



SRL SANMEDICO
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Mast Group Ltd.
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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 that reads "Susan Thomson".

Susan Thomson

Bootle UK

December 9th 2021

International business Manager, on behalf of Mast Group





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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/ GMDN code
Various (M-----)	MAST® ASSURE Salmonella Antisera – for serological identification and epidemiological typing of Salmonella bacteria.	Self certification Annex III excluding section 6	EDMS code - 1501000000 (code registered - 24/03/2003) GMDN code - 39521

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 Cristianley Date: 26th May 2022

C Winstanley, 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
Product Names: MAST® ASSURE Salmonella Antisera**

Serial No.	Product code	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
1	M10308	2ml	MAST® ASSURE Salmonella O - POLY O Factor O2, O4, O7, O8, O9, O9, 46, O3, 10, O1,3,19	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
2	M10309	2ml	MAST® ASSURE Salmonella O - POLY O1 Factor O11, O13, O6, 14, O16, O18, O21, O35	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
3	M14294	2ml	MAST® ASSURE Salmonella O - POLY O A-G	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
4	M14300	2ml	MAST® ASSURE Salmonella O - POLY O A-S	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
5	M92537	2ml	MAST® ASSURE Salmonella O - Omnivalent (Kauffmann-White group A-067)	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
6	M14317	2ml	MAST® ASSURE Salmonella H - POLYVALENT PHASE 1&2 (a-z29)	Liquid stable polyvalent antiserum for the determination of H antigens for the serological identification of salmonellae by slide agglutination.
7	M10339	2ml	MAST® ASSURE Salmonella H - POLYVALENT PHASE 2 (H-1)	Liquid stable polyvalent antiserum for the determination of H antigens for the serological identification of salmonellae by slide agglutination.
8	M14324	2ml	MAST® ASSURE Salmonella H - RAPID DIAGNOSTIC 1 Factors b, d, E, r	Liquid stable polyvalent antiserum for the determination of H antigens for the serological identification of salmonellae by slide agglutination.
9	M14331	2ml	MAST® ASSURE Salmonella H - RAPID DIAGNOSTIC 2 Factors b, E, k, l	Liquid stable polyvalent antiserum for the determination of H antigens for the serological identification of salmonellae by slide agglutination.
10	M14348	2ml	MAST® ASSURE Salmonella H - RAPID DIAGNOSTIC 3 Factors d, E, G, k	Liquid stable polyvalent antiserum for the determination of H antigens for the serological identification of salmonellae by slide agglutination.



Serial No.	Product code	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
11	M10310	2ml	MAST® ASSURE Salmonella O - Mono Factor O2	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
12	M10311	2ml	MAST® ASSURE Salmonella O - Mono Factor O4	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
13	M10312	2ml	MAST® ASSURE Salmonella O - Mono Factor O7	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
14	M10313	2ml	MAST® ASSURE Salmonella O - Mono Factor O8	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
15	M10314	2ml	MAST® ASSURE Salmonella O - Mono Factor O9	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
16	M10315	2ml	MAST® ASSURE Salmonella O - Mono Factor O9,46	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
17	M10316	2ml	MAST® ASSURE Salmonella O - Mono Factor O3,10	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
18	M10318	2ml	MAST® ASSURE Salmonella O - Mono Factor O1,3,19	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
19	M10319	2ml	MAST® ASSURE Salmonella O - Mono Factor O11	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
20	M10320	2ml	MAST® ASSURE Salmonella O - Mono Factor O13	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
21	M10321	2ml	MAST® ASSURE Salmonella O - Mono Factor O6,14	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
22	M10322	2ml	MAST® ASSURE Salmonella O - Mono Factor O16	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
23	M10323	2ml	MAST® ASSURE Salmonella O - Mono Factor O18	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
24	M10324	2ml	MAST® ASSURE Salmonella O - Mono Factor O21	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
25	M10325	2ml	MAST® ASSURE Salmonella O - Mono Factor O35	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
26	M10326	2ml	MAST® ASSURE Salmonella O - Mono Factor Vi	Liquid stable antiserum for the determination of Vi antigens for the serological identification of salmonellae by slide agglutination.



Serial No.	Product code	Pack Size	Brand/Trade Name	Intended Purpose of the Medical Device Type
27	M10327	2ml	MAST® ASSURE Salmonella H - Mono Factor a	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
28	M10328	2ml	MAST® ASSURE Salmonella H - Mono Factor b	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
29	M10329	2ml	MAST® ASSURE Salmonella H - Mono Factor c	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
30	M10330	2ml	MAST® ASSURE Salmonella H - Mono Factor d	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
31	M10331	2ml	MAST® ASSURE Salmonella H - Mono Factor e, h	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
32	M14335	2ml	MAST® ASSURE Salmonella H - Mono Factor E	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
33	M10332	2ml	MAST® ASSURE Salmonella H - Mono Factor G	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
34	M10333	2ml	MAST® ASSURE Salmonella H - Mono Factor i	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
35	M10334	2ml	MAST® ASSURE Salmonella H - Mono Factor k	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
36	M10336	2ml	MAST® ASSURE Salmonella H - Mono Factor r	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
37	M10344	2ml	MAST® ASSURE Salmonella H - Mono Factor 2	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
38	M10345	2ml	MAST® ASSURE Salmonella H - Mono Factor 5	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
39	M10346	2ml	MAST® ASSURE Salmonella H - Mono Factor 6	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
40	M10364	2ml	MAST® ASSURE Salmonella H - Mono Factor f	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
41	M10365	2ml	MAST® ASSURE Salmonella H - Mono Factor m	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
42	M10366	2ml	MAST® ASSURE Salmonella H - Mono Factor p	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.



Serial No.	Product code	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
43	M10367	2ml	MAST® ASSURE Salmonella H - Mono Factor q	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
44	M10368	2ml	MAST® ASSURE Salmonella H - Mono Factor s	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
45	M10369	2ml	MAST® ASSURE Salmonella H - Mono Factor t	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
46	M10376	2ml	MAST® ASSURE Salmonella H - Mono Factor x	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
47	M10335	2ml	MAST® ASSURE Salmonella H - Mono Factor L	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
48	M10337	2ml	MAST® ASSURE Salmonella H - Mono Factor y	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
49	M10338	2ml	MAST® ASSURE Salmonella H - Mono Factor e,n	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
50	M10340	2ml	MAST® ASSURE Salmonella H - Mono Factor v	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
51	M10341	2ml	MAST® ASSURE Salmonella H - Mono Factor w	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
52	M10342	2ml	MAST® ASSURE Salmonella H - Mono Factor z13	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
53	M10343	2ml	MAST® ASSURE Salmonella H - Mono Factor z28	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
54	M10347	2ml	MAST® ASSURE Salmonella H - Mono Factor 7	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
55	M10348	2ml	MAST® ASSURE Salmonella H - Mono Factor z6	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
56	M10370	2ml	MAST® ASSURE Salmonella H - Mono Factor u	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
57	M10372	2ml	MAST® ASSURE Salmonella H - Mono Factor z23	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
58	M10373	2ml	MAST® ASSURE Salmonella H - Mono Factor z24	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.



Serial No.	Product code	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
59	M10377	2ml	MAST® ASSURE Salmonella H - Mono Factor z15	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
60	M10374	2ml	MAST® ASSURE Salmonella H - Mono Factor z32	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
61	M10378	2ml	MAST® ASSURE Salmonella H - Mono Factor z	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
62	M10379	2ml	MAST® ASSURE Salmonella H - Mono Factor z4	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
63	M10380	2ml	MAST® ASSURE Salmonella H - Mono Factor z10	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
64	M10381	2ml	MAST® ASSURE Salmonella H - Mono Factor z29	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.



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EC DECLARATION OF CONFORMITY

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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 (M-----)	MAST® ASSURE Shigella Antisera – for serological identification and epidemiological typing and grouping of Shigella species.	Self certification Annex III excluding section 6	1501000000 (code registered - 24/03/2003) GMDN code - 39452

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



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® ASSURE Shigella Antiserum

Serial No.	Product code	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
1	M10109	2ml	MAST® ASSURE Shigella dysenteriae POLY A Types 1, 2, 3, 4, 5, 6, 7	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
2	M10110	2ml	MAST® ASSURE Shigella dysenteriae POLY A1 Types 8, 9, 10, 11, 12	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
3	M10111	2ml	MAST® ASSURE Shigella flexneri POLY B Types I, II, III, IV, V, VI,(Groups(3)4,6&7(8)	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of Shigella flexneri by slide agglutination.
4	M10112	2ml	MAST® ASSURE Shigella boydii POLY C Types 1, 2, 3, 4, 5, 6, 7	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
5	M10113	2ml	MAST® ASSURE Shigella boydii POLY C1 Types 8, 9, 10, 11	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
6	M10114	2ml	MAST® ASSURE Shigella boydii POLY C2 Types 12, 13, 14, 15	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
7	M10154	2ml	MAST® ASSURE Shigella boydii POLY C3 Types 16, 17, 18	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
8	M10115	2ml	MAST® ASSURE Shigella sonnei POLY D Phase I & II	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of Shigella sonnei by slide agglutination.



Serial No.	Product code	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
9	M10116	2ml	MAST® ASSURE Shigella dysenteriae - Mono Type 1	Liquid stable antisera for the determination of O antigen types for the serological identification of Shigella.
10	M10117	2ml	MAST® ASSURE Shigella dysenteriae - Mono Type 2	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
11	M10118	2ml	MAST® ASSURE Shigella dysenteriae - Mono Type 3	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
12	M10119	2ml	MAST® ASSURE Shigella dysenteriae - Mono Type 4	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
13	M10120	2ml	MAST® ASSURE Shigella dysenteriae - Mono Type 5	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
14	M10121	2ml	MAST® ASSURE Shigella dysenteriae - Mono Type 6	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
15	M10122	2ml	MAST® ASSURE Shigella dysenteriae - Mono Type 7	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
16	M10123	2ml	MAST® ASSURE Shigella dysenteriae - Mono Type 8	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
17	M10124	2ml	MAST® ASSURE Shigella dysenteriae - Mono Type 9	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
18	M10125	2ml	MAST® ASSURE Shigella dysenteriae - Mono Type 10	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
19	M10152	2ml	MAST® ASSURE Shigella dysenteriae - Mono Type 11	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
20	M10153	2ml	MAST® ASSURE Shigella dysenteriae - Mono Type 12	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.



Serial No.	Product code	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
21	M10126	2ml	MAST® ASSURE Shigella flexneri - Mono Type I	Liquid stable antisera for the determination of O antigen types for the serological identification of Shigella.
22	M10127	2ml	MAST® ASSURE Shigella flexneri - Mono Type II	Liquid stable antisera for the determination of O antigen types for the serological identification of Shigella.
23	M10128	2ml	MAST® ASSURE Shigella flexneri - Mono Type III	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella flexneri by slide agglutination.
24	M10129	2ml	MAST® ASSURE Shigella flexneri - Mono Type IV	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella flexneri by slide agglutination.
25	M10130	2ml	MAST® ASSURE Shigella flexneri - Mono Type V	Liquid stable antisera for the determination of O antigen types for the serological identification of Shigella.
26	M10131	2ml	MAST® ASSURE Shigella flexneri - Mono Type VI	Liquid stable antisera for the determination of O antigen types for the serological identification of Shigella.
27	M10132	2ml	MAST® ASSURE Shigella flexneri - Mono Group (3)4	Liquid stable antisera for the determination of O antigen group for the serological identification of Shigella.
28	M10133	2ml	MAST® ASSURE Shigella flexneri - Mono Group 6	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella flexneri by slide agglutination.
29	M10134	2ml	MAST® ASSURE Shigella flexneri - Mono Group 7 (8)	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella flexneri by slide agglutination.



Serial No.	Device ID Number	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
30	M10135	2ml	MAST® ASSURE Shigella boydii - Mono Type 1	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
31	M10136	2ml	MAST® ASSURE Shigella Boydii - Mono Type 2	Liquid stable antiserum for the determination of O antigen types for the serological identification of Shigella.
32	M10137	2ml	MAST® ASSURE Shigella boydii - Mono Type 3	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
33	M10138	2ml	MAST® ASSURE Shigella boydii - Mono Type 4	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
34	M10139	2ml	MAST® ASSURE Shigella boydii - Mono Type 5	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
35	M10140	2ml	MAST® ASSURE Shigella boydii - Mono Type 6	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
36	M10141	2ml	MAST® ASSURE Shigella boydii - Mono Type 7	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
37	M10142	2ml	MAST® ASSURE Shigella boydii - Mono Type 8	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
38	M10143	2ml	MAST® ASSURE Shigella boydii - Mono Type 9	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
39	M10144	2ml	MAST® ASSURE Shigella boydii - Mono Type 10	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
40	M10145	2ml	MAST® ASSURE Shigella boydii - Mono Type 11	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
41	M10146	2ml	MAST® ASSURE Shigella boydii - Mono Type 12	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
42	M10147	2ml	MAST® ASSURE Shigella boydii - Mono Type 13	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
43	M10148	2ml	MAST® ASSURE Shigella boydii - Mono Type 14	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
44	M10149	2ml	MAST® ASSURE Shigella boydii - Mono Type 15	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
45	M10155	2ml	MAST® ASSURE Shigella boydii - Mono Type 16	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.



Serial No.	Device ID Number	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
46	M10156	2ml	MAST® ASSURE Shigella boydii - Mono Type 17	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
47	M10157	2ml	MAST® ASSURE Shigella boydii - Mono Type 18	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.

Serial No.	Device ID Number	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
48	M10150	2ml	MAST® ASSURE Shigella sonnei - Mono Phase I	Liquid stable antisera for the determination of O antigen phases for the serological identification of Shigella.
49	M10151	2ml	MAST® ASSURE Shigella sonnei - Mono Phase II	Liquid stable antisera for the determination of O antigen phases for the serological identification of Shigella.

