

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

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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

Effective Date: 2022-01-27

Latest Revision Date: 2022-01-14

Expiry Date: 2025-01-26

Page: 1 of 1



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STATEMENT

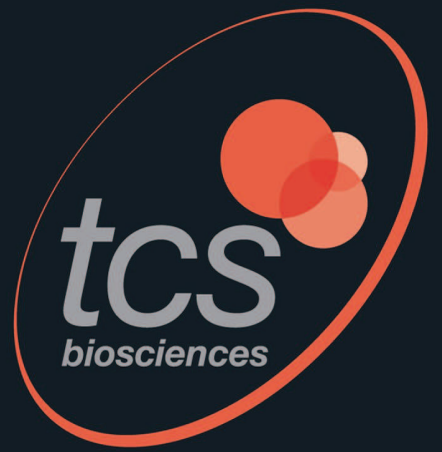
We, TCS Biosciences Ltd., having a registered office at Botolph Claydon, Buckingham, MK 18 2LR, England assign Sanmedico SRL having a registered office at str. A. Corobceanu 7A, apt. 9, Chişinău MD-2012, Moldova, as Authorized Representative in correspondence with the conditions of directive 98/79/EEC.

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*

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



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 |



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