STATEMENT

We, Zhejiang Orient Gene Biotech Co., Ltd , having a registered office at 3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as non-exclusive authorized representative for Orient Gene Brand product 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.

This Statement letter will be valid from Mar.22th,2024 to Mar.21th, 2025.

Zhejiang Orient Gene Biotech Co., Ltd

General Manager：

Date:2024/3/22

Digitally signed by Dolgopol Iulian
Date: 2025.01.15 14:35:50 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

地址：浙江省湖州市安吉县递铺镇阳光大道东段 3787 号
Add: **3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China**
电话 Tel:+86-572-5226111　　传真 Fax: +86-572-5226222　邮编 P.C.:313300

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 092305 0001 Rev. 02

Holder of Certificate: **Zhejiang Orient Gene Biotech Co., Ltd.**
3787#, East Yangguang Avenue, Dipu Street Anji
313300 Huzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagent and Instrument for the Detection of Drugs of Abuse, Fertility, Infectious Diseases, Oncology, Biochemistry, Cardiac Diseases, Allergic Disease based on Rapid Test, PCR and Liquid Biochip Method.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 092305 0001 Rev. 02

Report No.: SH2398804

Valid from: 2024-03-17
Valid until: 2027-03-16

Date, 2024-03-01

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 092305 0001 Rev. 02

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies):

Zhejiang Orient Gene Biotech Co., Ltd.
3787#, East Yangguang Avenue, Dipu Street Anji, 313300
Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

浙江东方基因生物制品股份有限公司
Zhejiang Orient Gene Biotech Co., LTD

CE-DOC-OG060
Version 1.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Zhejiang Orient Gene Biotech Co., Ltd*

Legal Manufacturer Address: *3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China*

Declares, that the products
Product Name and Model(s)

Fecal Occult Blood Rapid Test Strip (Feces)	GEFOB-601b
Fecal Occult Blood Rapid Test Cassette (Feces)	GEFOB-602b

Classification: *Other*
Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

EC Representative's Name: Shanghai International Holding Corp. GmbH (Europe)

EC Representative's Address: Eiffestrasse 80, 20537 Hamburg, Germany

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: November 28, 2017

Name of authorized signatory: Joyce Pang
Position held in the company: Vice-President

Fecal Occult Blood Rapid Test Cassette (Feces) CE

INTENDED USE

Fecal Occult Blood Rapid Test Cassette (Feces) is a rapid chromatographic immunoassay for the qualitative detection of human occult blood in feces by professional laboratories or physician's offices. It is useful to detect bleeding caused by a number of gastrointestinal disorders, e.g., diverticulitis, colitis, polyps, and colorectal cancer.
Fecal Occult Blood Rapid Test Cassette (Feces) is recommended for use in1) routine physical examinations, 2) hospital monitoring for bleeding in patients, and 3) screening for colorectal cancer or gastrointestinal bleeding from any source.

INTRODUCTION

Most of diseases can cause hidden blood in the stool. In the early stages, gastrointestinal problems such as colon cancer, ulcers, polyps, colitis, diverticulitis, and fissures may not show any visible symptoms, only occult blood. Traditional guaiac-based method lacks sensitivity and specificity, and has diet-restriction prior to the testing.
Fecal Occult Blood Rapid Test Cassette (Feces) is a rapid test to qualitatively detect low levels of fecal occult blood in feces. The test uses double antibod- sandwich assay to selectively detect as low as 50 ng/mL of hemoglobin or 6 µg hemoglobin/g feces. In addition, unlike the guaiac assays, the accuracy of the test is not affected by the diet of the patients.

PRINCIPLE

Fecal Occult Blood Rapid Test Cassette (Feces) is a lateral flow chromatographic immunoassay based on the principle of the double antibody-sandwich technique. The membrane is pre-coated with anti-hemoglobin antibodies on the test line region of the device. During testing, the specimen reacts with the colloidal gold coated withl anti-hemoglobin antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-hemoglobin antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS PROVIDED

20 Test cassettes
20 Specimen collection tubes with buffer
1 Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection containers 2. Clock or timer

STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test is not stable out of the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. Do not use specimen with visible blood for the testing.
6. Handel all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens.
7. Specimen extraction buffer contains Sodium Azide (0.1%). Avoid contact with skin or eyes. Do not ingest.
8. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assay.
9. Humidity and temperature can adversely affect results.
10. Do not perform the test in a room with strong air flow, ie. electric fan or strong airconditioning.

