftazidime 30 & Ceftazidime 30/Clavulanic Acid 10	6 x 50 Discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
28	D66C	Cefpodoxime 10 & Cefpodoxime 10/Clavulanic Acid 1	6 x 50 Discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.



Serial No.	Device ID	Product Description	Pack Size	Brand Name	Intended purpose of the medical device type
29	D67C	Extended Spectrum β Lactamase Set (CPD10)	6 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
30	D68C	AmpC & ESBL Detection Set	4 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
31	D69C	AmpC Detection Set	3 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
32	D70C	Carbapenemase Detection Set	4 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
33	D71C	CAT ID - Carbapenemase Activity Test (CAT) discs	5 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
34	D72C	MastDiscs® Combi AmpC, ESBL and Carbapenemase Detection Disc Set	6 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
35	D73C	Carba Plus. For the detection of carbapenemase and OXA-48 enzyme production in Enterobacteriaceae.	5 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
36	D74	MastDiscs® ID Indirect Carbapenemase Test (ICT)	25 Tests	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
37	D76C	MastDiscs® Combi ESBL Detection Set	50 Tests	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
38	STOX	Oxacillin Strips	50 Strips	MAST® ID	Oxacillin Strips for the detection of MRSA-Antibiotic Susceptibility Testing.
39	ETO/1	MAST® ID Intralactam Strips	25 strips	MAST® ID	A strip test for the rapid detection of β -lactamase.
40	ETO4	MAST® ID Oxidase Strips - for the performance of the oxidase reaction	25 strips	MAST® ID	A strip test for the rapid detection of cytochrome oxidase enzyme (Oxidase) in bacteria.
41	ETO7	MAST® ID PYR Strips - for the detection of pyrrolidonyl amino peptidase activity	25 strips	MAST-ID	A rapid strip test for the detection of pyrrolidonyl amino peptidase activity in streptococci and enterococci.
42	MIID/XV	MAST® ID XV Mirror ring. MASTRING™ containing X+V factor tips	50 rings	ID-MASTRING	For the identification of haemophilus spp.
43	MID8	MASTRING containing Erythromycin (60ug), Rifampicin (15ug), Colistin Sulphate (10ug), Penicillin G 2 units, Kanamycin (1000ug), Vancomycin (5ug)	50 rings	ID-MASTRING	For the presumptive identification of Gram negative non-sporing anaerobes.



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EC DECLARATION OF CONFORMITY

We hereby declare that the devices described below comply with those provisions which apply to them of the European Directive 98/79/EC 'on *in vitro* diagnostic medical devices', and are placed on the European market by Mast Group UK through our appointed EC Authorised Representative Mast Diagnostica GmbH, Feldstrasse 20, 23858 Reinfeld, Germany.

This declaration is valid for the IVD medical devices described below on or after the date hereof, and which bear the CE mark. It is also valid for all IVD medical devices described below which are manufactured by Mast and placed on the market on or after the date hereof by third parties with our consent and which bear the CE mark. All supporting documents relating to this declaration are retained at the manufacturer's premises.

Product code	Product description	IVD Directive classification	EDMS code
Various	MAST DISCS® AST – paper antimicrobial susceptibility test (AST) disc products. Each disc contains an antimicrobial agent of stated content in conformance to recognised AST standards such as European Committee on Antimicrobial Susceptibility Testing - EUCAST or US Clinical and Laboratory Standards Institute - CLSI.	Self-certification Annex III excluding section 6	1402050200 (Code registered - 02/12/2002) GMDN code - 63834

Standards applied: EN ISO 13485:2016, ISO 9001:2015, EN ISO 14971:2019, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2016, EN ISO 15223-2:2010.

Declaration made by C Winstanley

Date: 18th May 2022

C Winstanley, Quality Assurance and Regulatory Affairs Manager – Mast Group Ltd.

Document valid till: 18th May 2025



European In Vitro Diagnostic Medical Directive 98/79/EC, Annex III – General IVD
 EC DECLARATION OF CONFORMITY- Self-Certification (Annex III excluding section 6) – General IVD
 Product Names: Mast® Disc AST products

Annex – list of Mast® Disc AST products

Serial No.	Device ID Number	Product Description	Method of use	Pack Size	Brand Name	Intended purpose of the medical device type
1	AK30C	Amikacin 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
2	AP2C	Ampicillin 2ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
3	AP10C	Ampicillin 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
4	SAM20C	Ampicillin 10ug/Sulbactam 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
5	AUG3C	Amoxicillin/clavulanic acid 2-1	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
6	AUG30C	Amoxicillin/clavulanic acid 20-10	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
7	ATH15C	Azithromycin 15ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
8	ATM30C	Aztreonam 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
9	BA10C	Bacitracin 10 units	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
10	PY100C	Carbenicillin 100ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
11	CFC30C	Cefaclor 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
12	CFB30C	Ceftibuten 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
13	CMD30C	Cefamandole 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
14	CDX30C	Cefadroxil 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
15	BPR5C	Ceftobiprole 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
16	CPM30C	Cefepime 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
17	CFM5C	Cefixime 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
18	CPZ75C	Cefoperazone 75ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
19	CTX5C	Cefotaxime 5ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
20	CTX30C	Cefotaxime 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges