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

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...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

Latest Revision Date: 2021-12-03

Effective Date: 2021-11-11

Expiry Date: 2024-05-31

Page: 2 of 2

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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, 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

Page: 2 of 2

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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.

E. coli
Salmonella
Haemophilus

mastassure™

**Bacterial Agglutinating Antisera
and Febrile Antigens**

Shigella
Vibrio
Campylobacter
Bordetella
Clostridium
Legionella
Pseudomonas
Staphylococcus
Listeria
Streptococcus
Yersinia
Proteus
Brucella



- High quality performance
- Reliable identification
- Easy to read
- Extensive range available

Order No	Product	Packsize
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MAST ASSURE™ ANTISERA - STOCK LIST

All stock antisera are CE marked for IVD use

E.COLI O ANTISERA - MONOVALENT

M12014	<i>Escherichia coli</i> Factor	O26	2ml
M12016	<i>Escherichia coli</i> Factor	O111	2ml
M12017	<i>Escherichia coli</i> Factor	O119	2ml
M12018	<i>Escherichia coli</i> Factor	O127a	2ml
M12030	<i>Escherichia coli</i> Factor	O157	2ml

E.COLI O ANTISERA - POLYVALENT

M14263	<i>E.coli</i> POLY 2 Factors O26, O55, O111, O119, O126		2ml
M14270	<i>E.coli</i> POLY 3 Factors O86, O114, O125, O127, O128		2ml
M14287	<i>E.coli</i> POLY 4 Factors O44, O112, O124, O142		2ml

HAEMOPHILUS INFLUENZAE ANTISERA

M11303	<i>H.influenzae</i> Type b		2ml
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SALMONELLA O ANTISERA - MONOVALENT

M10310	Salmonella O Factor	O2	2ml
M10311	Salmonella O Factor	O4	2ml
M10312	Salmonella O Factor	O7	2ml
M10313	Salmonella O Factor	O8	2ml
M10314	Salmonella O Factor	O9	2ml
M10316	Salmonella O Factor	O3,10	2ml
M10320	Salmonella O Factor	O13	2ml
M10321	Salmonella O Factor	O6,14	2ml
M10326	Salmonella O Factor	Vi	2ml

SALMONELLA H ANTISERA - MONOVALENT

M10327	Salmonella H Factor	a	2ml
M10328	Salmonella H Factor	b	2ml
M10329	Salmonella H Factor	c	2ml
M10330	Salmonella H Factor	d	2ml
M10331	Salmonella H Factor	e, h	2ml
M14335	Salmonella H Factor	E	2ml
M10332	Salmonella H Factor	G	2ml
M10333	Salmonella H Factor	i	2ml
M10334	Salmonella H Factor	k	2ml
M10336	Salmonella H Factor	r	2ml
M10344	Salmonella H Factor	2	2ml
M10345	Salmonella H Factor	5	2ml
M10346	Salmonella H Factor	6	2ml
M10364	Salmonella H Factor	f	2ml
M10365	Salmonella H Factor	m	2ml
M10366	Salmonella H Factor	p	2ml
M10367	Salmonella H Factor	q	2ml
M10368	Salmonella H Factor	s	2ml
M10369	Salmonella H Factor	t	2ml

MAST ASSURE™ ANTISERA - STOCK LIST

All stock antisera are CE marked for IVD use

SALMONELLA O ANTISERA - POLYVALENT

M10308	POLY O	Factor O2, O4, O7, O8, O9, O9, 46, O3, 10 and O1,3,19	2ml
M10309	POLY O1	Factor O11, O13, O6, 14, O16, O18, O21 and O35	2ml
M14294	POLY O	A-G	2ml
M14300	POLY O	A-S	2ml
M92537	Omnivalent (Kauffmann-White group A-067)		2ml

SALMONELLA H ANTISERA - POLYVALENT

M14317	POLYVALENT PHASE 1&2 (a-z29)		2ml
M10339	POLYVALENT PHASE 2 (H-1)		2ml
M14324	RAPID DIAGNOSTIC 1 Factors b, d, E, r		2ml
M14331	RAPID DIAGNOSTIC 2 Factors b, E, k, l		2ml
M14348	RAPID DIAGNOSTIC 3 Factors d, E, G, k		2ml

SHIGELLA ANTISERA - MONOVALENT

M10116	<i>Shigella dysenteriae</i>	Type 1	2ml
M10126	<i>Shigella flexneri</i>	Type I	2ml
M10127	<i>Shigella flexneri</i>	Type II	2ml
M10130	<i>Shigella flexneri</i>	Type V	2ml
M10131	<i>Shigella flexneri</i>	Type VI	2ml
M10136	<i>Shigella boydii</i>	Type 2	2ml
M10150	<i>Shigella sonnei</i>	Phase I	2ml
M10151	<i>Shigella sonnei</i>	Phase II	2ml

SHIGELLA ANTISERA - POLYVALENT

M10109	<i>S.dysenteriae</i> POLY A	Types 1, 2, 3, 4, 5, 6, 7	2ml
M10110	<i>S.dysenteriae</i> POLY A1	Types 8, 9, 10, 11, 12	2ml
M10111	<i>S. flexneri</i> POLY B	Types I, II, III, IV, V, VI, Groups (3)4, 6, 7(8)	2ml
M10112	<i>S.boydii</i> POLY C	Types 1, 2, 3, 4, 5, 6, 7	2ml
M10113	<i>S.boydii</i> POLY C1	Types 8, 9, 10, 11	2ml
M10114	<i>S.boydii</i> POLY C2	Types 12, 13, 14, 15	2ml
M10154	<i>S.boydii</i> POLY C3	Types 16, 17, 18	2ml
M10115	<i>S.sonnei</i> POLY D	Phase I & II	2ml

VIBRIO ANTISERA

M11002	<i>Vibrio cholerae</i> POLY (INABA, OGAWA)		2ml
M11003	<i>Vibrio cholerae</i> INABA		2ml
M11004	<i>Vibrio cholerae</i> OGAWA		2ml
M15001	<i>Vibrio cholerae</i> O139 (Bengal)		2ml

MAST ASSURE™ ANTISERA - SUPPLEMENTARY LIST

Lead time 8 weeks

BORDETELLA ANTISERA

M11501/NCE	This antiserum agglutinates Phase I <i>B.pertussis</i> but does not agglutinate Phase III <i>B.pertussis</i> , <i>B.parapertussis</i> , nor <i>B.bronchiseptica</i> .	No CE Mark	2ml
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CAMPYLOBACTER ANTISERA

M13001	Campylobacter Antisera Set Reagents for the serotyping of Campylobacter by a passive haemagglutination (PHA) method. This set consists of: 2ml each of antisera (groups A, B, C, D, E, F, G, I, J, K, L, N, O, P, R, S, U, V, Y, Z, Z2, Z4, Z5, Z6 and Z7) 2ml x 1 vial of reference antiserum for red blood cells.		26 x 2ml
M13002	Campylobacter group A antiserum		2ml
M13003	Campylobacter group B antiserum		2ml
M13004	Campylobacter group C antiserum		2ml
M13005	Campylobacter group D antiserum		2ml
M13006	Campylobacter group E antiserum		2ml
M13007	Campylobacter group F antiserum		2ml
M13008	Campylobacter group G antiserum		2ml
M13009	Campylobacter group I antiserum		2ml
M13010	Campylobacter group J antiserum		2ml
M13011	Campylobacter group K antiserum		2ml
M13012	Campylobacter group L antiserum		2ml
M13013	Campylobacter group N antiserum		2ml
M13014	Campylobacter group O antiserum		2ml
M13015	Campylobacter group P antiserum		2ml
M13016	Campylobacter group R antiserum		2ml
M13017	Campylobacter group S antiserum		2ml
M13018	Campylobacter group U antiserum		2ml
M13019	Campylobacter group V antiserum		2ml
M13020	Campylobacter group Y antiserum		2ml
M13021	Campylobacter group Z antiserum		2ml
M13022	Campylobacter group Z2 antiserum		2ml
M13023	Campylobacter group Z4 antiserum		2ml
M13024	Campylobacter group Z5 antiserum		2ml
M13025	Campylobacter group Z6 antiserum		2ml
M13026	Campylobacter group Z7 antiserum		2ml
M13027	Reference antiserum		2ml
M42201	Reagent for preparing Sensitized Blood Cells Fixed Chick RBCs Extraction Reagent-1 Extraction Reagent-2 Extraction Reagent-3 Buffer solution		50 tests 13ml x 1 vial 13ml x 1 vial 13ml x 1 vial 50ml x 2 vials

MAST ASSURE™ ANTISERA - SUPPLEMENTARY LIST

Lead time 8 weeks

CLOSTRIDIUM PERFRINGENS TYPE A ANTISERA (HEAT RESISTANT C.WELCHII: HOBBS 1952)

M10601/NCE	<p>Clostridium perfringens type A Antisera Set This set consists of 4 Polyvalent and 17 Monovalent antisera.</p> <p>Polyvalent Polyvalent I: Type 1, 2, 3, 4 and 5 Polyvalent II: Type 6, 7, 8 and 9 Polyvalent III: Type 10, 11, 1,2 and 13 Polyvalent IV: Type 14, 15, 16 and 17</p> <p>Monovalent Type 1~17</p>	No CE Mark	2ml x 21
M10604/NCE	<p>Clostridium perfringens Polyvalent Polyvalent I: 1, 2, 3, 4 and 5</p>	No CE Mark	2ml

E.COLI ANTISERA SETS

M12001	<p>Escherichia coli Antisera Set 1 This set consists of 8 Polyvalents and 43 O (OK) sera.</p> <p>Polyvalent Serum Polyvalent 1: O1, O26, O86a, O111, O119, O127a and O128 Polyvalent 2: O44, O55, O125, O126, O146 & O166 Polyvalent 3: O18, O114, O142, O151, O157 & O158 Polyvalent 4: O6, O27, O78, O148, O159 and O168 Polyvalent 5: O20, O25, O63, O153 and O167 Polyvalent 6: O8, O15, O115 and O169 Polyvalent 7: O28ac, O112ac, O124, O136 and O144 Polyvalent 8: O29, O143, O152, and O164</p> <p>Monovalent Sera All individual types constituting above polyvalent sera.</p>		2ml x 51
M12002	<p>Escherichia coli Antisera Set 2 This set consists of 22 H-sera. H-sera: 2, 4, 5, 6, 7, 9, 10, 11, 12, 16, 18, 19, 20, 21, 27, 28, 34, 40, 42,41, 45 and 51</p>		5ml x 22

E.COLI O ANTISERA POLYVALENT

M12005	<i>E.coli</i> POLY D1 (O1, O26, O86a, O111, O119, O127a, O128)	2ml
M12006	<i>E.coli</i> POLY D2 (O44, O55, O125, O126, O146, O166)	2ml
M12007	<i>E.coli</i> POLY D3 (O18, O114, O142, O151, O157, O158)	2ml
M12008	<i>E.coli</i> POLY D4 (O6, O27, O78, O148, O159, O168)	2ml
M12009	<i>E.coli</i> POLY D5 (O20, O25, O63, O153, O167)	2ml
M12010	<i>E.coli</i> POLY D6 (O8, O15, O115, O169)	2ml
M12011	<i>E.coli</i> POLY D7 (O28ac, O112ac, O124, O136, O144)	2ml
M12012	<i>E.coli</i> POLY D8 (O29, O143, O152, O164)	2ml

MAST ASSURE™ ANTISERA - SUPPLEMENTARY LIST

Lead time 8 weeks

E.COLI O ANTISERA MONOVALENT

M12013	<i>E.coli</i> O1	2ml
M12015	<i>E.coli</i> O86a	2ml
M12019	<i>E.coli</i> O128	2ml
M12020	<i>E.coli</i> O44	2ml
M12021	<i>E.coli</i> O55	2ml
M12022	<i>E.coli</i> O125	2ml
M12023	<i>E.coli</i> O126	2ml
M12024	<i>E.coli</i> O146	2ml
M12025	<i>E.coli</i> O166	2ml
M12026	<i>E.coli</i> O18	2ml
M12027	<i>E.coli</i> O114	2ml
M12028	<i>E.coli</i> O142	2ml
M12029	<i>E.coli</i> O151	2ml
M12031	<i>E.coli</i> O158	2ml
M12032	<i>E.coli</i> O6	2ml
M12033	<i>E.coli</i> O27	2ml
M12034	<i>E.coli</i> O78	2ml
M12035	<i>E.coli</i> O148	2ml
M12036	<i>E.coli</i> O159	2ml
M12037	<i>E.coli</i> O168	2ml
M12038	<i>E.coli</i> O20	2ml
M12039	<i>E.coli</i> O25	2ml
M12040	<i>E.coli</i> O63	2ml
M12041	<i>E.coli</i> O153	2ml
M12042	<i>E.coli</i> O167	2ml
M12043	<i>E.coli</i> O8	2ml
M12044	<i>E.coli</i> O15	2ml
M12045	<i>E.coli</i> O115	2ml
M12046	<i>E.coli</i> O169	2ml
M12047	<i>E.coli</i> O28ac	2ml
M12048	<i>E.coli</i> O112ac	2ml
M12049	<i>E.coli</i> O124	2ml
M12050	<i>E.coli</i> O136	2ml
M12051	<i>E.coli</i> O144	2ml
M12052	<i>E.coli</i> O29	2ml
M12053	<i>E.coli</i> O143	2ml
M12054	<i>E.coli</i> O152	2ml
M12055	<i>E.coli</i> O164	2ml

E.COLI H ANTISERA MONOVALENT

M12056	<i>E.coli</i> H-2	5ml
M12057	<i>E.coli</i> H-4	5ml
M12058	<i>E.coli</i> H-5	5ml
M12059	<i>E.coli</i> H-6	5ml
M12060	<i>E.coli</i> H-7	5ml
M12061	<i>E.coli</i> H-9	5ml
M12062	<i>E.coli</i> H-10	5ml
M12063	<i>E.coli</i> H-11	5ml
M12064	<i>E.coli</i> H-12	5ml
M12065	<i>E.coli</i> H-16	5ml
M12066	<i>E.coli</i> H-18	5ml
M12067	<i>E.coli</i> H-19	5ml
M12068	<i>E.coli</i> H-20	5ml
M12069	<i>E.coli</i> H-21	5ml
M12070	<i>E.coli</i> H-27	5ml
M12071	<i>E.coli</i> H-28	5ml