PATIENT PREPARATION

1. A specimen should not be collected from a patient with following conditions that may interfere with the test results:

- Menstrual bleeding
- Bleeding hemorrhoids
- Constipating bleeding
- Urinary bleeding.

2. Dietary restrictions are not necessary.
3. Alcohol and certain medications such as aspirin, indomethacin, phenylbutazone, reserpine, cortocosteroids, and nonsteroidal anti-inflammatory drugs may cause gastrointestinal irritation and subsequent bleeding, thus gives positive reactions. On the advice of the physician, such substances should be discontinued at least 48 hours prior to testing.

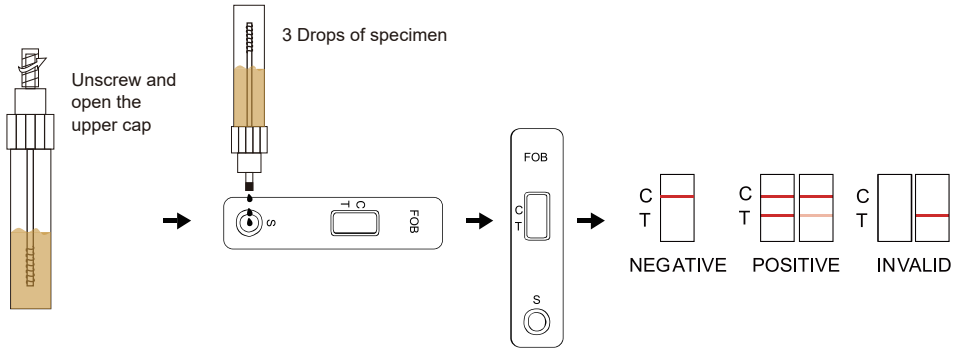
SPECIMEN COLLECTION AND PREPARATION

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.
1. Collect a random sample of feces in a clean, dry receptacle.
2. Unscrew the top of the collection tube and remove the applicator stick.
3. Randomly pierce the fecal specimen in at least five (5) different sites.
4. Remove excess sample off the shaft and outer grooves. Be sure sample remains on inside grooves.
5. Replace the stick in the tube and tighten securely.
6. Shake the specimen collection bottle so that there is proper homogenisation of feces in buffer solution.

Note: Specimens prepared in the specimen collection tube may be stored at room temperature (15-30°C) for 3 days maximum, at 2-8°C for 7 days maximum or at -20°C for 3 months maximum if not tested within 1 hour after preparation.

TEST PROCEDURE

Allow the test cassette, specimen, and/or controls to reach room temperature (15-30°C) prior to testing.
1. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test cassette on a clean, flat surface.
3. Shake the specimen collection tube several times.
4. Hold the specimen collection tube upright and then unscrew and open the upper cap.
5. Squeeze 3 drops (~90 µL) of the sample solution in the sample well of the cassette and start the timer.
6. Wait for the colored line(s) to appear. Read results in 5 minutes. Do not interpret the result after 5 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)
Positive: Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).
Negative: One colored line appears in the control line region(C). No line appears in the test line region (T).
Invalid: Control line fails to appear. The test should be repeated using a new cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.
NOTE:
1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and

Fecal Occult Blood Rapid Test Cassette (Feces)

cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correctl procedural technique. Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. This test kit is to be used for the qualitative detection of human hemoglobin in fecal samples. A positive result suggests the presence of human hemoglobin in fecal samples. In addition to intestinal bleeding the presence of blood in stools may have other causes such as hemorrhoids, blood in urine etc.
2. Not all colorectal bleedings are due to precancerous or cancerous polyps. The information obtained by this test should be used in conjunction with other clinical findings and testing methods, such as colonoscopy gathered by the physician.
3. Negative results do not exclude bleeding since some polyps and colorectal region cancers can bleed intermittently or not at all. Additionally, blood may not be uniformly distributed in fecal samples. Colorectal polyps at an early stage may not bleed.
4. Urine and excessive dilution of sample with water from toilet bowl may cause erroneous test results. The use of a receptacle is recommended.
5. Feces specimens should not collect during the menstrual period and not three day before or afterwards, at bleeding due to constipation, bleeding haemorrhoids,or at taking rectally administered medication. It could cause false positive results.
6. This test may be less sensitive for detecting upper g.i. Bleeding because blood degrades as it passes through the g.i. Track.
7. The Fecal Occult Blood Rapid Test Cassette (Feces) is to aid indiagnosis and is not intended to replace other diagnostic procedures such as G.I. fibroscope, endoscopy, colonoscopy, or X-ray analysis. Test results should not be deemed conclusive with respect to the presence or absence of gastrointestinal bleeding or pathology. A positive result should be followed up with additional diagnostic procedures to determine the exact cause and source for the occult blood in the feces.