Serial No.	Device ID Number	Product Description	Method of use	Pack Size	Brand Name	Intended purpose of the medical device type
22	CTF30C	Cefotiam 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
22	FOX30C	Cefoxitin 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
23	CPD10C	Cefpodoxime 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
24	CZL30	Cefprozil 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
25	CPT5C	Ceftaroline 5ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
26	CPT30C	Ceftaroline 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
27	CZA14C	Ceftazidime/avibactam 10-4	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
28	CZA50C	Ceftazidime/avibactam 30-20	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
29	CAZ10C	Ceftazidime 10ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
30	CAZ30C	Ceftazidime 30ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
31	CRO5C	Ceftriaxone 5ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
32	CRO30C	Ceftriaxone 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
33	C/T40C	Ceftolozone/Tazobactam 30-10	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
34	CXM30C	Cefuroxime 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
35	CFX30C	Cephalexin 30ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
36	KF30C	Cephalothin 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
37	CZ30C	Cephazolin 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
38	C30C	Chloramphenicol 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
39	CIP5C	Ciprofloxacin 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
40	CLA15C	Clarithromycin 15ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
41	CD2C	Clindamycin 2ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
42	DLX5C	Delafloxacin 5ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
43	DOR10C	Doripenem 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges



Serial No.	Device ID Number	Product Description	Method of use	Pack Size	Brand Name	Intended purpose of the medical device type
44	DXT30C	Doxycycline 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
45	ERV20C	Eravacycline 20ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
46	ETP10C	Ertapenem 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
47	E15C	Erythromycin 15ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
48	FOT200C	Fosfomycin/Trometamol 200ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
49	FC10C	Fusidic Acid 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
50	FDC30C	Cefiderocol 30ug discs	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
51	GM10C	Gentamicin 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
52	GM30C	Gentamicin 30ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
53	GM120C	Gentamicin 120ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
54	IMI10C	Imipenem 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
55	IMR35C	Imipenem/relebactam 35µg discs	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
56	K30C	Kanamycin 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
57	LEV5C	Levofloxacin 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
58	LZD10C	Linezolid 10ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
59	LZD30C	Linezolid 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
60	MEC10C	Mecillinam 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
61	MEM10C	Meropenem 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
62	MEM10	Meropenem 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
63	MEV30C	Meropenem/Vaborbactam 20-10ug	EUCAST/CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
64	MZ5C	Metronidazole 5ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
65	MZ5	Metronidazole 5ug	CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
66	MN30C	Minocycline 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
67	MFX5C	Moxifloxacin 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges



Serial No.	Device ID Number	Product Description	Method of use	Pack Size	Brand Name	Intended purpose of the medical device type
68	MUP200C	Mupirocin 200ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
69	NA30C	Nalidixic Acid 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
70	NA30	Nalidixic Acid 30ug	EUCAST/CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
71	NE10C	Neomycin 10ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
72	NET30C	Netilmicin 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
73	NI100C	Nitrofurantoin 100ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
74	NI300C	Nitrofurantoin 300ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
75	NIB30C	Nitroxoline 30ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
76	NOR10C	Norfloxacin 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
77	NO5C	Novobiocin 5ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
78	OFX5C	Ofloxacin 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
79	OX1C	Oxacillin 1ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
80	OX5C	Oxacillin 5ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
81	OX1	Oxacillin 1ug	EUCAST/CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
82	PEF5C	Pefloxacin 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
83	PG1C	Penicillin G 1 unit	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
84	PG1	Penicillin G 1 unit	EUCAST	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
85	PG10C	Penicillin G 10 unit	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
86	PG10	Penicillin G 10 unit	CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
87	PRL30C	Piperacillin 30ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
88	PRL100C	Piperacillin 100ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
89	PTZ36C	Piperacillin/Tazobactam 30-6	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
90	PTZ110C	Piperacillin/Tazobactam 100-10	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
91	SYN15C	Quinupristin/dalfopristin 15ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
92	RP5C	Rifampicin 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges



**Mast
Group**

Serial No.	Device ID Number	Product Description	Method of use	Pack Size	Brand Name	Intended purpose of the medical device type
93	RP5	Rifampicin 5ug	EUCAST/CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
94	SPC100C	Spectinomycin 100ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
95	S10C	Streptomycin 10ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
96	S300C	Streptomycin 300ug Discs	EUCAST	5x50 discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
97	TEC30C	Teicoplanin 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
98	TEL15C	Telithromycin 15ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
99	TEM30C	Temocillin 30ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
100	T30C	Tetracycline 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
101	TC75C	Ticarcillin 75ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
102	TGC15C	Tigecycline 15ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
103	TIM85C	Timentin 85ug (Ticarcillin 75ug/Clavulanic acid 10ug)	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
104	TN10C	Tobramycin 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
105	TM5C	Trimethoprim 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
106	TS25C	Cotrimoxazole 25ug (Trimethoprim 1.25ug/Sulphamethosazole 23.75ug)	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
107	TS25	Cotrimoxazole 25ug (Trimethoprim 1.25ug/Sulphamethosazole 23.75ug)	EUCAST/CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
108	VA5C	Vancomycin 5ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
109	VA5	Vancomycin 5ug	EUCAST	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
110	VA30C	Vancomycin 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges



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EC DECLARATION OF CONFORMITY

We hereby declare that the devices described below comply with those provisions which apply to them of the European Directive 98/79/EC 'on *in vitro* diagnostic medical devices', and are placed on the European market by Mast Group UK through our appointed EC Authorised Representative Mast Diagnostica GmbH, Feldstrasse 20, 23858 Reinfeld, Germany.