MAST ASSURE™ ANTISERA - SUPPLEMENTARY LIST

Lead time 8 weeks

E.COLI H ANTISERA MONOVALENT (cont)

M12072	<i>E.coli</i> H-34	5ml
M12073	<i>E.coli</i> H-40	5ml
M12074	<i>E.coli</i> H-41	5ml
M12075	<i>E.coli</i> H-42	5ml
M12076	<i>E.coli</i> H-45	5ml
M12077	<i>E.coli</i> H-51	5ml

TOXIGENIC E.COLI PILI ANTISERA

M11601/NCE	Toxigenic <i>Escherichia coli</i> Pili Antisera Set This set consists of the following K88, K99 and 987P	No CE Mark	5ml x 3
M11602/NCE	<i>E.coli</i> K88	No CE Mark	5ml
M11603/NCE	<i>E.coli</i> K99	No CE Mark	5ml
M11604/NCE	<i>E.coli</i> 987P	No CE Mark	5ml

HAEMOPHILUS INFLUENZAE ANTISERA

M11301	<i>Haemophilus influenzae</i> Antisera Set This set consists of: Type a, b, c, d, e and f		2ml x 6
	<i>Haemophilus influenzae</i> type listed below		
M11302	<i>H.influenzae</i> Type a		2ml
M11304	<i>H.influenzae</i> Type c		2ml
M11305	<i>H.influenzae</i> Type d		2ml
M11306	<i>H.influenzae</i> Type e		2ml
M11307	<i>H.influenzae</i> Type f	No CE Mark	2ml

KLEBSIELLA CAPSULAR TYPING ANTISERA

M11201/NCE	Klebsiella Capsular Typing Antisera Set This set consists of 6 typing sera. Type 1~6	No CE Mark	2ml x 6
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LEGIONELLA ANTISERA

M11701	Legionella O-Grouping Antisera Set This set consists of: <i>L.pneumophila</i> 1~6, <i>L.bozemanii</i> , <i>L.dumoffi</i> , <i>L.gormanii</i> and <i>L.micdadei</i>		2ml x 10
	Legionella O-Group listed below		
M11702	<i>L.pneumophila</i> Group 1		2ml
M11703	<i>L.pneumophila</i> Group 2		2ml
M11704	<i>L.pneumophila</i> Group 3		2ml
M11705	<i>L.pneumophila</i> Group 4		2ml
M11706	<i>L.pneumophila</i> Group 5		2ml
M11707	<i>L.pneumophila</i> Group 6		2ml
M11708	<i>L.bozemanii</i>		2ml
M11709	<i>L.dumoffi</i>		2ml
M11710	<i>L.gormanii</i>		2ml
M11711	<i>L.micdadei</i>		2ml

MAST ASSURE™ ANTISERA - SUPPLEMENTARY LIST

Lead time 8 weeks

LISTERIA ANTISERA

M14362	Listeria Antisera Set This set consists of 8 O antisera and 4 H antisera. O antisera: O I/II, O I, O IV, O V/VI, O VI, O VII, O VIII and O IX H antisera: H-A, H-AB, H-C and H-D	2ml x 8 vials 5ml x 4 vials
M14379	Listeria O I/II antiserum	2ml
M14386	Listeria O I antiserum	2ml
M14393	Listeria O IV antiserum	2ml
M14409	Listeria O V/VI antiserum	2ml
M14416	Listeria O VI antiserum	2ml
M14423	Listeria O VII antiserum	2ml
M14430	Listeria O VIII antiserum	2ml
M14447	Listeria O IX antiserum	2ml
M14454	Listeria H-A antiserum	5ml
M14461	Listeria H-AB antiserum	5ml
M14478	Listeria H-C antiserum	5ml
M14485	Listeria H-D antiserum	5ml

PSEUDOMONAS ANTISERA

M10702/NCE	Pseudomonas aeruginosa Antisera Set This set consists of 3 Polyvalent and 14 Monovalent antisera. Polyvalent Polyvalent I: A, C, H, I and L Polyvalent II: B, J, K and M Polyvalent III: D, E, F, G and N Monovalent Type A, B, C, D, E, F, G, H, I, J, K, L, M and N	No CE Mark	2ml x 17
M10704/NCE	Pseudomonas aeruginosa Antisera type listed below Polyvalent I: A, C, H, I and L	No CE Mark	2ml
M10705/NCE	Polyvalent II: B, J, K and M	No CE Mark	2ml
M10706/NCE	Polyvalent III: D, E, F, G and N	No CE Mark	2ml
M10707/NCE	<i>Pseudomonas aeruginosa</i> Group A	No CE Mark	2ml
M10712/NCE	<i>Pseudomonas aeruginosa</i> Group B	No CE Mark	2ml
M10708/NCE	<i>Pseudomonas aeruginosa</i> Group C	No CE Mark	2ml
M10716/NCE	<i>Pseudomonas aeruginosa</i> Group D	No CE Mark	2ml
M10717/NCE	<i>Pseudomonas aeruginosa</i> Group E	No CE Mark	2ml
M10718/NCE	<i>Pseudomonas aeruginosa</i> Group F	No CE Mark	2ml
M10719/NCE	<i>Pseudomonas aeruginosa</i> Group G	No CE Mark	2ml
M10709/NCE	<i>Pseudomonas aeruginosa</i> Group H	No CE Mark	2ml
M10710/NCE	Pseudomonas aeruginosa Antisera type listed below <i>Pseudomonas aeruginosa</i> Group I	No CE Mark	2ml
M10713/NCE	<i>Pseudomonas aeruginosa</i> Group J	No CE Mark	2ml
M10714/NCE	<i>Pseudomonas aeruginosa</i> Group K	No CE Mark	2ml
M10711/NCE	<i>Pseudomonas aeruginosa</i> Group L	No CE Mark	2ml
M10715/NCE	<i>Pseudomonas aeruginosa</i> Group M	No CE Mark	2ml
M10720/NCE	<i>Pseudomonas aeruginosa</i> Group N	No CE Mark	2ml

SALMONELLA O ANTISERA - MONOVALENT

M10315	Salmonella O Factor	O9.46	2ml
M10318	Salmonella O Factor	O1,3,19	2ml
M10319	Salmonella O Factor	O11	2ml
M10322	Salmonella O Factor	O16	2ml
M10323	Salmonella O Factor	O18	2ml
M10324	Salmonella O Factor	O21	2ml
M10325	Salmonella O Factor	O35	2ml

MAST ASSURE™ ANTISERA - SUPPLEMENTARY LIST

Lead time 8 weeks

SALMONELLA H ANTISERA - MONOVALENT

M10335	Salmonella H Factor	L	2ml
M10337	Salmonella H Factor	y	2ml
M10338	Salmonella H Factor	e,n	2ml
M10340	Salmonella H Factor	v	2ml
M10341	Salmonella H Factor	w	2ml
M10342	Salmonella H Factor	z13	2ml
M10343	Salmonella H Factor	z28	2ml
M10347	Salmonella H Factor	7	2ml
M10348	Salmonella H Factor	z6	2ml
M10370	Salmonella H Factor	u	2ml
M10372	Salmonella H Factor	z23	2ml
M10373	Salmonella H Factor	z24	2ml
M10376	Salmonella H Factor	x	2ml
M10377	Salmonella H Factor	z15	2ml
M10374	Salmonella H Factor	z32	2ml
M10378	Salmonella H Factor	z	2ml
M10379	Salmonella H Factor	z4	2ml
M10380	Salmonella H Factor	z10	2ml
M10381	Salmonella H Factor	z29	2ml
M91882/NCE	Salmonella H Factor	g,p	No CE Mark 5ml
M10303	Salmonella Antisera Set 1 This set consists of 17 O-grouping and Vi sera Polyvalent O: O2, O4, O7, O8, O9, O9, 46, O3,10 & O1, 3, 19 Polyvalent O1: O11, O13, O6, O14, O16, O18, O21 and O35 Monovalent: O2, O4, O7, O8, O9, O9, 46, O3, 10, O1, 3, 19, O11, O13, O6, 14, O16, O18, 21 and O35, Vi serum		2ml x 18
M10304	Salmonella Antisera Set 2 This set consists of 17 H antisera. a, b, c, d, e, h, G, i, k, L, r, y, e,n, l, z, z4, z10 and z29		5ml x 17
M10386	Salmonella Antisera Set 3 This set consists of four H-L Monovalent sera:- v, w, z13 and z28		5ml x 4
M10387	Salmonella Antisera Set 4 This set consists of five H-1 Monovalent sera 2, 5, 6, 7 and z6		5ml x 5
M10388	Salmonella Antisera Set 5 This set consists of seven H-G Monovalent sera:- f, m, p, q, s, t and u		5ml x 7
M10389	Salmonella Antisera Set 6 This set consists of three H-z4 and two H-e,n. Monovalent sera. z23, z24, z32, x and z15		5ml x 5
M10390	Salmonella Antisera Set 7 This set consists of the following. O-grouping sera: O2 and O9 H-sera: a and d Vi serum		2ml x 2 5ml x 2 2ml x 1

SHIGELLA ANTISERA - MONOVALENT

M10117	<i>Shigella dysenteriae</i>	Type 2	2ml
M10118	<i>Shigella dysenteriae</i>	Type 3	2ml
M10119	<i>Shigella dysenteriae</i>	Type 4	2ml
M10120	<i>Shigella dysenteriae</i>	Type 5	2ml
M10121	<i>Shigella dysenteriae</i>	Type 6	2ml

MAST ASSURE™ ANTISERA - SUPPLEMENTARY LIST

Lead time 8 weeks

SHIGELLA ANTISERA - MONOVALENT (cont)

M10122	<i>Shigella dysenteriae</i>	Type 7	2ml
M10123	<i>Shigella dysenteriae</i>	Type 8	2ml
M10124	<i>Shigella dysenteriae</i>	Type 9	2ml
M10125	<i>Shigella dysenteriae</i>	Type 10	2ml
M10152	<i>Shigella dysenteriae</i>	Type 11	2ml
M10153	<i>Shigella dysenteriae</i>	Type 12	2ml
M10128	<i>Shigella flexneri</i>	Type III	2ml
M10129	<i>Shigella flexneri</i>	Type IV	2ml
M10132	<i>Shigella flexneri</i>	Group (3)4	2ml
M10133	<i>Shigella flexneri</i>	Group 6	2ml
M10134	<i>Shigella flexneri</i>	Group 7 (8)	2ml
M10135	<i>Shigella boydii</i>	Type 1	2ml
M10137	<i>Shigella boydii</i>	Type 3	2ml
M10138	<i>Shigella boydii</i>	Type 4	2ml
M10139	<i>Shigella boydii</i>	Type 5	2ml
M10140	<i>Shigella boydii</i>	Type 6	2ml
M10141	<i>Shigella boydii</i>	Type 7	2ml
M10142	<i>Shigella boydii</i>	Type 8	2ml
M10143	<i>Shigella boydii</i>	Type 9	2ml
M10144	<i>Shigella boydii</i>	Type 10	2ml
M10145	<i>Shigella boydii</i>	Type 11	2ml
M10146	<i>Shigella boydii</i>	Type 12	2ml
M10147	<i>Shigella boydii</i>	Type 13	2ml
M10148	<i>Shigella boydii</i>	Type 14	2ml
M10149	<i>Shigella boydii</i>	Type 15	2ml
M10155	<i>Shigella boydii</i>	Type 16	2ml
M10156	<i>Shigella boydii</i>	Type 17	2ml
M10157	<i>Shigella boydii</i>	Type 18	2ml
M10104	Shigella Antisera Set 1		2ml x 49
	This set consists of 8 Polyvalent and 41 Monovalents.		
	Polyvalent serum		
	Polyvalent A: <i>S.dysenteriae</i> Type 1, 2, 3, 4, 5, 6 & 7		
	Polyvalent A1: <i>S.dysenteriae</i> Type 8, 9, 10, 11 & 12		
	Polyvalent B; <i>S.flexneri</i> Type I, II, III, IV, V, VI & Group (3) 4, 6 and 7 (8)		
	Polyvalent C: <i>S.boydii</i> Type 1, 2, 3, 4, 5, 6 and 7		
	Polyvalent C1: <i>S.boydii</i> Type 8, 9, 10 and 11		
	Polyvalent C2: <i>S.boydii</i> Type 12, 13, 14 and 15		
	Polyvalent C3: <i>S.boydii</i> Type 16, 17 and 18		
	Polyvalent D: <i>S.sonnei</i> Phase I and Phase II		
	Monovalent serum		
	All individual types and groups constituting above polyvalent sera.		
M10105	Shigella Antisera Set 2		2ml x 19
	This set consists of 8 Polyvalents and 11 Monovalents.		
	Polyvalent serum		
	Polyvalent A: <i>S.dysenteriae</i> Type 1, 2, 3, 4, 5, 6 & 7		
	Polyvalent A1: <i>S.dysenteriae</i> Type 8, 9, 10, 11 & 12		
	Polyvalent B; <i>S.flexneri</i> Type I, II, III, IV, V, VI and Group (3) 4, 6 and 7 (8)		
	Polyvalent C: <i>S.boydii</i> Type 1, 2, 3, 4, 5, 6 and 7		
	Polyvalent C1: <i>S.boydii</i> Type 8, 9, 10 and 11		
	Polyvalent C2: <i>S.boydii</i> Type 12, 13, 14 and 15		
	Polyvalent C3: <i>S.boydii</i> Type 16, 17 and 18		
	Polyvalent D: <i>S.sonnei</i> Phase I and Phase II		
	Monovalent serum		
	<i>S.flexneri</i> : type I, II, III, IV, V, VI and Group: (3) 4, 6 and 7 (8).		
	<i>S.sonnei</i> : Phase I and Phase II.		