PERFORMANCE CHARACTERISTICS

1. Sensitivity: 99.6%
Fecal Occult Blood Rapid Test Cassette (Feces) can detect the levels of human occult blood as low as 50 ng/mL hemoglobin or 6 µg hemoglobin/g feces.
2. Prozone Effect:
It is observed that this FOB test can detect 2 mg/mL hemoglobin.
3. Specificity: 99.9%
Fecal Occult Blood Rapid Test Cassette (Feces) is specific to human hemoglobin. Specimen containing the following substances at the standard concentration was tested on both positive and negative controls and showed no effects on test results at standards concentration.

Substances	Concentrations (Diluted with the extraction buffer)
Beef hemoglobin	2 mg/mL
Chicken hemoglobin	0.5 mg/mL
Pig hemoglobin	0.5 mg/mL
Goat hemoglobin	0.5 mg/mL
Horse hemoglobin	20 mg/mL
Rabbit hemoglobin	0.06 mg/mL

REFERENCES

1. Simon J.B. Occult Blood Screening for Colorectal Carcinoma: A Critical Review, Gastroenterology, Vol. 1985;88:820.
2. Blebea J. and Ncpherson RA. False-Positive Guaiac Testing With Iodine, Arch Pathol Lab Med, 1985;109:437-40.

INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2~30°C	LOT	Lot Number	REF	Catalog#

Zhejiang Orient Gene Biotech Co.,Ltd
Address: 3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China
Tel: +86-572-5226111 Fax: +86-572-5226222
Website: www.orientgene.com

EC REP Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffestrasse 80, 20537 Hamburg, Germany

REF GEFOB-602b

Revision Date: 2023-04-18
B21056-04

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tcs biosciences

Authorisation to Distribute

TCS Biosciences Limited, having registered offices in Botolph Claydon, Buckingham MK18 2LR, England, confirms that:

SanMedico SRL, 88/1 Petricani Str, Office 10, MS-2059, mun Chisinau, Republic of Moldova

Is authorised to promote and sell the TCS Biosciences range of products in the Republic of Moldova on a non-exclusive basis.

SanMedico SRL is also authorised to participate in tenders, to submit quotations and to deliver these products within the territory of Republic of Moldova.

This letter of authorisation is valid for 1 year from the date of issue but can be terminated by either party provided that a notice period of 3 months is given.

This authorisation may be extended by 1 year, by mutual agreement between TCS Biosciences Limited and San Medico SRL Limited

Signed: Lesley Ayres Date: 12th September 2024

Name: Lesley Ayres

Title: Key Account Manager

TCS Biosciences Ltd
Botolph Claydon Buckingham
MK18 2LR United Kingdom
t +44 (0) 1296 714222
f +44 (0) 1296 714806
e sales@tcsgroup.co.uk
i www.tcsbiosciences.co.uk

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

...making excellence a habit.™

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

...making excellence a habit.™

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

ANNEX TO SELF DECLARATION OF CONFORMITY – SELECTROL (Dated 30.04.2016)