This declaration is valid for the IVD medical devices described below on or after the date hereof, and which bear the CE mark. It is also valid for all IVD medical devices described below which are manufactured by Mast and placed on the market on or after the date hereof by third parties with our consent and which bear the CE mark. All supporting documents relating to this declaration are retained at the manufacturer's premises.

Product code	Product description	IVD Directive classification	EDMS code
PACE-ID	MAST® CARBA PAcE – A screening test for the rapid detection of carbapenemase producing Enterobacterales, <i>Pseudomonas</i> , OXA 48 and 23-like enzyme production in <i>Acinetobacter</i> .	Self certification Annex III excluding section 6	1402029000 (code registered - 24/03/2003)

Standards applied: EN ISO 13485:2016, ISO 9001:2015, EN ISO 14971:2012, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2016, EN ISO 15223-2:2010.

Declaration made by C Winstanley Date: 26th May 2022

C Winstanley, Quality Assurance and Regulatory Affairs Manager – Mast Group Ltd.

Document valid till: 26th May 2025



MASTDISCS®

Leading the field with a complete solution for AST and Identification disc testing

- Comprehensive range
- Premium quality products
- Compatible with EUCAST and CLSI standards
- Bespoke service available



Mast Group Ltd., has been a manufacturer of antibiotic susceptibility test products since 1957, and continues to be at the forefront of developments in this field. With an ever-expanding portfolio of antibiotic susceptibility, combination and identification discs, Mast Group Ltd. supplies the most comprehensive range available worldwide. Mast Group Ltd. also offers a range of services including **mastpharma®** development and **mastpharma®** stability for the evaluation of novel antimicrobial compounds for the pharmaceutical industry.

Disc diffusion is still the most popular method for determining bacterial antibiotic susceptibility in the treatment of infectious disease, as highlighted by the variety of international standardised procedures including The European Committee on Antimicrobial Susceptibility Testing (EUCAST) and The Clinical and Laboratory Standards Institute (CLSI).

MASTDISCS® are available as an extensive range of test discs presented in dispensing cartridges or vials, with quality assurance guaranteed in accordance to standardised test protocols as issued by the above national and international organisations.

Disc Diffusion Susceptibility Testing

Order No	Product	Packsize
MASTDISCS® AST - ANTIBIOTIC SUSCEPTIBILITY DISCS IN CARTRIDGES AND VIALS		
MASTDISCS®	in Cartridges (5 × 50 discs per pack)	
STOCKCART	Stock Susceptibility Cartridge Discs of a single type 	1 pack
FUNG CART	Stock Antifungal Cartridge Discs of a single type	1 pack
SPECIALCART	Cartridge Discs made to special order*	Min 18 packs
MASTDISCS®	(99+/- 2 discs per vial)	
STOCKDISC	Stock Susceptibility Discs of a single type	1 vial
FUNGDISC	Stock Antifungal Discs of a single type	1 pack
SPECIALDISC	Discs made to special order*	Min 22 packs
TOOL/C	*Set up charge for Special Discs in vials or cartridges A one off charge for customisation of each new specification	per new specification

Disc Diffusion Susceptibility Testing

MASTDISCS[®]AST

ANTIBIOTIC SUSCEPTIBILITY DISCS IN CARTRIDGES - STOCK RANGE

Description Antibiotic & Content µg per disc (unless otherwise stated)	STANDARD		Order Code Cartridges 5 × 50 discs
	EUCAST	CLSI	
Amikacin 30	✓	✓	AK30C
Amoxicillin/clavulanic acid 2-1	✓	-	AUG3C
Amoxicillin/clavulanic acid 20-10	✓	✓	AUG30C
Ampicillin 2	✓	-	AP2C
Ampicillin 10	✓	✓	AP10C
Ampicillin/Sulbactam 10-10	✓	✓	SAM20C
Azithromycin 15	-	✓	ATH15C
Aztreonam 30	✓	✓	ATM30C
Bacitracin 10 units	-	-	BA10C
Carbenicillin 100	✓	-	PY100C
Cefaclor 30	✓	✓	CFC30C
Cefadroxil 30	✓	-	CDX30C
Cefalexin 30	✓	-	CFX30C
Cefalothin 30	-	✓	KF30C
Cefazolin 30	-	✓	CZ30C
Cefepime 30	✓	✓	CPM30C
Cefiderocol 30	✓	✓	FDC30C
Cefixime 5	✓	✓	CFM5C
Cefotaxime 5	✓	-	CTX5C
Cefotaxime 30	-	✓	CTX30C
Cefoxitin 30	✓	✓	FOX30C
Cefpodoxime 10	✓	✓	CPD10C
Ceftaroline 5	✓	-	CPT5C
Ceftaroline 30	-	✓	CPT30C
Ceftazidime 10	✓	-	CAZ10C
Ceftazidime 30	-	✓	CAZ30C
Ceftazidime/avibactam 10-4	✓	-	CZA14C
Ceftazidime/avibactam 30-20	-	✓	CZA50C
Ceftibuten 30	✓	✓	CFB30C
Ceftolozane/tazobactam 30-10	✓	✓	C/T40C
Ceftobiprole 5	✓	-	BPR5C
Ceftriaxone 5	-	✓	CRO5C
Ceftriaxone 30	✓	✓	CRO30C
Cefuroxime 30	✓	✓	CXM30C
Chloramphenicol 30	✓	✓	C30C
Ciprofloxacin 5	✓	✓	CIP5C
Clarithromycin 15	-	✓	CLA15C
Clindamycin 2	✓	✓	CD2C
Delafloxacin 5	-	✓	DLX5C
Doripenem 10	✓	✓	DOR10C
Doxycycline 30	-	✓	DXT30C
Eravacycline 20	✓	✓	ERV20C
Ertapenem 10	✓	✓	ETP10C
Erythromycin 15	✓	✓	E15C
Fosfomycin/Glucose-6-Phosphate 200	✓	✓	FOT200C
Fusidic Acid 10	✓	-	FC10C
Gentamicin 10	✓	✓	GM10C
Gentamicin 30	✓	-	GM30C
Gentamicin 120	-	✓	GM120C
Imipenem 10	✓	✓	IMI10C
Imipenem/relebactam 10-25	-	✓	IMR35C
Kanamycin 30	-	✓	K30C
Lefamulin 20	-	✓	LMU20C
Levofloxacin 5	✓	✓	LEV5C
Linezolid 10	✓	-	LZD10C
Linezolid 30	-	✓	LZD30C
Mecillinam 10	✓	✓	MEC10C
Meropenem 10	✓	✓	MEM10C