MAST ASSURE™ ANTISERA - SUPPLEMENTARY LIST

Lead time 8 weeks

SHIGELLA ANTISERA SETS (cont)

M10106	<p>Shigella Antisera Set 3 Polyvalent A: <i>S.dysenteriae</i> Type 1, 2,3, 4, 5, 6, & 7 Polyvalent A1: <i>S. dysenteriae</i> Type 8, 9, 10, 11 & 12 Polyvalent B; <i>S.flexneri</i> Type I, II, III, IV, V, VI and Group (3) 4, 6 and 7 (8) Polyvalent C: <i>S.boydii</i> Type 1, 2, 3, 4, 5, 6 and 7 Polyvalent C1: <i>S.boydii</i> Type 8, 9, 10 and 11 Polyvalent C2: <i>S.boydii</i> Type 12, 13, 14 and 15 Polyvalent C3: <i>S.boydii</i> Type 16, 17 and 18 Polyvalent D: <i>S.sonnei</i> Phase I and Phase II</p>	2ml x 8
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STAPHYLOCOCCUS ANTISERA

M10801	<p>Staphylococcal Coagulase Typing Sera Set This set consists of 8 typing sera. Types: I, II, III, IV, V, VI, VII, and VIII</p>	5ml x 8
	Staphylococcal coagulase type listed below	
M10802	<i>Staphylococcal coagulase</i> type I	5ml
M10803	<i>Staphylococcal coagulase</i> type II	5ml
M10804	<i>Staphylococcal coagulase</i> type III	5ml
M10805	<i>Staphylococcal coagulase</i> type IV	5ml
M10806	<i>Staphylococcal coagulase</i> type V	5ml
M10807	<i>Staphylococcal coagulase</i> type VI	5ml
M10808	<i>Staphylococcal coagulase</i> type VII	5ml
M10809	<i>Staphylococcal coagulase</i> type VIII	5ml

HAEMOLYTIC STREPTOCOCCUS GROUP-A T-TYPING

	<p>Haemolytic Streptococcus Group-A T-Typing Sera type listed below</p>		
M10516/NCE	Group A Streptococcus T-2	No CE Mark	2ml
M10570	<p>Haemolytic Streptococcus Group-B Typing Sera Set This set consists of Antisera types: Ia, Ib, II, III, IV and V</p>		2ml x 6
	Haemolytic Streptococcus Group-B Typing		
	Sera type listed below		
M10540	Group B Streptococcus Ia		2ml
M10541	Group B Streptococcus Ib		2ml
M10542	Group B Streptococcus II		2ml
M10543	Group B Streptococcus III		2ml
M10544	Group B Streptococcus IV		2ml
M10545	Group B Streptococcus V		2ml
M93350	Group B Streptococcus VI		2ml
M93374	Group B Streptococcus VII		2ml
M93367	Group B Streptococcus VIII		2ml
M20209	<p>Auxiliary reagents for Haemolytic Streptococcus typing Swine pancreas extract pH correction solution Phenol Red solution</p>		5ml x 4 5ml x 2 5ml x 1

MAST ASSURE™ ANTISERA - SUPPLEMENTARY LIST

Lead time 8 weeks

STREPTOCOCCUS PNEUMONIAE ANTISERA

M00747	Streptococcus pneumoniae Antisera typing set This kit consists of 8 polyvalent and 39 monovalent antisera		2ml x 47
	Streptococcus pneumoniae POLYVALENT typing Antisera		
M15253	<i>Streptococcus pneumoniae</i> Polyvalent 1 antiserum: contains 1,2,3,4 and 5		2ml
M15260	2 antiserum: contains 6,8,9 and 10		2ml
M15277	3 antiserum: contains 11,12,14,15 and 16		2ml
M15284	4 antiserum: contains 17,18,21 and 22		2ml
M15291	5 antiserum: contains 20,29,31,33,34,35 and 47		2ml
M15307	6 antiserum: contains 23,25,28,41 and 46		2ml
M15314	7 antiserum: contains 27,32,36,38 and 39		2ml
M15321	8 antiserum: contains 7,19,24 and 40		2ml
M15338	<i>Streptococcus pneumoniae</i>	type 1 antiserum	2ml
M15345	<i>Streptococcus pneumoniae</i>	type 2 antiserum	2ml
M15352	<i>Streptococcus pneumoniae</i>	type 3 antiserum	2ml
M15369	<i>Streptococcus pneumoniae</i>	type 4 antiserum	2ml
M15376	<i>Streptococcus pneumoniae</i>	type 5 antiserum	2ml
M15383	<i>Streptococcus pneumoniae</i>	type 6 antiserum	2ml
M15390	<i>Streptococcus pneumoniae</i>	type 7 antiserum	2ml
M15406	<i>Streptococcus pneumoniae</i>	type 8 antiserum	2ml
M15413	<i>Streptococcus pneumoniae</i>	type 9 antiserum	2ml
M15420	<i>Streptococcus pneumoniae</i>	type 10 antiserum	2ml
M15437	<i>Streptococcus pneumoniae</i>	type 11 antiserum	2ml
M15444	<i>Streptococcus pneumoniae</i>	type 12 antiserum	2ml
M15451	<i>Streptococcus pneumoniae</i>	type 14 antiserum	2ml
M15468	<i>Streptococcus pneumoniae</i>	type 15 antiserum	2ml
M15475	<i>Streptococcus pneumoniae</i>	type 16 antiserum	2ml
M15482	<i>Streptococcus pneumoniae</i>	type 17 antiserum	2ml
M15499	<i>Streptococcus pneumoniae</i>	type 18 antiserum	2ml
M15505	<i>Streptococcus pneumoniae</i>	type 19 antiserum	2ml
M15512	<i>Streptococcus pneumoniae</i>	type 20 antiserum	2ml
M15529	<i>Streptococcus pneumoniae</i>	type 21 antiserum	2ml
M15536	<i>Streptococcus pneumoniae</i>	type 22 antiserum	2ml
M15543	<i>Streptococcus pneumoniae</i>	type 23 antiserum	2ml
M15550	<i>Streptococcus pneumoniae</i>	type 24 antiserum	2ml
M15567	<i>Streptococcus pneumoniae</i>	type 25 antiserum	2ml
M15574	<i>Streptococcus pneumoniae</i>	type 26 antiserum	2ml
M15581	<i>Streptococcus pneumoniae</i>	type 28 antiserum	2ml
M15598	<i>Streptococcus pneumoniae</i>	type 29 antiserum	2ml
M15604	<i>Streptococcus pneumoniae</i>	type 31 antiserum	2ml
M15611	<i>Streptococcus pneumoniae</i>	type 32 antiserum	2ml
M15628	<i>Streptococcus pneumoniae</i>	type 33 antiserum	2ml
M15635	<i>Streptococcus pneumoniae</i>	type 34 antiserum	2ml
M15642	<i>Streptococcus pneumoniae</i>	type 35 antiserum	2ml
M15659	<i>Streptococcus pneumoniae</i>	type 36 antiserum	2ml
M15666	<i>Streptococcus pneumoniae</i>	type 38 antiserum	2ml
M15673	<i>Streptococcus pneumoniae</i>	type 39 antiserum	2ml
M15680	<i>Streptococcus pneumoniae</i>	type 40 antiserum	2ml
M15697	<i>Streptococcus pneumoniae</i>	type 41 antiserum	2ml
M15703	<i>Streptococcus pneumoniae</i>	type 46 antiserum	2ml
M15710	<i>Streptococcus pneumoniae</i>	type 47 antiserum	2ml

MAST ASSURE™ ANTISERA - SUPPLEMENTARY LIST

Lead time 8 weeks

VIBRIO PARAHAEMOLYTICUS ANTISERA

Order No	Product	CE Mark	Packsizes
M10495/NCE	<p>Vibrio parahaemolyticus K-typing Antisera Set This set consists of 9 Polyvalent and 65 Monovalent K-Antisera. Polyvalent Antisera Polyvalent KI: 1, 3, 4, 5, 6, 7 and 8 Polyvalent KII: 9, 10, 11, 12, 13, 15 and 17 Polyvalent KIII: 18, 19, 20, 21, 22, 23 and 24 Polyvalent KIV: 25, 26, 28, 29, 30, 31 and 32 Polyvalent KV: 33, 34, 36, 37, 38, 39 and 40 Polyvalent KVI: 41, 42, 43, 44, 45, 46 and 47 Polyvalent KVII: 48, 49, 50, 51, 52, 53 and 54 Polyvalent KVIII: 55, 56, 57, 58, 59, 60 and 61 Polyvalent KIX: 63, 64, 65, 66, 67, 68 and 69 Monovalent K1~K71 except K2, K14, K16, K27, K35 and K62</p>	No CE Mark	2ml x 74
M10402/NCE	<p>Vibrio parahaemolyticus O-grouping Antisera Set This set consists of 11 O-grouping sera. 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 and 11</p>	No CE Mark	2ml x 11
	Vibrio parahaemolyticus Antisera type listed below		
M10405/NCE	<i>V.parahaemolyticus</i> Polyvalent KI contains types 1, 3, 4, 5, 6, 7, & 8	No CE Mark	2ml
M10406/NCE	<i>V.parahaemolyticus</i> Polyvalent KII contains types 9, 10, 11, 12, 13, 15 and 17	No CE Mark	2ml
M10407/NCE	<i>V.parahaemolyticus</i> Polyvalent KIII contains types 18, 19, 20, 21, 22, 23 and 24	No CE Mark	2ml
M10408/NCE	<i>V.parahaemolyticus</i> Polyvalent KIV contains types 25, 26, 28, 29, 30, 31 and 32	No CE Mark	2ml
M10409/NCE	<i>V.parahaemolyticus</i> Polyvalent KV contains types 33, 34, 36, 37, 38, 39 and 40	No CE Mark	2ml
M10410/NCE	<i>V.parahaemolyticus</i> Polyvalent KVI contains types 41, 42, 43, 44, 45, 46, and 47	No CE Mark	2ml
M10411/NCE	<i>V.parahaemolyticus</i> Polyvalent KVII contains types 48, 49, 50, 51, 52, 53 and 54	No CE Mark	2ml
M10412/NCE	<i>V.parahaemolyticus</i> Polyvalent KVIII contains types 55, 56, 57, 58, 59, 60 and 61	No CE Mark	2ml
M10482/NCE	<i>V.parahaemolyticus</i> Polyvalent KIX contains types 63, 64, 65, 66, 67, 68 and 69	No CE Mark	2ml
M10413/NCE	<i>V.parahaemolyticus</i> K1	No CE Mark	2ml
M10414/NCE	<i>V.parahaemolyticus</i> K3	No CE Mark	2ml
M10415/NCE	<i>V.parahaemolyticus</i> K4	No CE Mark	2ml
M10416/NCE	<i>V.parahaemolyticus</i> K5	No CE Mark	2ml
M10417/NCE	<i>V.parahaemolyticus</i> K6	No CE Mark	2ml
M10418/NCE	<i>V.parahaemolyticus</i> K7	No CE Mark	2ml
M10419/NCE	<i>V.parahaemolyticus</i> K8	No CE Mark	2ml
M10420/NCE	<i>V.parahaemolyticus</i> K9	No CE Mark	2ml
M10421/NCE	<i>V.parahaemolyticus</i> K10	No CE Mark	2ml
M10422/NCE	<i>V.parahaemolyticus</i> K11	No CE Mark	2ml
M10423/NCE	<i>V.parahaemolyticus</i> K12	No CE Mark	2ml
M10424/NCE	<i>V.parahaemolyticus</i> K13	No CE Mark	2ml
M10425/NCE	<i>V.parahaemolyticus</i> K15	No CE Mark	2ml
M10426/NCE	<i>V.parahaemolyticus</i> K17	No CE Mark	2ml
M10427/NCE	<i>V.parahaemolyticus</i> K18	No CE Mark	2ml
M10428/NCE	<i>V.parahaemolyticus</i> K19	No CE Mark	2ml
M10429/NCE	<i>V.parahaemolyticus</i> K20	No CE Mark	2ml
M10430/NCE	<i>V.parahaemolyticus</i> K21	No CE Mark	2ml
M10431/NCE	<i>V.parahaemolyticus</i> K22	No CE Mark	2ml
M10432/NCE	<i>V.parahaemolyticus</i> K23	No CE Mark	2ml
M10433/NCE	<i>V.parahaemolyticus</i> K24	No CE Mark	2ml
M10434/NCE	<i>V.parahaemolyticus</i> K25	No CE Mark	2ml
M10435/NCE	<i>V.parahaemolyticus</i> K26	No CE Mark	2ml

MAST ASSURE™ ANTISERA - SUPPLEMENTARY LIST

Lead time 8 weeks

VIBRIO PARAHAEMOLYTICUS ANTISERA (cont)

