SELF DECLARATION OF CONFORMITY

We declare under our sole responsibility in accordance with MHRA Registration Number IVD 000100 that the following CE marked products:

EDMA code(s)	EDMA description	TCS product code and description
14.50.01.90	Other Controls/Standards/Calibrators, Microbiology	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: 30.04.2016

Name: Sue Brown
Position: Regulatory Affairs Manager

Signed by: Lynda Preston Date: 30.04.2016

Name: Lynda Preston
Position: Managing Director

Digitally signed by Monastirschii Viorica
Date: 2021.12.28 18:53:36 EET
Reason: MoldSign Signature
Location: Moldova

By Royal Charter

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 and sale of a range of diagnostic products for clinical, pharmaceutical, food and environmental laboratory testing.

For and on behalf of BSI:

Andrew Launn, EMEA Systems Certification Director

Original Registration Date: 1994-08-11
Latest Revision Date: 2019-01-17

Effective Date: 2019-01-27
Expiry Date: 2022-01-26

...making excellence a habit.™

By Royal Charter

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 and sale of a range of diagnostic products for clinical, pharmaceutical, food and environmental laboratory testing.

For and on behalf of BSI:

Andrew Launn, EMEA Systems Certification Director

Original Registration Date: 2013-06-10
Latest Revision Date: 2019-01-18

Effective Date: 2019-01-27
Expiry Date: 2022-01-26

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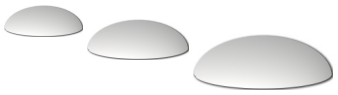
UKAS MANAGEMENT SYSTEMS 003

SELECTROL® DISCS: SUITABILITY FOR USE IN ACCREDITED LABORATORIES

Selectrol® discs are suitable for use in accredited laboratories because the organisms are only one generation from the source culture and are directly traceable to the source culture vial from which they are derived. As such, the discs are acceptable for use in producing working stock cultures subject to the following conditions stipulated by UKAS:

- The discs must be used in an appropriate manner that must be clearly documented.
- The discs are used to produce reference stock cultures from which working stocks are then prepared.
- Laboratories must initially demonstrate that organisms supplied as Selectrol® discs are suitable for their intended purpose by confirming that they exhibit the same characteristics as the source culture when used in accordance with the laboratory's standard operating procedures.

GENERAL PRODUCT DESCRIPTION



Selectrol® discs are designed to be a convenient source of viable micro-organisms which when recovered can be used as control organisms for a variety of QC and other testing purposes.

The principle of the discs is that first generation cultures (a single subculture from the parent strain) are suspended in an inert medium and freeze dried to form discs that are convenient to store and very flexible in their use.

The numbers in the discs are in the region of 10^6 to 10^9 when the vial is sealed. When opened these numbers may decrease with time, but a recovery of viable organisms is guaranteed over the shelf life period, i.e. the discs are guaranteed to provide sufficient organisms for preparation of a working stock culture.

Selectrol® is supplied in quantities of 10 or 25 discs per vial. The vials are sealed under vacuum, and also contain self-indicating silica gel.

Selectrol® is usually supplied with a minimum of 9 months shelf life.

STORAGE

The discs are very convenient to store, taking up minimal space. The usual storage temperature is within the range -20 to +8°C, i.e. refrigerator or freezer.

The exceptions are the more fastidious organisms, such as *Campylobacter, Neisseria, Haemophilus*, *Vibrio*, and the anaerobes, where freezer storage (-30 to -15°C) is required. These organisms are always presented as 10 discs per vial.

Freeze dried organisms are sensitive to moisture and temperature. Loss of viability may occur if the vial is left open for longer than necessary, or if the discs are not stored at the recommended temperature.

USE

The vials are supplied with detailed instructions for use. The following is a summary.

The discs are supplied in a glass vial sealed with a grey rubber bung and a cap containing a wad. It is very important that the vial is allowed to warm to room temperature prior to opening. If the vial is opened while still cold, moisture from the air will condense on the remaining discs, quickly rendering them non-viable.

We recommend that one disc is used each time a new culture is required. Selectrol® can be used in three ways:

- A disc can be placed directly on to the required culture plate and allowed to soften for approximately 5 to 10 minutes. The disc can then be spread over the surface of the plate with an inoculating loop.
- A disc can be dissolved in non-selective culture broth, or Maximum Recovery Diluent, and this suspension can be used immediately for inoculation.
- A disc can be grown up overnight in a suitable non-selective culture broth to produce a working stock.

QUALITY ASSURANCE

Strains are sourced from the Public Health England culture collections (PHE).