Disc Diffusion Susceptibility Testing

MASTDISCS[®]AST

ANTIBIOTIC SUSCEPTIBILITY DISCS IN CARTRIDGES - STOCK RANGE

Description Antibiotic & Content µg per disc (unless otherwise stated)	STANDARD		Order Code Cartridges 5 × 50 discs
	EUCAST	CLSI	
Meropenem/Vaborbactam 20-10	✓	✓	MEV30C
Metronidazole 5	✓	-	MZ5C
Minocycline 30	-	✓	MN30C
Moxifloxacin 5	✓	✓	MF5C
Mupirocin 200	✓	-	MUP200C
Nalidixic Acid 30	✓	✓	NA30C
Neomycin 10	✓	-	NE10C
Netilmicin 10	✓	-	NET10C
Netilmicin 30	✓	-	NET30C
Nitrofurantoin 100	✓	-	NI100C
Nitrofurantoin 300	-	✓	NI300C
Nitroxoline 30	✓	-	NIB30C
Norfloxacin 10	✓	✓	NOR10C
Novobiocin 5	-	-	NO5C
Ofloxacin 5	✓	✓	OF5C
Oxacillin 1	✓	✓	OX1C
Pefloxacin 5	✓	-	PEF5C
Penicillin G 1 unit	✓	-	PG1C
Penicillin G 10 units	-	✓	PG10C
Piperacillin 30	✓	-	PRL30C
Piperacillin 100	-	✓	PRL100C
Piperacillin/tazobactam 30-6	✓	-	PTZ36C
Piperacillin/tazobactam 100-10	-	✓	PTZ110C
Rifampicin 5	✓	✓	RP5C
Streptomycin 10	-	✓	S10C
Streptomycin 300	✓	✓	S300C
Tedizolid 2	✓	✓	TZD2C
Teicoplanin 30	✓	✓	TEC30C
Temocillin 30	✓	-	TEM30C
Tetracycline 30	✓	✓	T30C
Ticarcillin 75	✓	✓	TC75C
Ticarcillin/clavulanic acid 75-10	✓	✓	TIM85C
Tigecycline 15	✓	✓	TGC15C
Tobramycin 10	✓	✓	TN10C
Trimethoprim 5	✓	✓	TM5C
Trimethoprim/sulfamethoxazole 1.25/23.75	✓	✓	TS25C
Vancomycin 5	✓	-	VA5C
Vancomycin 30	-	✓	VA30C
Blank discs	-	-	BD0680W/C/NCE

Disc Diffusion Susceptibility Testing

MASTDISCS[®]AST

NON CLINICAL ANTIBIOTIC SUSCEPTIBILITY DISCS IN CARTRIDGES - STOCK RANGE

Description Antibiotic & Content µg per disc (unless otherwise stated)	Order Code Cartridges 5 × 50 discs
Amoxicillin 25	A25C/NCE
Colistin Sulphate 10	CO10C/NCE
Colistin Sulphate 25	CO25C/NCE
Polymyxin B 300 units	PB300C/NCE

MASTDISCS[®]AST

SPECIALIST VETERINARY SUSCEPTIBILITY DISCS - STOCK RANGE

Description Antibiotic & Content µg per disc (unless otherwise stated)	Order Code Cartridges 5 × 50 discs
Cefquinone 30	CEQ30C/NCE
Cefoperazone 30	CPZ30C/NCE
Enrofloxacin 5	ENF5C/NCE
Florfenicol 30	FFC30C/NCE
Gamithromycin 15	GAM15C/NCE
Marbofloxacin 5	MAR5/NCE
Pradofloxacin 5	PRA5/NCE
Tildipirison 60	TIP60/NCE
Tylosin 30	TY30C/NCE

Disc Diffusion Susceptibility Testing

Order No

Product

Mechanism

Packsize (tests)