List of product codes and descriptions – August 2018

Product	Description
MM01-10	Enterobacter cloacae 10 Disc
MM02-10	Escherichia coli 10 Disc
MM02-25	Escherichia coli 25 Disc
MM04-10	Klebsiella pneumoniae 10 Disc
MM04-25	Klebsiella pneumoniae 25 Disc
MM05-5	Neisseria gonorrhoeae 5 Disc
MM07-10	Shigella sonnei 10 Disc
MM08-10	Legionella pneumophila serogroup 1 10d
MM09-10	Proteus vulgaris 10 Disc
MM09-25	Proteus vulgaris 25 Disc
MM10-10	Pseudomonas aeruginosa 10 Disc
MM10-10	Pseudomonas aeruginosa 10 Disc
MM10-25	Pseudomonas aeruginosa 25 Disc
MM100-10	Haemophilus influenzae 10 Disc
MM11-10	Salmonella Typhimurium 10 Disc
MM11-25	Salmonella Typhimurium 25 Disc
MM12-10	Serratia marcescens 10 Disc
MM13-10	Staphylococcus aureus 10 Disc
MM13-10	Staphylococcus aureus 10 Disc
MM13-25	Staphylococcus aureus 25 Disc
MM14-10	Staphylococcus aureus 10 Disc
MM14-25	Staphylococcus aureus 25 Disc
MM15-10	Staphylococcus epidermidis 10 Disc
MM15-10	Staphylococcus epidermidis 10 Disc
MM15-25	Staphylococcus epidermidis 25 Disc
MM16-10	Streptococcus agalactiae 10 Disc
MM17-10	Enterococcus faecalis 10 Disc
MM17-25	Enterococcus faecalis 25 Disc
MM18-10	Enterococcus faecalis 10 Disc
MM18-10	Enterococcus faecalis 10 Disc
MM18-25	Enterococcus faecalis 25 Disc
MM19-10	Streptococcus pneumoniae 10 Disc
MM20-10	Streptococcus pyogenes 10 Disc
MM20-25	Streptococcus pyogenes 25 Disc
MM21-10	Bacillus cereus 10 Disc
MM24-10	Escherichia coli 10 Disc
MM24-25	Escherichia coli 25 Disc
MM26-10	Enterobacter aerogenes 10 Disc
MM26-25	Enterobacter aerogenes 25 Disc

Product	Description
MM27-10	Citrobacter freundii 10 Disc
MM28-10	Candida albicans 10 Disc
MM28-25	Candida albicans 25 Disc
MM29-10	Bacillus subtilis 10 Disc
MM29-25	Bacillus subtilis 25 Disc
MM30-10	Staphylococcus aureus 10 Disc
MM30-25	Staphylococcus aureus 25 Disc
MM31-10	Clostridium sporogenes 10 Disc
MM33-10	Escherichia coli 10 Disc
MM33-25	Escherichia coli 25 Disc
MM34-10	Escherichia coli (mcr-1) 10 Disc
MM35-10	Enterococcus hirae 10 Disc
MM36-10	Campylobacter jejuni 10 Disc
MM37-10	Haemophilus influenzae 10 Disc
MM38-10	Escherichia coli 10 Disc
MM38-25	Escherichia coli 25 Disc
MM40-25	Pseudomonas aeruginosa 25 Disc
MM41-10	Pseudomonas aeruginosa 10 Disc
MM42-10	Candida albicans 10 Disc
MM42-25	Candida albicans 25 Disc
MM43-10	Proteus mirabilis 10 Disc
MM44-10	Bacteroides fragilis 10 Disc
MM44-10	Bacteroides fragilis 10 Disc
MM45-10	Clostridium perfringens 10 Disc
MM45-10	Clostridium perfringens 10 Disc
MM46-10	Staphylococcus aureus 10 Disc
MM46-10	Staphylococcus aureus 10 Disc
MM46-25	Staphylococcus aureus 25 Disc
MM47-10	Listeria monocytogenes 10 Disc
MM48-10	Listeria monocytogenes 10 Disc
MM48-25	Listeria monocytogenes 25 Disc
MM50-10	Saccharomyces cerevisiae 10 Disc
MM51-10	Enterobacter cloacae 10 Disc
MM52-10	Enterococcus faecalis 10 Disc
MM53-10	Candida krusei 10 Disc
MM54-10	Candida parapsilosis 10 Disc
MM55-10	Klebsiella pneumoniae 10 disc
MM56-10	Klebsiella pneumoniae 10 Disc
MM57-10	Escherichia coli 10 Disc
MM58-10	Klebsiella pneumoniae 10 Disc
MM59-10	Klebsiella pneumoniae 10 Disc
MM60-10	Streptococcus dysgalactiae 10 Disc
MM62-10	Salmonella Enteritidis 10 Disc

