



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,

A handwritten signature in black ink, appearing to read "Susan Thomson".

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: 2024-03-05

Effective Date: 2024-06-01

Expiry Date: 2027-05-31

Page: 1 of 2



...making excellence a habit.™

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

Effective Date: 2024-06-01

Latest Revision Date: 2024-03-05

Expiry Date: 2027-05-31

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

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, development, manufacture, installation, service and distribution of in-vitro diagnostic reagents and instruments for clinical microbiology and molecular biology and bacteriological media.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2020-10-07

Latest Revision Date: 2024-05-09

Effective Date: 2024-06-01

Expiry Date: 2027-05-31

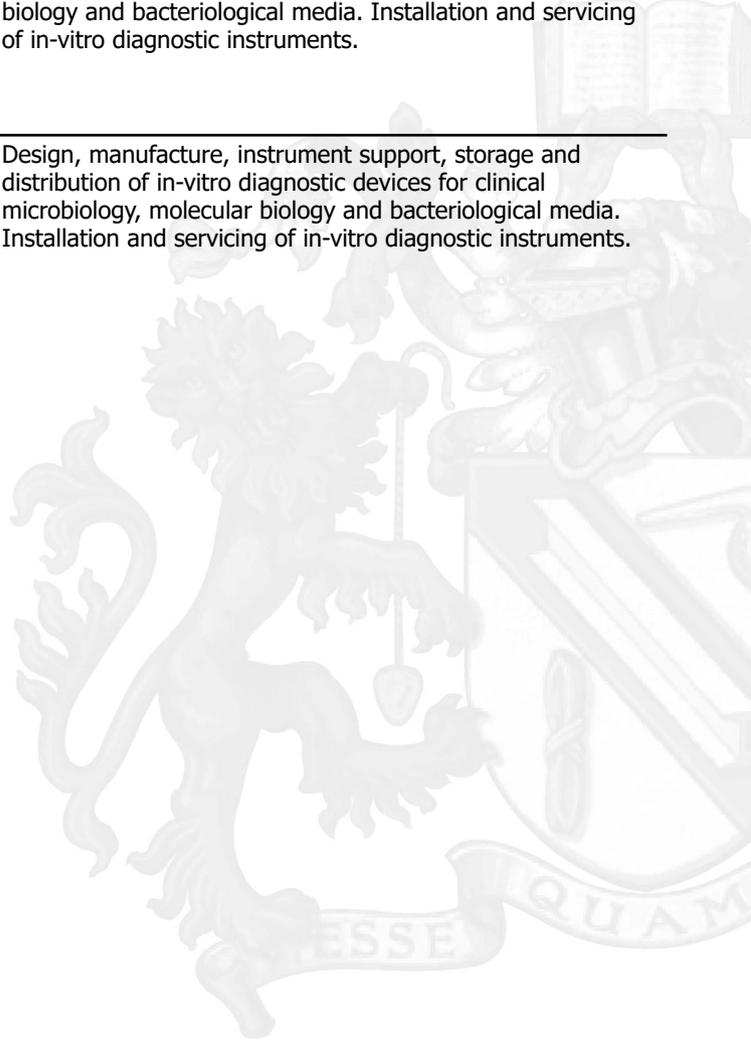
Page: 1 of 2



...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, distribution and customer services of in-vitro diagnostic devices for clinical microbiology, molecular biology, and bacteriological media.
Mast Group Ltd Atlantic House, Derby Road Bootle Liverpool L20 1EA United Kingdom	Manufacture, instrument support, storage and distribution of in-vitro diagnostic devices for clinical microbiology, molecular biology and bacteriological media. Installation and servicing of in-vitro diagnostic instruments.
Mast Group Ltd Unit 107, Tenth Avenue, Zone three, Deeside Industrial Park, Deeside Flintshire CH5 2UA United Kingdom	Design, manufacture, instrument support, storage and distribution of in-vitro diagnostic devices for clinical microbiology, molecular biology and bacteriological media. Installation and servicing of in-vitro diagnostic instruments.