MASTDISCS[®]AST

ANTIBIOTIC SUSCEPTIBILITY DISCS IN VIALS - STOCK RANGE

Description Antibiotic & Content µg per disc (unless otherwise stated)	STANDARD		Order Code Vials 99+/- 2 discs
	EUCAST	CLSI	
Bacitracin 10 units	-	-	BA10
Cefpodoxime 10	✓	✓	CPD10
Gentamicin 10	✓	✓	GM10
Metronidazole 5	✓	-	MZ5
Nalidixic Acid 30	✓	-	NA30
Oxacillin 1	✓	✓	OX1
Penicillin G 1 unit	✓	-	PG1
Vancomycin 5	✓	-	VA5
Blank discs	-	-	BD0638W/NCE

MASTDISCS[®]AST

NON CLINICAL ANTIFUNGAL SUSCEPTIBILITY DISCS IN CARTRIDGES AND VIALS - STOCK RANGE

Description Antibiotic & Content µg per disc (unless otherwise stated)	Order Code Cartridges 5 × 50 discs
Amphotericin B 20	AMB20C/NCE
Clotrimazole 10	CTM10C/NCE
Econazole 10	ECN10C/NCE
Fluconazole 10	FCN10C/NCE
Fluconazole 25	FCN25C/NCE
Flucytosine 1	FY1C/NCE
Ketoconazole 10	KCA10C/NCE
Miconazole 10	MCL10C/NCE
Nystatin 100	NY100C/NCE

Disc Diffusion Susceptibility Testing

Order No	Product	Mechanism	Packsize (tests)
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MASTDISCS[®] Combi

COMBINATION DISC SETS FOR THE DETECTION OF ANTIBIOTIC RESISTANCE

D52C	Extended Spectrum β Lactamase Set	ESBL	50 tests
D62C	Cefotaxime 30 & Cefotaxime 30/Clavulanic Acid 10	ESBL	150 tests
D63C	Cefepime 30 & Cefepime 30/Clavulanic Acid 10	ESBL	150 tests
D64C	Ceftazidime 30 & Ceftazidime 30/Clavulanic Acid 10	ESBL	150 tests
D66C	Cefpodoxime 10 & Cefpodoxime 10/Clavulanic Acid 1	ESBL	150 tests
D67C	Extended Spectrum β Lactamase Set (CPD10)	ESBL	50 tests
D68C	AmpC & ESBL Detection Set	AmpC/ESBL	50 tests
D69C	AmpC Detection Set	AmpC	50 tests
D72C	AmpC, ESBL & Carbapenemase Detection Set	AmpC/ESBL/Carbapenemase	50 tests
D73C	MAST [®] Carba plus	MBL/KPC/OXA	50 tests
D76C	ESBL Detection Set (EUCAST)	ESBL	50 tests

Additional carbapenemase screening and identification tests

D71C	MAST [®] CAT-ID - For presumptive identification of carbapenemase production	250 tests
D74	MAST [®] ICT - screening test for the detection of carbapenemase production in Enterobacterales, <i>Pseudomonas</i> and <i>Acinetobacter</i> spp.	25 tests
TEM30C	To aid presumptive identification of OXA-48	5 × 50 discs

RAPID CARBAPENEMASE DETECTION

DNA/LYO5	Rapid molecular carbapenemase detection in Enterobacterales, <i>Pseudomonas</i> spp. and <i>Acinetobacter</i> spp.	10 tests
PACE-ID	Colorimetric test for the rapid detection of carbapenemase producing <i>Pseudomonas</i> spp., <i>Acinetobacter</i> spp. and Enterobacterales.	48 tests

MASTDISCS[®] AST

PENICILLIN DISCS

For detecting the emergence of penicillin resistance. (99+/- 2 discs or 5 × 50 discs in cartridges)

PG1	Penicillin G	1 unit (vials)	1 vial
PG1C	Penicillin G	1 unit (cartridges)	1 pack

HIGH CONTENT AMINOGLYCOSIDE DISCS

The following discs are available to special order and subject to 6 weeks lead time.

For detecting high level aminoglycoside resistance. (99+/- 2 discs or 5 × 50 discs in cartridges)

GM500C	500 μ g	Min order
K1000C/NCE	1000 μ g	18 packs
K1000/NCE	1000 μ g	Min order
		22 vials

Any code with a suffix of '/NCE' is not CE marked and for veterinary or research use only.

Disc Diffusion Susceptibility Testing

Order No

Product

Packsize

DISCMASTER DISPENSER

Robust and reliable antimicrobial cartridge disc dispensers designed for use with MASTDISCS® Antimicrobial Susceptibility Test Cartridges.

MDD65	MAST® DISCMASTER Dispenser - 6 place	1
SILICA63	Silica Gel Capsule for MAST® DISCMASTER	4
SHD5	Single Cartridge Hand Dispenser	5
CANISTER	Canister for MDD64 models and below	1
CANISTER65	Canister for MDD65 MAST® DISCMASTER Dispenser	1



IVD solutions through partnership

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MASTDISCS®

Antimicrobial Susceptibility Test Discs

MASTDISCS®. An extensive range of individual antimicrobial susceptibility test discs in glass vials and plastic dispensing cartridges.

FOR IN VITRO DIAGNOSTIC USE ONLY

Contents: 100 discs in a vial or a pack of 5 cartridges each cartridge containing 50 discs.

Formulation*

6mm diameter filter paper discs printed with an appropriate identification code of letters and/or numbers and impregnated with accurately assayed quantities of antimicrobial agent.

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. Return to the refrigerator promptly after use.