Product	Description
MM63-10	Escherichia coli 10 Disc
MM64-10	Staphylococcus aureus 10 Disc
MM65-10	Pseudomonas aeruginosa 10 Disc
MM68-10	Proteus mirabilis 10 Disc
MM70-10	Burkholderia cepacia 10 Disc
MM73-10	Saccharomyces cerevisiae 10 Disc
MM73-25	Saccharomyces cerevisiae 25 Disc
MM75-10	Escherichia coli 10 Disc
MM76-10	Lactobacillus brevis 10 Disc
MM77-10	Listeria monocytogenes 10 Disc
MM80-10	Yersinia enterocolitica 10 Disc
MM80-25	Yersinia enterocolitica 25 Disc
MM81-10	Haemophilus influenzae 10 Disc
MM82-10	Campylobacter jejuni 10 Disc
MM83-10	Klebsiella pneumoniae 10 Disc
MM84-10	Salmonella Nottingham 10 Disc
MM85-10	Staphylococcus aureus 10 Disc
MM86-10	Bacillus cereus 10 Disc
MM86-25	Bacillus cereus 25 Disc
MM87-10	Listeria monocytogenes 10 Disc
MM88-10	Klebsiella aerogenes 10 Dis
MM89-10	Salmonella Poona 10 Disc
MM89-25	Salmonella Poona 25 Disc
MM91-10	Staphylococcus aureus 10 Disc
MM91-10	Staphylococcus aureus 10 Disc
MM92-10	Listeria innocua 10 Disc
MM93-10	Escherichia coli 0157 non-toxigenic 10d
MM93-25	Escherichia coli 0157 non-toxigenic 25D
MM94-10	Aspergillus brasiliensis 10 Disc
MM95-10	Streptococcus pneumoniae 10 Disc
MM97-10	Rhodococcus equi 10 Disc
MM99-10	Legionella anisa 10 Disc
MM99-10	Legionella anisa 10 Disc

Signed by: Sue Brown Date: 21.08.2018

Name: Sue Brown
Position: Regulatory Affairs Manager

Signed by: Lynda Preston Date: 21.08.2018

Name: Lynda Preston
Position: Managing Director

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tcs biosciences

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 10^6 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.

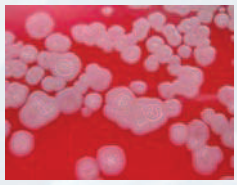
***Bacillus cereus*:**

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 carbapenem[2] 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.

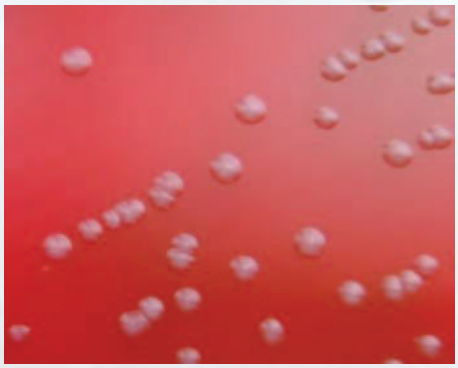
MM51– NCTC® 13406 – PHE recommended strain for QC of AmpC (de-repressed) detection.

***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.

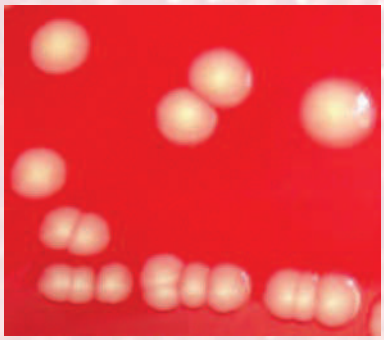


***Enterococcus hirae*:**

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.

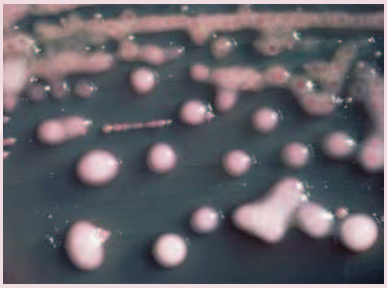
MM37 – NCTC® 12975 / ATCC® 49766 – recommended by EUCAST.

