TCS BIOSCIENCES LTD, CHANGE NOTICE: CCI 116

To: Customers purchasing Selectrol strains

It is our intention to change the Instructions for Use of the Selectrol range of products. The details of the change and the reason for it are given below.

Please acknowledge receipt of this notification and confirm your acceptance of the change by completing the section below and emailing a copy of the form to qc@tcsgroup.co.uk. Acceptance of the change is assumed if a response is not received within two weeks of issue of this notification.

If you have any difficulties or concerns accepting the change, please contact us immediately.

Product: Selectrol

Product codes: All MM codes

Proposed Change Date: 1 July 2023 (or sooner if current IFU stocks run out)

Change Details: Selectrol Instructions For Use (IFU) will change to a format that meets IVDR requirements. The IFU supplied in the clamshell pack with the Selectrol vial(s) will be in English only. Electronic versions of the IFU (eIFU) translated into all EU languages will be available on our website https://www.tcsbiosciences.co.uk/qcerts/

Reason for Change: TCS continues to work towards meeting the requirements of the In Vitro Diagnostics Medical Device Regulation (IVDR) in accordance with the timeline for Class B devices. The IFU has been updated to include additional details (IVDR Annex II).

Considerations: There is no change to the intended use of Selectrol. There is no change to the way in which Selectrol discs are to be removed from the vial or used on solid / liquid media by the end user. The IFU contains additional details including 'in use stability' and 'serious incident reporting'.

Conclusion:
The changes to the IFU have been made to meet the IVDR requirements. The IFU has been translated into all the languages of the EU and the translations are available electronically.

Appendix 1 – Selectrol Discs Instructions For Use Issue 14.

Note – Total 2 pages including this page

I understand and accept the changes to the product given above.

Signed: Date:

Position:
On Behalf of (Company):

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Selectrol®

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EC REP

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IVD

ISO 9001 FS28907
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SELECTROL® DISCS

Selectrol® Discs are first generation freeze-dried microorganisms manufactured exclusively from NCTC® (National Collection of Type Cultures) and NCPF® (National Collection of Pathogenic Fungi) cultures. They are preserved during long-term storage as freeze-dried cells in order to minimize any alterations to the phenotype caused by mutations.

The use of Selectrol® Discs is standardized, therefore all strains are supplied with this general Instructions for Use (IFU). A full list of strains, along with description, product code and pack size (supplied as vials of 5, 10 or 25 discs) can be found online: https://www.tcsbiosciences.co.uk/qcerts/

Intended Use

Selectrol® Discs are suitable for use in laboratories for quality control of culture media, biochemical identification tests and antimicrobial susceptibility testing.

Selectrol® Discs are used in microbiological applications to control and validate the isolation and testing procedures used to detect and identify pathogenic microorganisms. They are also used to control subsequent manual or automated identification and susceptibility testing of significant isolates, involving biochemistry or by MIC determination, Maldi-Tof, disc diffusion or molecular methodology (see Limitations).

Each strain of Selectrol® is identified by organism name and culture collection number and possesses one or more specific characteristics for quality control purposes.

Testing procedures, recommended media, updates and appropriate control organisms are described in documents, such as those available from EUCAST, ISO, CLSI, the Manual of Clinical Microbiology and UKHSA.

Selectrol® Discs use is a manual process and provides a qualitative result.

Precautions & storage

- **For professional use only.**
- **Selectrol® Discs contain viable Category 1 and Category 2 pathogenic organisms and must only be used in appropriately equipped laboratories by microbiologists or persons under the supervision of microbiologists qualified by training or experience to work with micro-organisms.**
- **Store at the temperature indicated on the label. Loss of viability may occur if the discs are left above this temperature range for longer than necessary.**
- **Allow the vial to reach room temperature before opening and replace the cap and bung on each vial immediately after a disc has been removed. Moisture in air entering thevial will cause a reduction in the number of viable organisms, eventually leading to complete loss of viability.**
- **Do not use discs that are past their expiry date. These may show a loss of viability.**

Serious incident reporting

EU only: Users should report any serious incident related to the device to the Manufacturer and National Competent Authority.

Outside EU: Contact TCS for any incident or inquiry related to this device. Contact details: QC@tcsgroup.co.uk or +44 (0) 1296 714222

INSTRUCTIONS FOR USE

Removing the disc from the vial: A Disc is easily removed from the vial by using sterile forceps or a sterile 10µl inoculating loop.

For use on solid media: Place a Disc on appropriate solid medium. Allow the disc to soften for 10 –15 minutes. The plate may be placed in an incubator to accelerate the process. Spread the softened Disc around the plate and incubate under optimum conditions for the strain.

For use in liquid media: Place the Disc in 1-10ml of the appropriate broth. Avoiding the production of aerosols, shake the broth gently to dissolve the Disc and incubate under optimum conditions.

Alternatively, for rapid use, dissolve the Disc, allow the culture to recover by incubating at 35 – 37˚C for 1 hour and then use immediately. By experimentation you will be able to find the best dilution for your own application.

In use stability

In use stability is strain specific. This information is displayed on the Quality Control Test Report for Selectrol® Discs as "Storage" and "Important Note: Use withing x months of opening". Quality Control Test Reports for all product codes / lot numbers can be downloaded by visiting: https://www.tcsbiosciences.co.uk/qcerts/

Limitations

Repeated sub-culture can cause the characteristics of a strain to change. A Selectrol® Disc is a first generation subculture from a master culture sourced from UKHSA 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 five passages (successive subcultures) should be made from the master culture, in order to avoid genetic drift and mutant selection. Therefore, no more than four passages from the Selectrol® Disc working stock culture should be made.

Use within automated culture systems must be validated by the end user.

Breakages, spillage & disposal

1. All exposed Discs, contaminated packaging and broken glassware should be placed in a suitable container and either incinerated or autoclaved at 121˚C for 30 minutes.
2. Unbroken vials may be removed with forceps, washed in a suitable bactericidal solution, rinsed, dried and retained for further use.

All contaminated surfaces must be disinfected with a suitable bactericidal solution.

Terms

EUCAST – European Committee on Antimicrobial Susceptibility Testing
CLSI – Clinical and Laboratory Standards Institute
UKHSA – UK Health Security Agency, formerly PHE Public Health England
ISO – International Organization for Standardization

References

Manual of Clinical Microbiology: 12th edition (ASM Books)

Instructions for use translations

See website https://www.tcsbiosciences.co.uk/qcerts/