One batch of Selectrol® discs is produced from a single culture collection vial, and the batch is directly traceable to the parent culture through a detailed Manufacturing Batch Record.

Every batch is QC tested to ensure that its characteristics remain standard. The testing of biochemical characteristics is carried out in our UKAS accredited Quality Control testing laboratory, No. 2496.

Selectrol® discs are manufactured under our ISO 9001 Management System. Our assessment body is BSI.

Copies of our certificates of accreditation are available.

ISO 9001 FS 28907
ISO 14001 EMS 590359

PRODUCTION PROCESS SUMMARY

The source freeze dried strain is reconstituted and allowed to recover.

The strain is then grown on culture media and retained for reference (see Quality Control Checks).

The growth is harvested from the culture medium and suspended in a preservation solution.

The solution is then dispensed as drops and frozen without delay. Once frozen, the discs are freeze dried.

The manufacturing process, culture media and quality control tests are fully documented in our Management System.

QUALITY CONTROL CHECKS

The Quality Control tests are designed to check for the following parameters:

Purity : absence of contamination.

Viability : sufficient cells to enable recovery of the organism during the shelf life period.

Confirmation of the main characteristics of the strain : including a comparison of the post -processing colony characteristics with those of the source culture.

PROCESS CHECKS

All media used to grow the organisms are inspected to ensure the absence of contaminants throughout the process.

The following are checked during processing:

A sample from the source culture.

Samples from the suspension solutions before and after addition of the organism.

Samples of the discs after freeze-drying. These are checked for purity using five methods:

Culturing the “neat” discs and visually examining the plates.

Taking a sweep from the plate growth, making a Gram stain smear and examining this under the microscope.

Suspending the disc in solution, plating it out and testing it with antibiotic discs. *Note* - this is not an antibiotic susceptibility test but a means of revealing the presence of any possible contaminants that may otherwise remain hidden.

Checking for contaminants whilst examining viability.

Checking for characteristic colony morphology as defined by the culture collection.

VIABILITY

Viability is assessed by dissolving sample discs in broth and making serial dilutions to estimate the actual numbers.

FINAL QC TESTS

After filling and sealing the vials, one vial is selected at random from which two discs are examined for purity. A further five discs are then examined for viable counts and colony morphology.

Two discs are cultured, and the cultures are examined for reactions to biochemical tests. The tests vary in detail from strain to strain, and typically include specific tests which are highly characteristic for the strain.

BATCH NUMBERS, TRACEABILITY AND CERTIFICATES ON THE WEB

To maintain clear traceability back to the source culture, we use one new source vial for each batch of Selectrol® manufactured. The lot number of the source vial is recorded on our manufacturing batch record.

Each Selectrol® vial is traceable to the originating batch using the lot number which appears on the vial. Lot numbers take the form e.g. 020099 where

- The first two digits denote the strain. In this case, 02 = *E. coli* NCTC 12241, as defined in our product catalogue.
- The last two digits indicate the lot number.

Thus 020099 = lot 99 of *E. coli* NCTC 12241.

We keep definitive records of the despatch date and destination of each vial, to ensure batch traceability is complete.

Test reports and statements of origin issued by our UKAS accredited Quality Control testing laboratory can be accessed on our company website at www.tcsbiosciences.co.uk

Click on the "Selectrol Certificates" icon and follow the search instructions to access and print the QC test report you require.

Quality Control Test Report For Selectrol® Discs

Lot number	980049
Product code	MM98
Expiry	2014.10
	Important Note: Use within 9 months of opening.
Strain	Haemophilus influenzae
Designation	NCTC 11931
A first generation derivative of	NCTC No: 11931
Source lot	05 white
ACDP hazard group	2
Storage	-30°C to -15°C

TEST REPORT on SELECTROL® DISC Quality Control Samples from: Lot 980049

Issue date	2013.08.23
Testing date	2013.08.20
Biochemical profile	API NH: Satisfactory profile (available on request)
Gram stain	Gram negative rods
Catalase	Positive
X and V Factor	XV Dependent

Unless marked (*) all tests are included in the current schedule of accreditation.

Visit the UKAS web site: www.ukas.org

Testing carried out by the Quality Control Department of:

TCS Biosciences Ltd
Botolph Claydon
Buckingham
MK18 2LR
United Kingdom

UKAS TESTING 2496

For questions and queries regarding Selectrol® certificates, please email qc@tcsgroup.co.uk

Organisms derived from NCPF and NCTC cultures
ATCC® is the registered trade mark of the American Type Culture Collection
NCTC® - National Collection of Type Cultures
NCPF® - National Collection of Pathogenic Fungi
ACDP – Advisory Committee on Dangerous Pathogens

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