***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 CO_2 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.

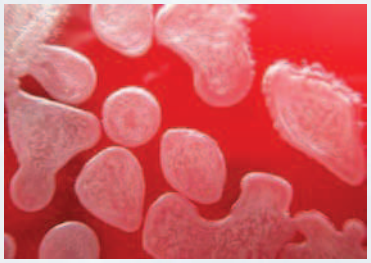
MM68 – NCTC® 10975 – media control. PHE recommended control for motility test.

***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 cefoxitin / 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 cefoxitin / 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. Cefoxitin / methicillin / oxacillin sensitive. Penicillin resistant. Colonies are weakly beta-haemolytic, coagulase positive and beta-lactamase negative.

(C) MRSA (cefoxitin / 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 cefoxitin /oxacillin/methicillin resistance (4.0 mg/l MIC of oxacillin, 8.0 mg/l MIC of cefoxitin – methicillin sensitive strains have MIC of 0.12-0.5 for oxacillin and 1-4 for cefoxitin.); 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 cefoxitin / 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 cefoxitin / 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).

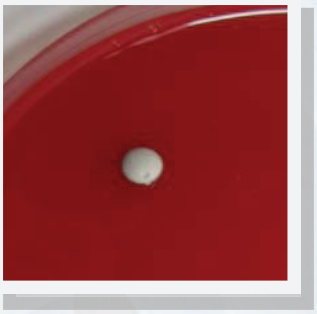
3 Performance Standards for Antimicrobial Disc Susceptibility Tests: Approved Standard—11th Edition. Clinical and Laboratory Standards Institute (CLSI).

How to use Selectrol®

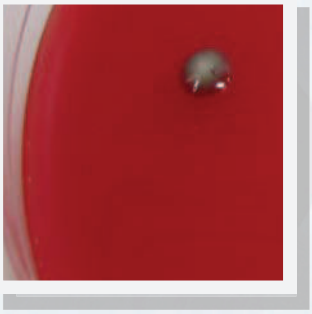
Always warm the vial to ambient temperature before opening.

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.

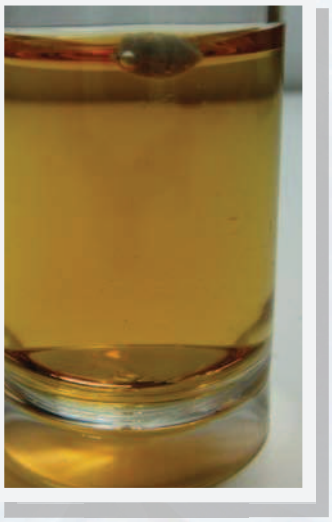


Place disc on suitable growth medium such as blood agar



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

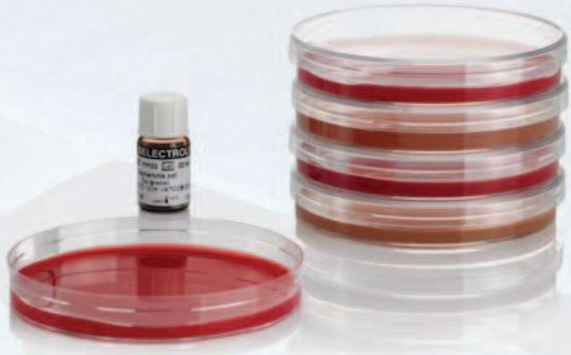
Laboratories use Selectrol® for Quality Control of culture media, biochemical identification tests and antimicrobial susceptibility testing. When a laboratory test result, an MIC or biochemical reaction, is unexpected or out-of-specification, the test should first be repeated to confirm it; an out-of-specification 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 µl of (A) to 100 ml of saline or ¼ strength Ringer's solution -- (B)
- Mix and transfer 100 µl of (B) to 10 ml of saline or ¼ strength Ringer's solution --- (C)
- Mix and transfer 100 µl of (C) to your homogenised food sample.

Verifying the inoculum

- Pipette 5 x 10 µl 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 µl to 10 µl
- If the count was too low by a factor of 10, increase the volume transferred from (A) to (B) from 100 µl 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.

Selectrol Strain Index

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

Selectrol Strain Index

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

Selectrol Strains Listed by WDCM Number

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

Notes

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