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, swabs, applicator sticks, incinerators and incubators, etc., as well as serological and biochemical reagents and additives such as blood. Suitable interpretive criteria from standardised reference methods. MAST® DiscMaster Dispenser.

Procedure

MASTDISCS® should be used according to an appropriate standardised susceptibility test method. Various alternative methodologies are available and **MASTDISCS®** are compatible with these.

1. Remove the **MASTDISCS®** container from the refrigerator and allow to equilibrate to room temperature before opening.
2. Using a sterile needle or forceps, transfer each disc required onto the surface of a suitable plate of MAST® susceptibility test medium e.g. Mueller-Hinton Agar (DM170) dried and pre-inoculated with test organism according to the methodology followed.
3. If using **MASTDISCS®** in cartridges, load each cartridge required into a MAST® DiscMaster Dispenser.

4. Place the loaded DiscMaster Dispenser over the Petri Dish and dispense discs (see DiscMaster instructions for full details).
5. Incubate plates in air at 35 to 37°C for 18 to 24 hours (or alternative incubation conditions according to the methodology followed).
6. Measure (to the nearest whole mm) and record the diameter of any zones of inhibition that are observed around the antibiotic impregnated discs.

Interpretation of results

Interpret measured zones of inhibition by reference to published tables of critical zone diameter breakpoints provided by appropriate authorities and classify test isolate as Susceptible (S), Intermediate (I) or Resistant (R).

Quality control

Check for signs of deterioration. Quality control must be performed with at least one organism to demonstrate a correct susceptibility pattern. 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 Organisms	
<i>Escherichia coli</i> ATCC® 25922	Correct susceptibility pattern*
<i>Pseudomonas aeruginosa</i> ATCC® 27853	Correct susceptibility pattern*
<i>Staphylococcus aureus</i> ATCC® 25923	Correct susceptibility pattern*

*See appropriate quality control table

Limitations

Any deviation from the prescribed method may produce incorrect results.

The latest published version of the method used should be consulted for complete details of test procedures and interpretive criteria.

References

Bibliography available on request.

MASTDISCS® Combi Carba plus

D73C

Intended use

For the detection of carbapenemase and OXA-48 enzyme production in Enterobacterales.

FOR IN VITRO DIAGNOSTIC USE ONLY

Contents and Formulation*

5 cartridges per pack, each cartridge containing approximately 50 discs:

Cartridge A	Penem
Cartridge B	Penem + MβL inhibitor
Cartridge C	Penem + KPC inhibitor
Cartridge D	Penem + AmpC inhibitor
Cartridge E	Temocillin + MβL inhibitor

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

- Using a pure, fresh culture of the test organism, prepare a suspension equivalent in density to a 0.5 McFarland standard in physiological saline.
- 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.
- Using a MAST® DISCMASTER Dispenser, or alternatively a sterile needle or forceps, place one of each disc on to the plate of inoculated medium, ensuring sufficient space between the discs to allow formation of clearly defined zones of inhibition.
- Incubate at 35 ± 1 °C for 18 ± 2 hours.
- Measure and record the diameter of any zones of inhibition, to the nearest whole millimetre, **ignoring any microcolonies in the zone**. Discs showing no zone of inhibition should be recorded as 6 mm.

Interpretation of results

To interpret results based on observed zones of inhibition, use the D73C calculator. The calculator is available for download and can be accessed via www.mast-group.com, in the registered members section. Alternatively, results can be interpreted manually by comparing inhibition zone diameters as described below:

Compare the zone of inhibition of the penem disc (A) to the zones of inhibition of each of the penem plus inhibitor discs (B, C and D).

If disc B **only** shows a zone difference ≥5 mm than disc A (C - A and D - A should be <5 mm), record the organism as demonstrating MβL activity.

If disc C **only** shows a zone difference ≥5mm than disc A (B - A and D - A should be <5 mm), record the organism as demonstrating KPC activity.

If discs C and D both show significant zone differences (≥5 mm) compared to disc A (B - A should be <4 mm), record the organism as demonstrating AmpC activity coupled with porin loss (impermeability). If no synergy is obtained between discs A, B, C and D and disc E shows a zone of inhibition of ≤10 mm, record the organism as demonstrating OXA-48 activity. **If an equivocal or negative result is generated but resistance to disc A is shown, the organism may still be expressing a carbapenemase enzyme. Molecular testing or MASTDISCS® ID D74 Indirect Carbapenemase Test (ICT) can be performed to verify this.**

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 using the combination discs with inhibitor and corresponding penem only disc against negative control organism *E. coli* ATCC® 25922 should be equal or show no greater difference in diameter than ±2 mm. The zone diameter for disc E should be >10 mm. Any deviation 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
<i>Klebsiella pneumoniae</i> NCTC 13440	MβL Positive
<i>Klebsiella pneumoniae</i> NCTC 13438	KPC Positive
<i>Klebsiella pneumoniae</i> NCTC 13442	OXA-48 Positive
<i>Escherichia coli</i> ATCC® 25922	Negative

Limitations

D73C is not suitable for detection of carbapenemase production in *Pseudomonas* spp. or *Acinetobacter* spp. To avoid potentially erroneous results, do not mix cartridges from different batches of D73C and ensure all discs in the set are tested on the same plate. D73C may give equivocal results against clinical isolates that have acquired complex co-resident carbapenemase mediated resistance mechanisms. Users are obliged to always use the latest version of the D73C calculator.