M10436/NCE	<i>V.parahaemolyticus</i> K28	No CE Mark	2ml
M10437/NCE	<i>V.parahaemolyticus</i> K29	No CE Mark	2ml
M10438/NCE	<i>V.parahaemolyticus</i> K30	No CE Mark	2ml
M10439/NCE	<i>V.parahaemolyticus</i> K31	No CE Mark	2ml
M10440/NCE	<i>V.parahaemolyticus</i> K32	No CE Mark	2ml
M10442/NCE	<i>V.parahaemolyticus</i> K34	No CE Mark	2ml
M10445/NCE	<i>V.parahaemolyticus</i> K38	No CE Mark	2ml
M10448/NCE	<i>V.parahaemolyticus</i> K41	No CE Mark	2ml
M10449/NCE	<i>V.parahaemolyticus</i> K42	No CE Mark	2ml
M10450/NCE	<i>V.parahaemolyticus</i> K43	No CE Mark	2ml
M10451/NCE	<i>V.parahaemolyticus</i> K44	No CE Mark	2ml
M10452/NCE	<i>V.parahaemolyticus</i> K45	No CE Mark	2ml
M10453/NCE	<i>V.parahaemolyticus</i> K46	No CE Mark	2ml
M10454/NCE	<i>V.parahaemolyticus</i> K47	No CE Mark	2ml
M10455/NCE	<i>V.parahaemolyticus</i> K48	No CE Mark	2ml
M10456/NCE	<i>V.parahaemolyticus</i> K49	No CE Mark	2ml
M10457/NCE	<i>V.parahaemolyticus</i> K50	No CE Mark	2ml
M10458/NCE	<i>V.parahaemolyticus</i> K51	No CE Mark	2ml
M10459/NCE	<i>V.parahaemolyticus</i> K52	No CE Mark	2ml
M10460/NCE	<i>V.parahaemolyticus</i> K53	No CE Mark	2ml
M10461/NCE	<i>V.parahaemolyticus</i> K54	No CE Mark	2ml
M10462/NCE	<i>V.parahaemolyticus</i> K55	No CE Mark	2ml
M10463/NCE	<i>V.parahaemolyticus</i> K56	No CE Mark	2ml
M10464/NCE	<i>V.parahaemolyticus</i> K57	No CE Mark	2ml
M10465/NCE	<i>V.parahaemolyticus</i> K58	No CE Mark	2ml
M10466/NCE	<i>V.parahaemolyticus</i> K59	No CE Mark	2ml
M10467/NCE	<i>V.parahaemolyticus</i> K60	No CE Mark	2ml
M10479/NCE	<i>V.parahaemolyticus</i> K61	No CE Mark	2ml
M10480/NCE	<i>V.parahaemolyticus</i> K63	No CE Mark	2ml
M10488/NCE	<i>V.parahaemolyticus</i> K66	No CE Mark	2ml
M10489/NCE	<i>V.parahaemolyticus</i> K67	No CE Mark	2ml
M10490/NCE	<i>V.parahaemolyticus</i> K68	No CE Mark	2ml
M10496/NCE	<i>V.parahaemolyticus</i> K71	No CE Mark	2ml
M10468/NCE	<i>V.parahaemolyticus</i> O1	No CE Mark	2ml
M10469/NCE	<i>V.parahaemolyticus</i> O2	No CE Mark	2ml
M10470/NCE	<i>V.parahaemolyticus</i> O3	No CE Mark	2ml
M10471/NCE	<i>V.parahaemolyticus</i> O4	No CE Mark	2ml
M10472/NCE	<i>V.parahaemolyticus</i> O5	No CE Mark	2ml

MAST ASSURE™ ANTISERA - SUPPLEMENTARY LIST

Lead time 8 weeks

VIBRIO CHOLERAEE ANTISERA

M11001	Vibrio cholerae Antisera Set This set consists of: Polyvalent antiserum: Serovar Inaba and Ogawa Monovalent antisera: Serovar Inaba, Serovar Ogawa.	2ml x 3
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YERSINIA ENTEROCOLITICA O-GROUPING ANTISERA

M11101	Yersinia enterocolitica O-Grouping Antisera Set This set consists of 1 Polyvalent and 4 Monovalent O sera. Polyvalent: Group O1, O2 Mixture Monovalent: O3, O5, O8 and O9 Yersinia enterocolitica type listed below	2ml x 5
M11102	Polyvalent: Group O1, O2 Mixture	2ml
M11103	Group O3	2ml
M11104	Group O5	2ml
M11105	Group O9	2ml
M11106	Group O8	2ml
M11801/NCE	Yersinia pseudotuberculosis Grouping Antisera Set This set consists of: Group 1~6 Yersinia pseudotuberculosis Group listed below	No CE Mark 2ml x 6
M11802/NCE	<i>Y.pseudotuberculosis</i> Group 1	No CE Mark 2ml
M11803/NCE	<i>Y.pseudotuberculosis</i> Group 2	No CE Mark 2ml
M11804/NCE	<i>Y.pseudotuberculosis</i> Group 3	No CE Mark 2ml
M11805/NCE	<i>Y.pseudotuberculosis</i> Group 4	No CE Mark 2ml

MAST ASSURE™ FEBRILE STAINED ANTIGENS

Available to special order

Contact Mast Customer Service for more information on lead times and minimum order quantities

P00018	<i>Brucella abortus</i>	5ml
P00020	<i>Brucella melitensis</i>	5ml
P00022	Proteus OX2	5ml
P00024	Proteus OX19	5ml
P00026	Proteus OXK	5ml
P00002	Salmonella typhi H	5ml
P00004	Salmonella H paratyphi A	5ml
P00006	Salmonella H Paratyphi B	5ml
P00008	Salmonella H Paratyphi C	5ml
P00010	Salmonella typhi O	5ml
P00011	Salmonella typhi Vi (unstained)	5ml
P00012	Salmonella O paratyphi A	5ml
P00014	Salmonella O paratyphi B	5ml
P00016	Salmonella O paratyphi C	5ml
P00032	Negative Febrile Control	1ml
P00030	Positive Polyvalent Febrile Control	1ml

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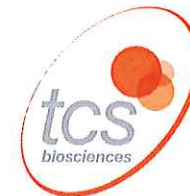
STATEMENT

We, TCS Biosciences Ltd., having a registered office at Botolph Claydon, Buckingham, MK 18 2LR, England assign Sanmedico SRL having a registered office at str. A. Corobceanu 7A, apt. 9, Chişinău MD-2012, Moldova, as Authorized Representative in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Date : 21 August 2018

Signature: *Jul Brown*



SELF DECLARATION OF CONFORMITY

We declare under our sole responsibility in accordance with MHRA account number 0000009546 that the following CE marked products:

GMDN Term	GMDN Code	TCS product code and description
General microbial isolate identification control IVD	63319	Selectrol – All MM codes

conform to the relevant provisions of the In-vitro Diagnostic Medical Devices Directive 98/79/EC and The Medical Devices Regulations 2002 (SI 2002 No.618) and The Medical Devices (Amendment) Regulations 2003 (SI 2003 No.1697) for in-vitro diagnostic medical devices.

This declaration is made on the basis of meeting the requirements of Annexes I and III of the In-Vitro Diagnostic Medical Devices Directive 98/79/EC and continued maintenance of an approved Quality Management System meeting the requirements of ISO 9001, as certified by BSI, certificate number FS 28907.

Signed by: Sue Brown

Date: September 2020

Name: Sue Brown
Position: Quality Assurance & Regulatory Affairs Manager

Signed by: Lynda Preston

Date: September 2020

Name: Lynda Preston
Position: Managing Director

Manufacturer
TCS Biosciences Ltd
Botolph Claydon
Buckingham MK18 2LR
UK

EC Authorised Representative
TCS Biosciences Europe B.V.
Provincialeweg 6
9864 PD Kornhorn
The Netherlands

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

TCS Biosciences Limited
Botolph Claydon
Buckingham
MK18 2LR
United Kingdom

Holds Certificate Number:

FS 28907

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

The procurement, manufacture, design, development and sale of a range of diagnostic products for clinical, pharmaceutical, food and environmental laboratory testing.

For and on behalf of BSI:

Matt Page, Managing Director Assurance - UK & Ireland

Original Registration Date: 1994-08-11

Latest Revision Date: 2022-01-14

Effective Date: 2022-01-27

Expiry Date: 2025-01-26

Page: 1 of 1



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Certificate of Registration

ENVIRONMENTAL MANAGEMENT SYSTEM - ISO 14001:2015

This is to certify that:

TCS Biosciences Ltd
Botolph Claydon
Buckingham
MK18 2LR
United Kingdom

Holds Certificate Number:

EMS 590359

and operates an Environmental Management System which complies with the requirements of ISO 14001:2015 for the following scope:

The procurement, manufacture, design, development and sale of a range of diagnostic products for clinical, pharmaceutical, food and environmental laboratory testing.

For and on behalf of BSI:

Matt Page, Managing Director Assurance - UK & Ireland

Original Registration Date: 2013-06-10

Latest Revision Date: 2022-01-14

Effective Date: 2022-01-27

Expiry Date: 2025-01-26

Page: 1 of 1



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SELECTROL

Discurile cu tulpini de referință Selectrol® sunt destinate utilizării în laboratoarele de microbiologie în scop de control a metodelor de testare. Fiind **derivați de primă generație** trasabili la tulpinile de tip național renumite, discurile Selectrol sunt bine primite în laboratoare acreditate pentru producția culturilor de lucru.

Discurile Selectrol sunt un produs microbial congelat fabricat exclusiv din culturi ale NCTC (Colecția Națională a Tipurilor de Culturi) și NCPF (Colecția Națională a Fungilor Patogeni). Viabilitatea microorganismelor este stabilizată prin incorporarea cărbunelui activat în disc și a silica gelului din flacon.

PRECAUȚIUNI ȘI PĂSTRARE

- Discurile Selectrol conțin microorganisme patogene și trebuie folosite doar în laboratoarele special echipate pentru manipularea acestora de către microbiologi calificați.
- Păstrați la temperatura indicată pe flacon. Pierdere de viabilitate poate apărea la păstrarea necorespunzătoare pe timp îndelungat (temperaturi mai mari decât cea indicată pe flacon).
- Lăsați flaconul să ajungă la temperatura camerei și închideți flaconul imediat după îndepărtarea duscului/discurilor. Umiditatea din aer ar putea duce la reducerea numărului de microorganisme de pe disc.
- Nu folosiți produsul după expirarea termenului de valabilitate sau dacă culoarea silica gelului din flacon își schimbă culoarea. Aceștia sunt indicatori ai pierderii viabilității și modificărilor în antibiotice și reacții chimice.

Îndepărtarea unui disc din flacon: aceasta se efectuează ușor cu forceps steril sau ansă sterilă de 10 μl.

Utilizarea cu medii solide: Plasați discul pe mediul solid corespunzător. Lăsați discul să se înmoaie timp de 10-15 minute. Placa poate fi plasată în incubator pentru a grăbi procesul. Apoi împrăștiați discul pe suprafața mediului și incubați la condițiile optime/corespunzătoare.

Utilizarea cu medii lichide: Plasați discul în 1-10ml de bulion corespunzător. Amestecați ușor bulionul pentru a dilua discul, evitând formarea aerosolilor. Incubați la condițiile optime/corespunzătoare. Pentru uz rapid, folosiți metode alternative precum dizolvarea discului și incubarea bulionului la 35-37°C timp de o oră apoi să-l folosiți imediat. Puteți face careva experiențe proprii pentru a descoperi metoda de diluție corespunzătoare Dvs.

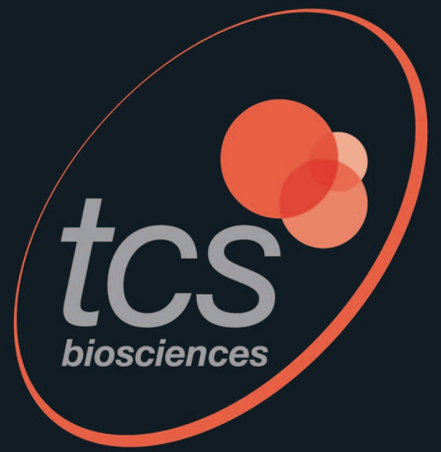
Limitări: Sub-cultura repetată poate cauza modificare a caracteristicilor tulpinii. Este recomandată folosirea discurilor proaspete pentru fiecare set de testări.

În laboratoarele de acreditare, discurilor pot fi folosite doar pentru producerea stocurilor de lucru. Sub-cultura de apoi va invalida uzul lor.

RUPERE, SCURGERI ȘI ELIMINARE

1. Toate discurile expuse, pachetele contaminate și sticlele stricate trebuie plasate într-un container corespunzător și incinerate sau autoclavate la 121°C timp de 30 minute.
2. Flacoanele întregi pot fi îndepărtate cu forceps, spălate cu soluție bactericidă corespunzătoare, uscate și utilizate ulterior.
3. Toate suprafețele contaminate trebuie dezinfectate cu soluție bactericidă corespunzătoare.

accuracy and quality as a science



Selectrol®
Technical
Guide



Selectrol® : Manufactured under licence from Public Health England Culture Collections

SELECTROL® - FREEZE-DRIED ORGANISMS IN A DISC

Quality control of microbial characterisation tests, culture media and antimicrobial susceptibility determinations is best accomplished by the use of microorganisms with well-documented and stable phenotypic and genotypic characteristics.

Bacterial and fungal strains have been selected and recommended by expert bodies, such as **EUCAST**, **CLSI** and the European Pharmacopoeia, on the basis of their suitability for monitoring test performance and ensuring the validity of results for testing used in clinical, food, pharmaceutical, water and veterinary laboratories.

Products derived from the cultures in the collections should be manufactured using the minimum number of sub-cultures, to minimise the possibility of alterations to the phenotype due to mutations. See also page 14.

Selectrol strains are manufactured exclusively from Public Health England Culture Collections (NCTC® and NCPF®) and are first generation subcultures, unlike many products on the market which are 2nd, 3rd or 4th generation subcultures. They are preserved by long-term storage as freeze-dried cells in order to minimise any alterations to the phenotype caused by mutations.

Passages

A Selectrol® disc is a first generation subculture from a **master culture** sourced from Public Health England Culture Collections, and is designed to be used to obtain **working stock** cultures for use in testing. It is generally accepted that no more than a total of five passages should be made from the **master culture**, in order to avoid genetic drift and mutant selection. Therefore, no more than four passages (fresh cultures) from the **working stock** should be made.

Shelf life

For most strains, Selectrol® discs are guaranteed to contain at least 10⁶ organisms at the time of purchase; this number is sufficient to ensure that when the discs are used and stored as directed there will be viable organisms cultivable up to the stated end of the shelf life, which is usually 9 months from the time the vial is first opened.

Quality Control

Selectrol® batches are tested in our UKAS accredited testing laboratory number 2496. A test report for each batch of Selectrol® can be accessed via our website. The reporting of Selectrol® test results via the website comes under our UKAS accreditation.