Original Registration Date: 2020-10-07

Latest Revision Date: 2024-05-09

Effective Date: 2024-06-01

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 United Kingdom
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 Fax +44 (0)151 944 1332
 www.mastgrp.com

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	<p>MAST DISCS® AST – paper antimicrobial susceptibility test (AST) disc products.</p> <p>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.</p>	<p>Self-certification Annex III excluding section 6</p>	<p>1402050200 (Code registered - 02/12/2002)</p> <p>GMDN code - 63834</p>

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: 01st May 2022

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



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	Ampicillin10ug/Sulbactam10ug	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 Vials
10	PY100C	Carbenicillin 100ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
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
21	FOX30C	Cefoxitin 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
22	CPD10C	Cefpodoxime 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
23	CZL30	Cefprozil 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
24	CPT5C	Ceftaroline 5ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
25	CPT30C	Ceftaroline 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
26	CZA14C	Ceftazidime/avibactam 10-4	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
27	CZA50C	Ceftazidime/avibactam 30-20	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
28	CAZ10C	Ceftazidime 10ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
29	CAZ30C	Ceftazidime 30ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
30	CRO5C	Ceftriaxone 5ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
31	CRO30C	Ceftriaxone 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
32	C/T40C	Ceftolozone/Tazobactam 30-10	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
33	CXM30C	Cefuroxime 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
34	CFX30C	Cephalexin 30ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
35	KF30C	Cephalothin 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
36	CZ30C	Cephazolin 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
37	C30C	Chloramphenicol 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
38	CIP5C	Ciprofloxacin 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
39	CLA15C	Clarithromycin 15ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
40	CD2C	Clindamycin 2ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
41	DLX5C	Delafloxacin 5ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
42	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
43	DXT30C	Doxycycline 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
44	ERV20C	Eravacycline 20ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
45	ETP10C	Ertapenem 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
46	E15C	Erythromycin 15ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
47	FOT200C	Fosfomycin/Trometamol 200ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
48	FC10C	Fusidic Acid 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
49	FDC30C	Cefiderocol 30ug discs	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
50	GM10C	Gentamicin 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
51	GM30C	Gentamicin 30ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
52	GM120C	Gentamicin 120ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
53	IMI10C	Imipenem 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
54	IMR35C	Imipenem/relebactam 35µg discs	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
55	K30C	Kanamycin 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
56	LEV5C	Levofloxacin 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
57	LZD10C	Linezolid 10ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
58	LZD30C	Linezolid 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
59	MEC10C	Mecillinam 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
60	MEM10C	Meropenem 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
61	MEM10	Meropenem 10ug	EUCAST/CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
62	MEV30C	Meropenem/Vaborbactam 20-10ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
63	MZ5C	Metronidazole 5ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
64	MZ5	Metronidazole 5ug	CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
65	MN30C	Minocycline 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
66	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
67	MUP200C	Mupirocin 200ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
68	NA30C	Nalidixic Acid 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
69	NA30	Nalidixic Acid 30ug	EUCAST/CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
70	NE10C	Neomycin 10ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
71	NET10C	Netilmicin 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/dalfopristin15ug	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



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
111	A20C	Amoxicillin 20ug	CA-SFM/EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges



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EC DECLARATION OF CONFORMITY

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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: 01st May 2022

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



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, ES β L 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.

MASTDISCS®

Intended use

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*

6 mm 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 as indicated on the label 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 storage 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 (DM170D) 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 MAST® 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.



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MASTDISCS® *Combi* Ceftazidime ESβL ID Disc Set

D64C

Intended use

For the detection of extended spectrum beta-lactamases (ESβLs) in Enterobacterales.

FOR IN VITRO DIAGNOSTIC USE ONLY

Contents and Formulation*

3 x paired sets of cartridges per pack, each cartridge containing approximately 50 discs:

CAZ30	Ceftazidime 30 µg discs (x3)
CAZCV	Ceftazidime 30 µg + clavulanic acid 10 µg discs (x3)

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 ± 2°C.

Procedure

- Using a pure, fresh culture of the test organism, prepare a suspension equivalent in density to a 0.5 McFarland standard.
- Using a sterile swab, spread the suspension uniformly across the surface of a single Mueller Hinton Agar plate in accordance with the Clinical and Laboratory Standards Institute (CLSI) procedure.
- Using a MAST® DISCMASTER Dispenser, or alternatively a sterile needle or forceps, place one of each type of disc onto the plate of inoculated medium, ensuring sufficient space between the discs to allow formation of clearly defined zones of inhibition.
- Incubate at 35 ± 2°C for 17±1 hours.
- Measure and record the diameter of any zones of inhibition, to the nearest whole millimetre. Discs showing no zone of inhibition should be recorded as 6 mm.

Interpretation of results

Compare the zone of inhibition for the ceftazidime disc to that of the ceftazidime plus clavulanic acid combination disc. An increase in zone diameter of ≥5 mm in the presence of clavulanic acid indicates the presence of ESβL in the test organism.