References

Bibliography available on request.

MAST[®] CARBA PAcE

Pseudomonas, *Acinetobacter*, Enterobacterales
Rapid carbapenemase detection



- Rapid results in less than 10 minutes
- Simple test process in 5 easy steps
- Cost effective screening solution
- High sensitivity and specificity

MAST[®] CARBA PAcE

An increase in antimicrobial resistance is one of the most urgent global challenges facing the field of healthcare. Healthcare associated infections (HAI) are one of the most common adverse effects in care delivery and the occurrences of epidemics of HAI are a major public health problem (WHO 2017).

Carbapenem resistant Gram negative bacteria, including Enterobacterales (CRE), *Pseudomonas aeruginosa* and *Acinetobacter baumannii* are an emerging cause of HAI and accordingly a global public healthcare concern due to high levels of antimicrobial resistance and ability for widespread transmission. It is important to recognise carriers quickly to prevent and control the spread in nosocomial and community settings and also to aid antibiotic stewardship.

MAST[®] CARBA PAcE

Mast Group Ltd. remains at the forefront of the fight against such threats and as such has developed a colorimetric test which rapidly detects carbapenemase producing *Pseudomonas* spp., *Acinetobacter* spp. and Enterobacterales using a novel chromogenic cephalosporin analogue for which there is a patent pending for its application.

The new **MAST[®] CARBA PAcE** is a simple cost effective screening solution providing fast results within 10 minutes, yet reliable in detecting carbapenemase production to support patient treatment. Additionally, no special equipment is required allowing it to be easily integrated into any laboratory workflows.

The basis of this colorimetric test is the hydrolysis of the chromogenic cephalosporin analogue, eliminating the effects of ESBL and AmpC enzymes using suitable inhibitor compounds, providing specific carbapenemase detection. Therefore only distinguishing epidemiologically significant carbapenem resistance, avoiding unnecessary patient isolation.

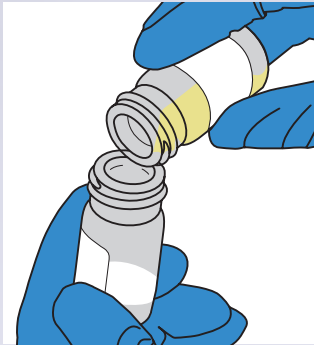
Benefits of MAST[®] CARBA PAcE

Rapid time to result	– Once the test organism is added to the test solution results are available within 10 minutes
Cost effective	– Conveniently contains 48 tests per kit, allowing quick identification of carbapenemase producers, assisting with prompt isolation of carriers to prevent cross transmission
Easily integrated into any laboratory	– Requiring only standard microbiological supplies making this adaptable to any laboratory workflows
Easy to Use	– Simple test procedure, with 5 simple steps (see figure 1), colour change from yellow to orange/red indicates carbapenemase activity
Quality	– Validated using a panel of organisms including VIM, IMP, NDM, OXA-48-like, OXA-23 and KPC high sensitivity and specificity of 96% and 91% respectively
Complementary molecular range	– Provides a quality first tier screen prior to molecular detection and characterisation using MAST ISOPLEX[®] CRE-ART .

MAST[®] CARBA PAcE

Simple test Process

Reconstitute



Reconstitute the pellet by tipping the entire contents of vial RB into vial PEL.



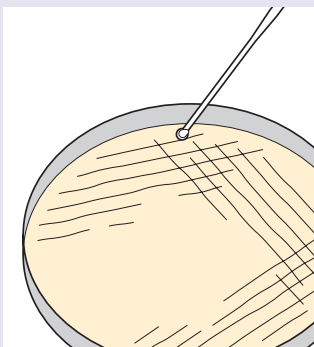
Allow the pellet to fully dissolve at room temperature for 1 minute and mix contents by gently vortexing for 10 seconds.

Dispense

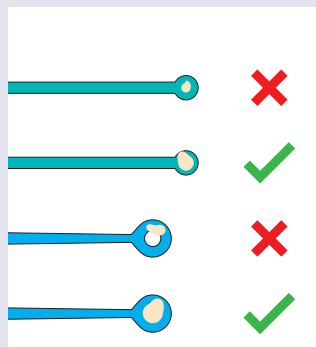


Dispense 250µl of reconstituted solution into the tubes provided. One tube per test.

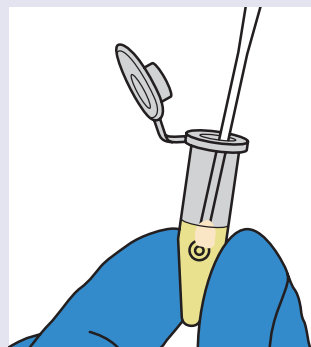
Inoculate



Use a pure, fresh culture of the test organism.



Take an approximate 1 - 5µl loopful of organism.

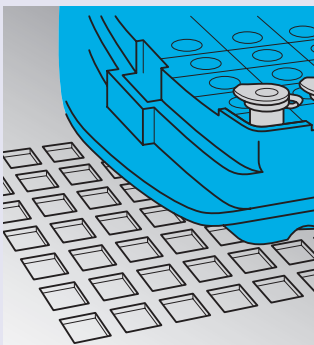


Add to the tube containing test solution.



Mix well by vortexing for 20 seconds.