Selectrol® cultures are rigorously tested to confirm identity, to confirm the possession of essential phenotypic characteristics and to exclude contamination with other organisms. Photographic evidence of the test results is retained for each batch, along with retained appropriately stored samples.



Glossary

AMRHAI: Antimicrobial Resistance and Healthcare Associated Infections reference unit

ATCC®: American Type Culture Collection. ATCC® strains are listed for reference only. ATCC® is a registered trademark of the American Type Culture Collection.

BSAC: British Society for Antimicrobial Chemotherapy - Now superseded by EUCAST

CLSI: Clinical Laboratory Standards Institute. (USA)

CPE: Carbapenemase Producing Enterobacteriaceae

CRE: Carbapenem Resistant Enterobacteriaceae

Culture collection: Cultures of fully characterised organisms maintained in such a way as to minimise sub-culturing. See page 14.

ESBL: Extended Spectrum Beta-Lactamase-producing organism.

EUCAST: European Committee on Antimicrobial Susceptibility Testing.

First generation derivative: A single passage from a master culture, for example a Selectrol® disc.

Master culture: Culture derived from a reference culture vial.

NCPF®: National Collection of Pathogenic Fungi. NCPF® is a registered trademark of Public Health England.

NCTC®: National Collection of Type Cultures. NCTC® is a registered trademark of Public Health England.

Passage: An equivalent term for a subculture.

PHE: Public Health England.

Reference cultures: Quality control strains selected on the basis of their phenotypic biochemical and antimicrobial susceptibility characteristics to be used as controls in microbiological testing. These are obtained as freeze-dried vials from culture collections.

Stock culture: Cultures derived from a Selectrol® disc, which can be stored for up to a week, usually on agar slants.

Working cultures: Stock cultures further sub-cultured to provide 18-24 hour growth for use in testing.

WDCM: World Data Centre for Microorganisms

WFCC: World Federation for Culture Collections

SIGNIFICANT PROPERTIES AND USES OF SELECTROL® ORGANISMS

Aspergillus brasiliensis (formerly *Aspergillus niger*):

MM94 – NCPF® 2275 / ATCC® 16404 / WDCM 00053 – used in pharmaceutical industry for testing media and preservatives. Colonies are initially white or yellowish and on the reverse greyish or greenish-yellow. Sporing heads on the colony surface are initially pale, becoming dark brown to black. Sporulation may be inhibited in sealed plates.

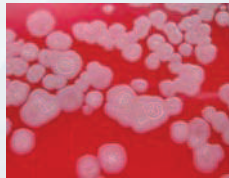
Bacillus cereus:

MM21 – NCTC® 10320 / ATCC® 9634 / WDCM 00001 (recently renamed *Bacillus toyonensis*) – ISO 11133 recommended media and ID test control organism.

MM86 – NCTC® 7464 / ATCC® 10876 – **PHE** recommended media and ID test control organism.

Bacillus subtilis (*Bacillus subtilis* subsp. *spizizenii*):

MM29 – NCTC® 10400 / ATCC® 6633 / WDCM 00003 – used in antibiotic assays (fully sensitive), **PHE** recommended media and ID test control organism.



Bacteroides fragilis:

MM44 – NCTC® 9343 / ATCC® 25285 – type strain, **PHE** recommended strain for media and sensitivity test control.

Campylobacter jejuni (*Campylobacter jejuni* subsp. *jejuni*):

MM82 – NCTC® 11322 / ATCC® 29428 / WDCM 00156 – **PHE** recommended strain for media control.

MM36 – NCTC® 11351 / ATCC® 33560 – **EUCAST** recommended strain for susceptibility testing.

Candida albicans:

MM28 – NCPF® 3255 / ATCC® 2091 / WDCM 00055 – sensitivity control / industrial use.

MM42 – NCPF® 3179 / ATCC® 10231 / WDCM 00054 – pharmaceutical / media testing / **PHE** recommended strain for media control.

CRE ≡ ‘Carbapenem Resistant Enterobacteriaceae’ / CPE ≡ ‘Carbapenemase Producing Enterobacteriaceae’

There are 5 carbapenemases which are currently a significant problem in the UK – KPC, OXA-48, IMP, NDM and VIM – and PHE recommend that all clinically-significant Gram-negative bacteria should be routinely screened for carbapenemase production, using a recommended carbapenem² such as ertapenem or meropenem. Resistant isolates may be investigated further to determine which resistance mechanism is involved using the Modified Hodge Test, MALDI-TOF, PCR or a reference laboratory.

MM55 *Klebsiella pneumoniae* – NCTC® 13440 – produces a Class B VIM-1 Carbapenemase.

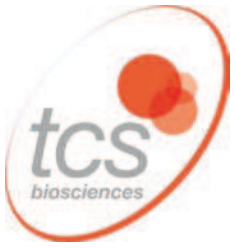
MM56 *Klebsiella pneumoniae* – NCTC® 13443 – produces a Class B NDM-1 Carbapenemase.

MM58 *Klebsiella pneumoniae* – NCTC® 13438 – produces a Class A KPC-3 Carbapenemase.

MM59 *Klebsiella pneumoniae* – NCTC® 13442 – produces a Class D OXA-48 Carbapenemase.

MM57 *Escherichia coli* – NCTC® 13476 – produces a Class B IMP Carbapenemase.

MM33 *Escherichia coli* – NCTC® 10418 / ATCC® 10536 – recommended by **PHE** as a negative control for CRE testing.



Citrobacter freundii:

MM27 – NCTC® 9750 / ATCC® 8090 – type strain.

Clostridium perfringens:

MM45 – NCTC® 8237 / ATCC® 13124 / WDCM 00007 – type strain. **PHE** recommended strain for food testing (Tryptose Sulphite Cycloserine agar – lactose and gelatin positive) and sensitivity test control. *Clostridium perfringens* is listed in Schedule 5 of the Anti-terrorism, Crime and Security Act 2001, and should be securely stored in accordance with the guidelines of the Act. However, MM45 is a type A strain, which does not produce the lethal epsilon toxin of potential interest to bioterrorists.

Clostridium sporogenes:

MM31 – NCTC® 532 / ATCC® 19404 / WDCM 00008 – used for media control. **PHE** recommended strain for media QC (lactose gelatin medium for ID of *C. perfringens* lactose negative and gelatin positive).

Enterobacter aerogenes:

MM26 – NCTC® 10006 / ATCC® 13048 / WDCM 00175 – type strain; used in water, paint and adhesive testing.

Enterobacter cloacae:

MM01 – NCTC® 13380 / ATCC® 23355 / WDCM 00082 – disinfectant control, media testing.

MM51 – NCTC® 13406 – **PHE** recommended strain for QC of AmpC (de-repressed) detection.

Enterococcus faecalis:

MM52 – NCTC® 13379 / ATCC® 51299 / WDCM 00085 – is vancomycin resistant (low-level VanB mediated) and also shows high-level resistance to aminoglycosides. It is used to confirm methodologies used to detect these resistances are working correctly. Lancefield group D.

MM17 – NCTC® 775 / ATCC® 19433 / WDCM 00009 – used in water industry and QC. **PHE** recommended strain for media control. Fully sensitive. Lancefield group D.

MM18 – NCTC® 12697 / ATCC® 29212 / WDCM 00087 – is fully sensitive to vancomycin and gentamicin. **PHE** recommended positive control strain for aesculin test. **CLSI, EUCAST** recommended media control for sulpha / trimethoprim testing and general susceptibility testing control. Lancefield group D.



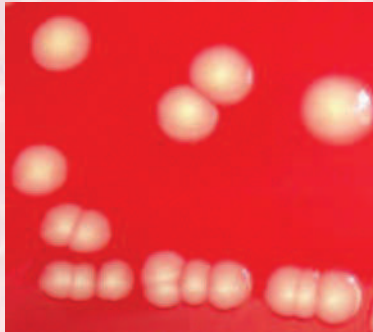


Enterococcus hirae:

MM35 – NCTC® 13383 / ATCC® 10541 / WDCM 00011 – disinfectant control. Used in microbiological assays. Colonies are alpha-haemolytic on sheep blood agar.

***Escherichia coli* strains:**

MM02 – NCTC® 12241 / ATCC® 25922 / WDCM 00013 – **EUCAST**, **CLSI**, **PHE** recommended control strain for susceptibility testing (fully sensitive). Exhibits 2 colony types – the most prevalent type is slightly irregular, smooth and translucent. The secondary type appears more opaque. It is preferable to maintain cultures on agar as passage in broth can result in a change in MIC levels.



MM57 – NCTC® 13476 – CRE testing control; produces a Class B IMP Carbapenemase.

MM33 – NCTC® 10418 / ATCC® 10536 – (**PHE** recommended alternative to NCTC 12241) fully sensitive control strain. **PHE** recommended positive control for indole test, ONPG test, negative control for oxidase test, **PHE** recommended negative control for CRE and ESBL testing.

MM24 – NCTC® 11954 / ATCC® 35218 – beta-lactamase positive strain. **CLSI** recommended strain for susceptibility testing ONLY for penicillin / beta-lactamase inhibitor combinations. Sensitive to amoxicillin / clavulanic acid.

MM75 – NCTC® 9001 / ATCC® 11775 / WDCM 00090 – used in water / chemical industry. **PHE** recommended strain for media QC.

MM93 – NCTC® 12900 / ATCC® 700728 / WDCM 00014 – O157 strain (non-toxigenic). **PHE** recommended strain for media QC.

MM63 – NCTC® 11560 – beta-lactamase positive strain.

MM38 – NCTC® 12923 / ATCC® 8739 / WDCM 00012 – used in pharmaceutical / water industry. Three colony types: A) Entire, glistening, smooth and translucent. B) Entire, glistening smooth and opaque. C) Irregular, rough and translucent. The rough colonies appear after 48 hours incubation.

MM34 – NCTC® 13846 – Possesses the plasmid-mediated *mcr-1* colistin resistance mechanism gene and is recommended by **PHE** and **EUCAST** as a control for tests to detect this increasingly prevalent resistance, in conjunction with NCTC® 12241 / ATCC® 25922 (Selectrol strain MM02) as a negative control.

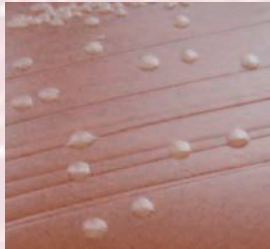
***Haemophilus influenzae* strains:**

MM81 - NCTC® 12699 / ATCC® 49247 – is a ‘BLNAR’ strain – (beta-lactamase non-producing ampicillin / amoxycillin resistant). These strains are important clinically because the susceptibility results obtained using conventional testing procedures maybe misleading in the case cephalosporins. **PHE**, **CLSI** recommended QC strain for susceptibility testing media.

MM98 – NCTC® 11931 – a fully sensitive strain. **PHE** recommended strain for porphyrin synthesis test, chocolate agar control.

MM100 – NCTC® 8468 / ATCC® 9334 / CCUG 23946 – another fully sensitive strain, which reportedly gives results which are easier to interpret when Mueller-Hinton medium is used in preference to Iso-Sensitest medium. MIC for amoxycillin is 0.5 mg/l.

MM37 – NCTC® 12975 / ATCC® 49766 – recommended by **EUCAST**.



***Klebsiella* strains:**

MM04 *Klebsiella pneumoniae* – NCTC® 9633 / ATCC® 13883 / WDCM 00097 – type strain. Two colony types may be seen. The predominant type is entire and opaque. The secondary type is slightly smaller and translucent.

MM83 *Klebsiella pneumoniae* – NCTC® 13368 / ATCC® 700603 – ESBL-producing strain used as control for ESBL testing. There are two colony types.

MM55 *Klebsiella pneumoniae* – NCTC® 13440 – CRE testing control; produces a Class B VIM-1 Carbapenemase.



MM56 *Klebsiella pneumoniae* – NCTC® 13443 – CRE testing control; produces a Class B NDM-1 Carbapenemase.

MM58 *Klebsiella pneumoniae* – NCTC® 13438 – CRE testing control; produces a Class A KPC-3 Carbapenemase.

MM59 *Klebsiella pneumoniae* – NCTC® 13442 – CRE testing control; produces a Class D OXA-48 Carbapenemase.

MM88 *Klebsiella aerogenes* (*Raoultella planticola*) – NCTC® 9528 – used in water / pharmaceutical industry. **PHE** recommended negative control for Tryptone Bile X-Glucuronide agar and Yeast Extract agar.



Lactobacillus brevis:

MM76 – NCTC® 13386 / ATCC® 8287 – used in food industry.

Legionella pneumophila serogroup 1:

MM08 – NCTC® 11192 / ATCC® 33152 / WDCM 00107 – derived from strain isolated from first recognised outbreak of legionellosis in Philadelphia at the Legionnaires' Convention 1976

Listeria innocua:

MM92 – NCTC® 11288 / ATCC® 33090 / WDCM 00017 – type strain. Non-pathogenic.

Listeria monocytogenes:

MM87 – NCTC® 11994 / WDCM 00019 – type strain, **PHE** recommended positive control strain for Listeria detection in food. Serotype 4b, most common serovar isolated from human infections.

MM48 – NCTC® 7973 / ATCC® 35152 / WDCM 00109 – produces 2 phenotypes, one is beta-haemolytic and virulent, the other non-haemolytic and non-virulent. Serovar 1/2a.

MM77 – NCTC® 13372 / ATCC® 7644 – used in food microbiology Q.C. Colonies exhibit beta-haemolysis on sheep blood agar.

Neisseria gonorrhoeae:

MM96 – NCTC® 12700 / ATCC® 49226 – has low-level, but clinically relevant, resistance to penicillin – MIC of penicillin is 0.5 mg/l. **PHE** recommended control for susceptibility testing – methodology assesses the ability of testing to detect resistance rather than sensitivity; this strain has low-level, but clinically relevant, resistance to penicillin – MIC of penicillin is 0.5 mg/l. Some variation in size and texture of colonies may be observed. Increased CO₂ is helpful in growth.