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 disc plus clavulanic acid and corresponding ceftazidime only disc against ESβL-negative control organism *E. coli* ATCC® 25922, should be equal or show no greater difference in diameter than ±2 mm. Any greater difference 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>Escherichia coli</i> NCTC 13351	Positive
<i>Escherichia coli</i> NCTC 13353	Positive
<i>Escherichia coli</i> ATCC® 25922	Negative

Limitations

D64C is not suitable for testing *Pseudomonas* spp. or *Acinetobacter* spp. D64C should always be used in conjunction with MASTDISCS® *Combi* Cefotaxime ESβL ID disc set (D62C); a positive result using one or both tests indicates the presence of an ESβL in the test organism. To avoid potentially erroneous results do not mix cartridges from different batches of D64C and ensure both discs in the set are tested on the same plate.

References

Bibliography available on request.



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MASTDISCS® *Combi* Cefepime ESβL ID Disc Set

D63C

Intended use

For the detection of extended spectrum beta-lactamases (ESβLs) in Enterobacterales with chromosomal AmpC.

FOR IN VITRO DIAGNOSTIC USE ONLY

Contents and Formulation*

3 x paired sets of cartridges per pack, each cartridge containing approximately 50 discs:

CPM30	Cefepime 30 µg discs (x3)
CPMCV	Cefepime 30 µg + clavulanic acid 10 µg discs (x3)

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 type of disc onto 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. Discs showing no zone of inhibition should be recorded as 6 mm.

Interpretation of results

Compare the zone of inhibition for the cefepime disc to that of the cefepime plus clavulanic acid combination disc. An increase in zone diameter of ≥5 mm in the presence of clavulanic acid indicates the presence of ESβL in the test organism.

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 disc plus clavulanic acid and corresponding cefepime only disc against ESβL-negative control organism *E. coli* ATCC® 25922, should be equal or show no greater difference in diameter than ±2 mm. Any greater difference 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>Enterobacter cloacae</i> NCTC 13464	Positive
<i>Escherichia coli</i> NCTC 13351	Positive
<i>Escherichia coli</i> NCTC 13352	Positive
<i>Escherichia coli</i> NCTC 13353	Positive
<i>Escherichia coli</i> ATCC® 25922	Negative

Limitations

D63C is not suitable for testing *Pseudomonas* spp. or *Acinetobacter* spp. To optimise ESBL detection it is recommended that these discs are used in combination with other products in the MASTDISCS® *Combi* range. To avoid potentially erroneous results do not mix cartridges from different batches of D63C and ensure both discs in the set are tested on the same plate.

References

Bibliography available on request.

MASTDISCS® *Combi* Cefotaxime ESβL ID Disc Set

D62C

Intended use

For the detection of extended spectrum beta-lactamases (ESβLs) in Enterobacteriales.

FOR IN VITRO DIAGNOSTIC USE ONLY

Contents and Formulation*

3 x paired sets of cartridges per pack, each cartridge containing approximately 50 discs:

CTX30	Cefotaxime 30 µg discs (x3)
CTXCV	Cefotaxime 30 µg + clavulanic acid 10 µg discs (x3)

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±2 °C.

Procedure

- Using a pure, fresh culture of the test organism, prepare a suspension equivalent in density to a 0.5 McFarland standard.
- Using a sterile swab, spread the suspension uniformly across the surface of a single Mueller Hinton Agar plate in accordance with the Clinical and Laboratory Standards Institute (CLSI) procedure.
- Using a MAST® DISCMASTER Dispenser, or alternatively a sterile needle or forceps, place one of each type of disc onto the plate of inoculated medium, ensuring sufficient space between the discs to allow formation of clearly defined zones of inhibition.
- Incubate at 35±2 °C for 17±1 hours.
- Measure and record the diameter of any zones of inhibition, to the nearest whole millimetre. Discs showing no zone of inhibition should be recorded as 6 mm.

Interpretation of results

Compare the zone of inhibition for the cefotaxime disc to that of the cefotaxime plus clavulanic acid combination disc. An increase in zone diameter of ≥5 mm in the presence of clavulanic acid indicates the presence of ESβL in the test organism.

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 disc plus clavulanic acid and corresponding cefotaxime only disc against ESβL-negative control organism *E. coli* ATCC® 25922, should be equal or show no greater difference in diameter than ±2 mm. Any greater difference 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>Escherichia coli</i> NCTC 13351	Positive
<i>Escherichia coli</i> NCTC 13353	Positive
<i>Escherichia coli</i> ATCC® 25922	Negative

Limitations

D62C is not suitable for testing *Pseudomonas* spp. or *Acinetobacter* spp. D62C should always be used in conjunction with MASTDISCS® *Combi* Ceftazidime ESβL ID disc set (D64C); a positive result using one or both tests indicates the presence of an ESβL in the test organism. To avoid potentially erroneous results do not mix cartridges from different batches of D62C and ensure both discs in the set are tested on the same plate.

References

Bibliography available on request.