Incubate



Incubate at 35±1°C for 10 minutes.

Read by eye



Record the colour of the test solution immediately or up to 20 minutes after incubation.

Figure 1 - MAST[®] CARBA PAcE Process

MAST® CARBA PAcE

Ordering Information

Order Code	Product	Pack Size	No. Tests
PACE-ID	MAST® CARBA PAcE For the rapid detection of carbapenemase producing Enterobacterales, <i>Pseudomonas</i> spp. & <i>Acinetobacter</i> spp.	4 × 12 tests	48

Additional products from Masts AMR range

Order Code	Product	Pack Size	No. Tests
DNA/LYO5	MAST ISOPLEX® CRE-ART	10	10
D73C	MASTDISCS® Combi Carba plus	5 × 50 discs	50
D72C	MASTDISCS® Combi AmpC, ESBL & Carbapenemase Detection Set	6 × 50 discs	50
D74	MAST®ICT Indirect Carbapenemase Test	25	25
D71C	MASTDISCS® ID CAT-ID - Carbapenemase Activity Test	5 × 50 discs	250

References

Guidelines for the prevention and control of carbapenem-resistant Enterobacteriaceae, *Acinetobacter baumannii* and *Pseudomonas aeruginosa* in health care facilities. World Health Organisation 2017.

Acute trust toolkit for the early detection, management and control of carbapenemase-producing Enterobacteriaceae (Published: December 2013
PHE publications gateway number: 2013314)

Acknowledgement

HMRZ compound used in this product was developed by Dr. Hideaki Hanaki of Kitasato Institute, Japan.

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MAST® CARBA PACe

Intended Use

PACE-ID. For the rapid detection of carbapenemase producing Enterobacterales, *Pseudomonas*, OXA 48 and 23-like enzyme production in *Acinetobacter*.

FOR IN VITRO DIAGNOSTIC USE ONLY

Contents

- **Vial PEL.** Freeze dried pellet* - 4 vials containing inhibitors and lysis components, each designed for 12 tests.
- **Vial RB.** Reconstitution buffer* - 4 vials containing chromogenic indicator resuspension buffer, each sufficient for 12 tests.
- Plastic 0.5 ml tubes, sufficient for 48 tests.

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. Once reconstituted, test solution stored at 2 to 8°C, must be used within 4 weeks.

Precautions

For *in vitro* diagnostic use only. Observe approved biohazard and aseptic techniques. To be used by only trained and qualified laboratory personnel. Sterilise all biohazard waste before disposal. Refer to product safety data sheets.

Materials required but not provided

Standard microbiological supplies and equipment such as loops, MAST Group Ltd. culture media, table top vortexes, pipettes, incinerators and incubators, etc.

Procedure

1. Reconstitute the pellet by tipping the entire contents of vial RB into vial PEL.
2. Allow the pellet to fully dissolve at room temperature for 1 minute and mix contents by gently vortexing for 10 seconds. Reconstituted solution should be yellow, if the solution is any other colour do not use.
3. Dispense 250µl of reconstituted solution into the tubes provided. One tube per test.
4. Using a pure, fresh culture of the test organism, take an approximate 1 to 5µl loopful of organism, and add to the tube containing test solution. Mix well by vortexing for 20 seconds.

Note: to obtain distinct results, ensure that the bacterial resuspension is similar to the turbidity of a 3.0 to 3.5 McFarland standard; Approx. 10⁹ CFU/ml.

5. Incubate at 35±1°C for 10 minutes.
6. Record the colour of the test solution immediately or up to 20 minutes after incubation.

Please refer to corresponding steps on the image page.

Interpretation of results

If a colour change is recorded; from yellow to orange/red, record the organism as demonstrating carbapenemase activity.

If no colour change is recorded; solution remains yellow, record the organism as negative for carbapenemase activity.

Quality control

Check for signs of deterioration. Quality control must be performed with at least one organism to demonstrate a positive reaction and another to demonstrate a negative reaction. 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
<i>Acinetobacter baumannii</i> NCTC 13301	Orange/Red Carbapenemase positive
<i>Pseudomonas aeruginosa</i> NCTC 13437	Orange/Red Carbapenemase positive
<i>Acinetobacter lwoffii</i> ATCC® 15309	Remains Yellow Carbapenemase negative
<i>Pseudomonas aeruginosa</i> ATCC® 25668	Remains Yellow Carbapenemase negative
<i>Klebsiella pneumoniae</i> NCTC 13438	Orange/Red Carbapenemase positive

Limitations

1. Colonies isolated from indicator media are not recommended.
2. This product only detects the presence of a carbapenemase, differentiation can be carried out by using a suitable genotypic or phenotypic test (for example **MASTDISCS® Combi Carba Plus**; D73C).
3. Some GES-type carbapenemases might be difficult to detect.
4. To avoid potentially erroneous results, ensure that equipment used for testing is free of contamination.
5. Test results must be recorded within 20 minutes following the initial 10 minute incubation.
6. Results obtained with this kit must be considered alongside other clinically relevant data when diagnosing an infection.

References

Bibliography available on request.

Acknowledgement

HMRZ compound used in this product was developed by Dr. Hideaki Hanaki of Kitasato, Institute, Japan.

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MAST is a Registered Trademark

ATCC is a trademark of the American

Type Culture Collection, Manassas, Virginia, USA

*Formulation may change to meet performance criteria



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