MM05 – NCTC® 8375 / ATCC® 19424 – is fully sensitive – MIC of penicillin is 0.06 mg/l. **PHE** recommended strain for media QC.

Proteus mirabilis:

MM43 – NCTC® 13376 / ATCC® 14153 – pharmaceutical / disinfectant / media control.

MM68 – NCTC® 10975 – media control. **PHE** recommended control for motility test.

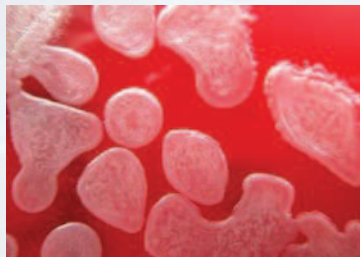


Proteus vulgaris:

MM09 – NCTC® 4175 / ATCC® 13315 – was the type strain, but is atypical and has been recognised as a separate species – *Proteus hauseri* – it is used for media control. Colonies are glistening with spreading edges.

***Pseudomonas aeruginosa* strains:**

MM10 – NCTC® 12903 / ATCC® 27853 / WDCM 00025 – is fully sensitive to anti-pseudomonal antibiotics (EUCAST susceptibility test control). 2 colony types may be observed: A) predominantly flat, spreading edges and rough surface; B) small and compact. Produces both fluorescein and pyocyanin pigments.



MM65 – NCTC® 10662 / ATCC® 25668 / WDCM 00114 – is fully sensitive. PHE recommended control strain for media control

MM40 – NCTC® 12924 / ATCC® 9027 / WDCM 00026 – used in water industry / disinfectant testing. Colonies on agar plates are entire, glistening and mucoid with a grainy surface. This strain also produces both fluorescein and pyocyanin pigments.

MM41 – NCTC® 13359 / ATCC® 15442 – used in water industry / disinfectant testing. May produce up to 3 different colony types. Pyocyanin is not produced.

Rhodococcus equi:

MM97 – NCTC® 1621 / ATCC® 6939 / WDCM 00028 – type strain.

Saccharomyces cerevisiae:

MM73 – NCPF® 3178 – PHE recommended strain for food testing and enumeration of yeasts and moulds.

MM50 — NCTC® 10716 / WDCM 00058 – used for QC of culture media and for antifungal susceptibility testing.

***Salmonella* serotypes:**

MM11 *Salmonella* Typhimurium – NCTC® 12023 / ATCC® 14028 / WDCM 00031 – (1,4,5,12: i: 1,2) Used for media/test QC. This is a common serotype from animals and from human infections.

The strains listed below are unusual serotypes, used to avoid any chance of confusion with strains commonly found in animals, food, etc, and are used to control media and detection methods in the food industry:

MM89 *Salmonella* Poona – NCTC® 4840 – (13,22: z: 1,6) PHE recommended control strain for food testing.

MM84 *Salmonella* Nottingham – NCTC® 7832 – (16: d: e,n,z15) PHE recommended control for water testing.

Serratia marcescens:

MM12 – NCTC® 13382 / ATCC® 8100 – used for disinfectant testing. PHE recommended negative control for indole test. Colonies are entire, glistening, smooth and translucent. Non-pigmented.

Staphylococcus aureus:

(A) Fully sensitive:

MM85 – NCTC[®] 6571 / ATCC[®] 9144 / WDCM 00035 – historically used for susceptibility testing ('Oxford staph'), but largely superseded by MM13 as it has unusually low MIC's and so is unrepresentative of normal range of Staph aureus strains. Sensitive to penicillin and ceftazidime / methicillin / oxacillin. **PHE** recommended coagulase, DNase and catalase positive control.

MM13 – NCTC[®] 12981 / ATCC[®] 25923 / WDCM 00034 – used in susceptibility and media testing/QC. Fully sensitive to all anti-staphylococcal antibiotics (including penicillin and methicillin / oxacillin). It is preferable to maintain cultures on agar as passage in broth can result in a change in MIC levels. Colonies are circular white to cream, convex to flat in elevation. After 48 hours incubation a few grey/translucent variants may be noted. Beta-haemolytic on sheep blood agar.

B) Penicillin resistant:

MM14 – NCTC[®] 12973 / ATCC[®] 29213 / WDCM 00131 – used for susceptibility testing, especially for automated methodology. **EUCAST**, **CLSI** strain. Sensitive to ceftazidime / methicillin / oxacillin. Penicillin resistant – weak beta-lactamase producer. Colonies are beta-haemolytic, and a golden-orange colour.

MM30 – NCTC[®] 7447 / ATCC[®] 6538P / WDCM 00033 – used for susceptibility testing/antibiotic assay, disinfectant testing. Ceftazidime / methicillin / oxacillin sensitive. Penicillin resistant. Colonies are weakly beta-haemolytic, coagulase positive and beta-lactamase negative.

(C) MRSA (ceftazidime / methicillin / oxacillin resistant):

MM91 – NCTC[®] 13373 / ATCC[®] 43300 / WDCM 00211 (MRSA) – Possesses mecA gene but is hetero-resistant, (so as few as one per thousand cells demonstrate the resistance) and consequently has low-level ceftazidime / oxacillin/methicillin resistance (4.0 mg/l MIC of oxacillin, 8.0 mg/l MIC of ceftazidime – methicillin sensitive strains have MIC of 0.12-0.5 for oxacillin and 1-4 for ceftazidime.); it is used to confirm testing procedures for methicillin resistance are working and provides a more stringent test than testing with an MRSA which shows homogeneous resistance and has a much higher MIC. This organism will have a zone of inhibition reduced in size compared to a fully ceftazidime / oxacillin / methicillin sensitive strain (such as MM13). **CLSI** recommended strain for MRSA testing. There are two colony types: 1) Beta-haemolytic with a slight yellow tint. 2) Non-haemolytic and white.

MM64 – NCTC[®] 12493 / WDCM 00212 (MRSA) – possesses mecA gene and shows homogeneous resistance with MIC of >64 for methicillin, which produces high-level ceftazidime / methicillin / oxacillin resistance. **EUCAST** recommended strain. Instances have been reported where loss of the mecA gene has occurred during storage.

D) Other:

MM46 – NCTC[®] 10788 / ATCC[®] 6538 / WDCM 00032 – used in pharmaceutical industry for testing disinfectants etc. Usually yellow pigmented colonies, or can produce a white colonial variant. Beta-haemolytic.





Staphylococcus epidermidis:

MM15 – NCTC® 13360 / ATCC® 12228 / WDCM 00036 – used for media control / antibiotic assay. Colonies are small and beta-haemolytic.

Streptococcus agalactiae: (Beta-haemolytic Streptococcus group B)

MM16 – NCTC® 8181 / ATCC® 13813 – type strain, used for QC. PHE recommended negative control for aesculin test.

Streptococcus pneumoniae strains:

MM95 – NCTC® 12977 / ATCC® 49619 – has low-level, but clinically relevant, resistance to penicillin – this organism is used to assess detection of resistance rather than sensitivity. PHE recommended positive control for bile solubility test. CLSI, EUCAST recommended control strain for susceptibility testing. Serotype 19F.

MM19 – NCTC® 12695 / ATCC® 6303 – is fully sensitive. Colonies are mucoid and alpha-haemolytic. A few colonies may have an irregular edge. Serotype 3.



Streptococcus pyogenes:

MM20 – NCTC® 12696 / ATCC® 19615 – used for QC and media testing. Lancefield group A, beta-haemolytic. PHE recommended blood agar control.

Vibrio parahaemolyticus:

MM06 – NCTC® 10885 / WDCM 00185 – used for QC of media and ID testing. PHE recommended strain used mainly in the food industry.

Yersinia enterocolitica:

MM80 – NCTC® 12982 / ATCC® 9610 / WDCM 00038 – type strain, used for media control. Serotype O:8, which is a pathogenic serotype, commonest in USA.

References:

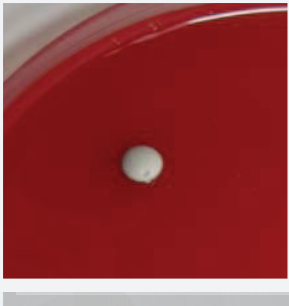
- 1 European Committee on Antimicrobial Susceptibility Testing (EUCAST). Routine and Extended Internal Quality Control for MIC Determination and Disc Diffusion. Version 7.0 - 01.01.2017.
- 2 UK Standards for Microbiology Investigations. Example Reference Strains for Microbiology Investigations Test Procedures: Bacteriology—Test Procedures | TP 1 | Issue No. 2 | 05.01.2015. Public Health England (PHE).
- 3 Performance Standards for Antimicrobial Disc Susceptibility Tests: Approved Standard—11th Edition. Clinical and Laboratory Standards Institute (CLSI).

How to use Selectrol®

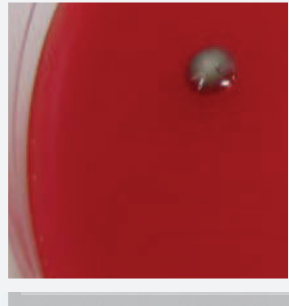
Always warm the vial to ambient temperature before opening.

Be sure to use non-selective culture media to revive the organisms.

For the more fastidious organisms, such as anaerobes, it is generally better to use agar rather than broth for revival.



Place disc on suitable growth medium such as blood agar



Leave disc for a few minutes to liquefy, then spread plate and incubate to produce isolated colonies



Obtain a stock culture which can be used to prepare an inoculum for biochemical and antibiotic susceptibility tests



Place disc in a small volume of a suitable broth medium such as brain-heart infusion



Allow disc a few minutes to dissolve, then spread aliquot onto a plate of suitable growth medium



Out-of-specification results

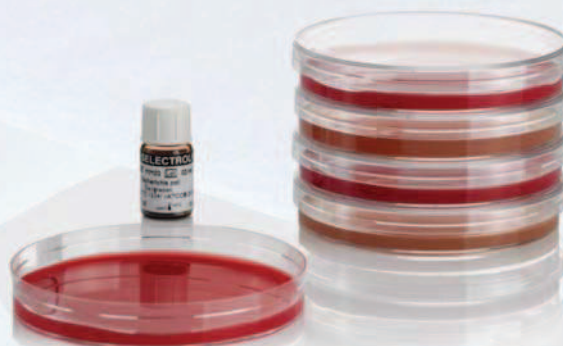
Laboratories use Selectrol® for Quality Control of culture media, biochemical identification tests and antimicrobial susceptibility testing. When a laboratory test result, an MIC or biochemical reaction, is unexpected or out-of-specification, the test should first be repeated to confirm it; an out-of-specification result is an indication that the testing procedure should be reviewed; it is not, in the first instance, a sign of a problem with the control organism.

If incorrect results are obtained on retesting, the explanation could be:

- The test procedure was not followed correctly – check standard operating procedures
- There is an instrumentation error – check calibration, mechanical functioning, etc
- There is a problem with the consumables – out of date, incorrect storage, etc
- The culture of the control organism has become contaminated

Technical Support

If no explanation for out-of-spec results can be found, but repeated tests still give unacceptable results, please contact TCS and / or your relevant reference laboratory or instrument manufacturer for advice. For example, contact AMRHAI at Colindale, London if MIC results are consistently outside the acceptable range. Please retain any remaining discs of organisms about which you have concerns so they can be returned to TCS and investigated alongside retained samples.



Preparing QC and Validation Spikes from Selectrol®

Preparing the spike

- Place a Selectrol® disc in Brain Heart Infusion (BHI) broth* or equivalent, and culture (typically for 18 hours) at the appropriate temperature for the organism (typically 37°C)
- Assume the count in the broth to be 10^8 organisms per ml ----- (A)
- Mix and transfer 100 μ l of (A) to 100 ml of saline or $\frac{1}{4}$ strength Ringer's solution -- (B)
- Mix and transfer 100 μ l of (B) to 10 ml of saline or $\frac{1}{4}$ strength Ringer's solution --- (C)
- Mix and transfer 100 μ l of (C) to your homogenised food sample.

Verifying the inoculum

- Pipette 5 x 10 μ l drops from (C) onto each of two agar plates for Miles and Misra counts.

Using the assumptions and dilutions above:

- (A) contains 10^8 organisms per ml
- (B) contains 10^5 organisms per ml
- (C) contains 10^3 organisms per ml

If the Miles and Misra counts indicate that the required count was not achieved:

- If the count was too high by a factor of 10, reduce the volume transferred from (A) to (B) from 100 μ l to 10 μ l
- If the count was too low by a factor of 10, increase the volume transferred from (A) to (B) from 100 μ l to 1 ml.

Keep a record of the correct dilutions for each organism type for future use. You will find that this method is very repeatable.

*Note: BHI broth will work for most of the Selectrol® organisms; however, for fastidious organisms an appropriate culture broth must be selected, e.g. Fastidious Anaerobe Broth for strictly anaerobic organisms.





Culture Collections

Cultures of microorganisms have been deposited and subsequently maintained in 589 collections in 68 countries, and many of the cultures are derived from the same original isolate; the history of each organism, its properties and names of the culture collections which hold it are detailed in the relevant catalogues and websites.

Some of the organisms have been selected and recommended by expert organisations to be supplied as controls for microbiological tests, and when the identical cultures are present in more than one collection they will have a specific designation for each, incorporating the abbreviation for the collection and a reference number.

For example:- *Staphylococcus aureus* NCTC 7447, widely recommended as a control for antimicrobial susceptibility testing, is held in 30 collections, and consequently the phenotypically and genotypically identical organism has 30 different references, such as ATCC 6538P, CIP 53.156, DSM 346 and so on.

In an effort to minimise potential confusion and help users find local sources of reference strains, the WFCC and the WDCM initiated a system that ascribes each recommended QC strain a reference number (WDCM 00001 onwards), cites all collections that contain it and provides contact details and each collection's unique reference. For example, the strain of *Staphylococcus aureus* NCTC 7447 (Selectrol® strain MM33) mentioned above is designated WDCM 00033.

***Staphylococcus aureus* WDCM 00033**

AHU 1142; **ATCC™ 6538P**; BCRC 10451 ; BTCC 209P; BU 395; CCM 2022; CCTM 596; CCUG 1828; CECT 240; CIP 53.156; CN 3784; CNCTC Mau 28/58; DSM 346; FIRDI 451; IAM 1011; IAM 12082; IEM Mau 28/58; IFO 12732; IFO 3061; IID 671; IMET 10904; JCM 2151; LMG 8195; NCIMB 8625; **NCTC 7447**; NRRL B-313; OUT 8232; PCI 1209; PZH 8/54; RIMD 3109007; VNIIA 209P;

Products derived from the cultures in the collections should be manufactured using the minimum number of sub-cultures, to minimise the possibility of alterations to the phenotype due to mutations. Ideally, as in the case of **Selectrol®**, a single sub-culture only is used, so the **Selectrol®** product is a 'first generation derivative' of a culture supplied by NCTC, and will be identical with regard to its properties and suitability for use in QC applications to a culture of the particular organism obtained from any of the other WDCM listed culture collections.

Every effort has been made to ensure the accuracy of the information in this document, however TCS makes no warranties, expressed or implied, regarding errors or omissions and assumes no legal liability or responsibility for loss or damage resulting from the use of information contained within.

Selectrol Strain Index

Strain Name	Designation	Code	WDCM
<i>Aspergillus brasiliensis</i>	NCPF [®] 2275 / ATCC [®] 16404	MM94	00053
<i>Bacillus cereus</i>	NCTC [®] 10320 / ATCC [®] 9634	MM21	00001
<i>Bacillus cereus</i>	NCTC [®] 7464 / ATCC [®] 10876	MM86	
<i>Bacillus subtilis</i>	NCTC [®] 10400 / ATCC [®] 6633	MM29	00003
<i>Bacteroides fragilis</i>	NCTC [®] 9343 / ATCC [®] 25285	MM44	
<i>Campylobacter jejuni</i>	NCTC [®] 11351 / ATCC [®] 33560	MM36	
<i>Campylobacter jejuni</i>	NCTC [®] 11322 / ATCC [®] 29428	MM82	00156
<i>Candida albicans</i>	NCPF [®] 3255 / ATCC [®] 2091	MM28	00055
<i>Candida albicans</i>	NCPF [®] 3179 / ATCC [®] 10231	MM42	00054
<i>Citrobacter freundii</i>	NCTC [®] 9750 / ATCC [®] 8090	MM27	
<i>Clostridium perfringens</i>	NCTC [®] 8237 / ATCC [®] 13124	MM45	00007
<i>Clostridium sporogenes</i>	NCTC [®] 532 / ATCC [®] 19404	MM31	00008
<i>Enterobacter aerogenes</i>	NCTC [®] 10006 / ATCC [®] 13048	MM26	00175
<i>Enterobacter cloacae</i>	NCTC [®] 13380 / ATCC [®] 23355	MM01	00082
<i>Enterobacter cloacae</i>	NCTC [®] 13406	MM51	
<i>Enterococcus faecalis</i>	NCTC [®] 775 / ATCC [®] 19433	MM17	00009
<i>Enterococcus faecalis</i>	NCTC [®] 12697 / ATCC [®] 29212	MM18	00087
<i>Enterococcus faecalis</i>	NCTC [®] 13379 / ATCC [®] 51299	MM52	00085
<i>Enterococcus hirae</i>	NCTC [®] 13383 / ATCC [®] 10541	MM35	00011
<i>Escherichia coli</i>	NCTC [®] 12241 / ATCC [®] 25922	MM02	00013
<i>Escherichia coli</i>	NCTC [®] 11954 / ATCC [®] 35218	MM24	
<i>Escherichia coli</i>	NCTC [®] 10418 / ATCC [®] 10536	MM33	
<i>Escherichia coli</i>	NCTC [®] 12923 / ATCC [®] 8739	MM38	00012
<i>Escherichia coli</i>	NCTC [®] 11560	MM63	
<i>Escherichia coli</i>	NCTC [®] 9001 / ATCC [®] 11775	MM75	00090
<i>Escherichia coli</i> CRE	NCTC [®] 13476	MM57	
<i>Escherichia coli</i> (mcr-1)	NCTC [®] 13846	MM34	
<i>Escherichia coli</i> O157 (non-toxigenic)	NCTC [®] 12900 / ATCC [®] 700728	MM93	00014
<i>Haemophilus influenzae</i>	NCTC [®] 8468 / ATCC [®] 9334	MM100	
<i>Haemophilus influenzae</i>	NCTC [®] 12975 / ATCC [®] 49766	MM37	
<i>Haemophilus influenzae</i>	NCTC [®] 12699 / ATCC [®] 49247	MM81	
<i>Haemophilus influenzae</i>	NCTC [®] 11931	MM98	
<i>Klebsiella aerogenes</i>	NCTC [®] 9528	MM88	
<i>Klebsiella pneumoniae</i>	NCTC [®] 9633 / ATCC [®] 13883	MM04	00097
<i>Klebsiella pneumoniae</i>	NCTC [®] 13368 / ATCC [®] 700603	MM83	
<i>Klebsiella pneumoniae</i> CRE	NCTC [®] 13440	MM55	
<i>Klebsiella pneumoniae</i> CRE	NCTC [®] 13443	MM56	
<i>Klebsiella pneumoniae</i> CRE	NCTC [®] 13438	MM58	

Selectrol Strain Index

Strain Name	Designation	Code	WDCM
<i>Klebsiella pneumoniae</i> CRE	NCTC [®] 13442	MM59	
<i>Lactobacillus brevis</i>	NCTC [®] 13386 / ATCC [®] 8287	MM76	
<i>Legionella pneumophila</i> serogroup 1	NCTC [®] 11192 / ATCC [®] 33152	MM08	00107
<i>Listeria innocua</i>	NCTC [®] 11288 / ATCC [®] 33090	MM92	00017
<i>Listeria monocytogenes</i>	NCTC [®] 7973 / ATCC [®] 35152	MM48	00109
<i>Listeria monocytogenes</i>	NCTC [®] 13372 ATCC [®] 7644	MM77	
<i>Listeria monocytogenes</i>	NCTC [®] 11994	MM87	00019
<i>Neisseria gonorrhoeae</i>	NCTC [®] 8375 / ATCC [®] 19424	MM05	
<i>Neisseria gonorrhoeae</i>	NCTC [®] 12700 / ATCC [®] 49226	MM96	
<i>Proteus mirabilis</i>	NCTC [®] 13376 / ATCC [®] 14153	MM43	
<i>Proteus mirabilis</i>	NCTC [®] 10975	MM68	
<i>Proteus vulgaris</i>	NCTC [®] 4175 / ATCC [®] 13315	MM09	
<i>Pseudomonas aeruginosa</i>	NCTC [®] 12903 / ATCC [®] 27853	MM10	00025
<i>Pseudomonas aeruginosa</i>	NCTC [®] 12924 / ATCC [®] 9027	MM40	00026
<i>Pseudomonas aeruginosa</i>	NCTC [®] 13359 / ATCC [®] 15442	MM41	
<i>Pseudomonas aeruginosa</i>	NCTC [®] 10662 / ATCC [®] 25668	MM65	00114
<i>Rhodococcus equi</i>	NCTC [®] 1621 / ATCC [®] 6939	MM97	00028
<i>Saccharomyces cerevisiae</i>	NCTC [®] 10716/ ATCC [®] 9763	MM50	00058
<i>Saccharomyces cerevisiae</i>	NCPF [®] 3178	MM73	
<i>Salmonella</i> Nottingham	NCTC [®] 7832	MM84	
<i>Salmonella</i> Poona	NCTC [®] 4840	MM89	
<i>Salmonella</i> Typhimurium	NCTC [®] 12023/ ATCC [®] 14028	MM11	00031
<i>Serratia marcescens</i>	NCTC [®] 13382 / ATCC [®] 8100	MM12	
<i>Staphylococcus aureus</i>	NCTC [®] 12981 / ATCC [®] 25923	MM13	00034
<i>Staphylococcus aureus</i>	NCTC [®] 12973 / ATCC [®] 29213	MM14	00131
<i>Staphylococcus aureus</i>	NCTC [®] 7447 / ATCC [®] 6538P	MM30	00033
<i>Staphylococcus aureus</i>	NCTC [®] 10788 / ATCC [®] 6538	MM46	00032
<i>Staphylococcus aureus</i>	NCTC [®] 6571 / ATCC [®] 9144	MM85	00035
<i>Staphylococcus aureus</i> (MRSA)	NCTC [®] 12493	MM64	00212
<i>Staphylococcus aureus</i> (MRSA)	NCTC [®] 13373 / ATCC [®] 43300	MM91	00211
<i>Staphylococcus epidermidis</i>	NCTC [®] 13360 / ATCC [®] 12228	MM15	00036
<i>Streptococcus agalactiae</i>	NCTC [®] 8181 / ATCC [®] 13813	MM16	
<i>Streptococcus pneumoniae</i>	NCTC [®] 12695 / ATCC [®] 6303	MM19	
<i>Streptococcus pneumoniae</i>	NCTC [®] 12977 / ATCC [®] 49619	MM95	
<i>Streptococcus pyogenes</i>	NCTC [®] 12696 / ATCC [®] 19615	MM20	
<i>Vibrio parahaemolyticus</i>	NCTC [®] 10885	MM06	00185
<i>Yersinia enterocolitica</i>	NCTC [®] 12982 / ATCC [®] 9610	MM80	00038

Selectrol Strains Listed by WDCM Number

WDCM	Strain Name	Designation	Code
00001	<i>Bacillus cereus</i>	NCTC [®] 10320 / ATCC [®] 9634	MM21
00003	<i>Bacillus subtilis</i>	NCTC [®] 10400 / ATCC [®] 6633	MM29
00007	<i>Clostridium perfringens</i>	NCTC [®] 8237 / ATCC [®] 13124	MM45
00008	<i>Clostridium sporogenes</i>	NCTC [®] 532 / ATCC [®] 19404	MM31
00009	<i>Enterococcus faecalis</i>	NCTC [®] 775 / ATCC [®] 19433	MM17
00011	<i>Enterococcus hirae</i>	NCTC [®] 13383 / ATCC [®] 10541	MM35
00012	<i>Escherichia coli</i>	NCTC [®] 12923 / ATCC [®] 8739	MM38
00013	<i>Escherichia coli</i>	NCTC [®] 12241 / ATCC [®] 25922	MM02
00014	<i>Escherichia coli</i> O157 (non-toxigenic)	NCTC [®] 12900 / ATCC [®] 700728	MM93
00017	<i>Listeria innocua</i>	NCTC [®] 11288 / ATCC [®] 33090	MM92
00019	<i>Listeria monocytogenes</i>	NCTC [®] 11994	MM87
00025	<i>Pseudomonas aeruginosa</i>	NCTC [®] 12903 / ATCC [®] 27853	MM10
00026	<i>Pseudomonas aeruginosa</i>	NCTC [®] 12924 / ATCC [®] 9027	MM40
00028	<i>Rhodococcus equi</i>	NCTC [®] 1621 / ATCC [®] 6939	MM97
00031	<i>Salmonella</i> Typhimurium	NCTC [®] 12023 / ATCC [®] 14028	MM11
00032	<i>Staphylococcus aureus</i>	NCTC [®] 10788 / ATCC [®] 6538	MM46
00033	<i>Staphylococcus aureus</i>	NCTC [®] 7447 / ATCC [®] 6538P	MM30
00034	<i>Staphylococcus aureus</i>	NCTC [®] 12981 / ATCC [®] 25923	MM13
00035	<i>Staphylococcus aureus</i>	NCTC [®] 6571 / ATCC [®] 9144	MM85
00036	<i>Staphylococcus epidermidis</i>	NCTC [®] 13360 / ATCC [®] 12228	MM15
00038	<i>Yersinia enterocolitica</i>	NCTC [®] 12982 / ATCC [®] 9610	MM80
00053	<i>Aspergillus brasiliensis</i>	NCPF [®] 2275 / ATCC [®] 16404	MM94
00054	<i>Candida albicans</i>	NCPF [®] 3179 / ATCC [®] 10231	MM42
00055	<i>Candida albicans</i>	NCPF [®] 3255 / ATCC [®] 2091	MM28
00058	<i>Saccharomyces cerevisiae</i>	NCTC [®] 10716 / ATCC [®] 9763	MM50
00082	<i>Enterobacter cloacae</i>	NCTC [®] 13380 / ATCC [®] 23355	MM01
00085	<i>Enterococcus faecalis</i>	NCTC [®] 13379 / ATCC [®] 51299	MM52
00087	<i>Enterococcus faecalis</i>	NCTC [®] 12697 / ATCC [®] 29212	MM18
00090	<i>Escherichia coli</i>	NCTC [®] 9001 / ATCC [®] 11775	MM75
00097	<i>Klebsiella pneumoniae</i>	NCTC [®] 9633 / ATCC [®] 13883	MM04
00107	<i>Legionella pneumophila</i> serogroup 1	NCTC [®] 11192 / ATCC [®] 33152	MM08
00109	<i>Listeria monocytogenes</i>	NCTC [®] 7973 / ATCC [®] 35152	MM48
00114	<i>Pseudomonas aeruginosa</i>	NCTC [®] 10662 / ATCC [®] 25668	MM65
00131	<i>Staphylococcus aureus</i>	NCTC [®] 12973 / ATCC [®] 29213	MM14
00156	<i>Campylobacter jejuni</i>	NCTC [®] 11322 / ATCC [®] 29428	MM82
00175	<i>Enterobacter aerogenes</i>	NCTC [®] 10006 / ATCC [®] 13048	MM26
00185	<i>Vibrio parahaemolyticus</i>	NCTC [®] 10885	MM06
00211	<i>Staphylococcus aureus</i> (MRSA)	NCTC [®] 13373 / ATCC [®] 43300	MM91
00212	<i>Staphylococcus aureus</i> (MRSA)	NCTC [®] 12493	MM64

Notes





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