CultiControl™

Freeze-dried bacterial strains

INTENDED USE

The Liofilchem® CultiControl™ microorganisms are lyophilized, reference stock culture preparations containing a single strain of a microorganism. These microorganism preparations are intended to be used for quality control of culture media, educational/instructional programs and industrial applications. The microorganism preparations are derived from the American Type Culture Collection (ATCC®) or other authentic reference culture collections.

SUMMARY AND HISTORY

A reliable source of reference stock cultures for use in microbiology quality assurance programs is essential.
Microorganisms with known and predictable characteristics are used in quality control, education and proficiency programs.
Lyophilization is a well-documented and recommended method for long-term preservation of microorganisms.
The use of this lyophilized material provides equivalent results to traditional methods used in preparing, storing and maintaining reference stock culture collections.

PRINCIPLE

CultiControl™ microorganisms incorporate a lyophilization method reported by Obara et.al. which uses a suspending medium consisting of gelatin, skim milk, ascorbic acid, dextrose, and charcoal. The gelatin serves as a carrier for the microorganism. Skim milk, ascorbic acid, and dextrose protect the microorganism by preserving the integrity of the cell wall during freeze-drying and storage. The charcoal is included to neutralize any toxic substances formed during the lyophilization process.

PRODUCT DESCRIPTION

CultiControl™ microorganisms are packaged in a resealable vial that contains five (5) lyophilized pellets of a single microorganism strain and a desiccant to prevent adverse accumulations of moisture.

- Each lyophilized microorganism preparation is less than or equal to four (4) passages from a reference culture.

MATERIALS REQUIRED BUT NOT PROVIDED

CultiControl™ microorganisms require sterile tubes and 0.5 ml of sterile liquid such as, Tryptic Soy Broth, Brain Heart Infusion Broth, saline, or deionized water to hydrate the lyophilized preparation. Sterile swabs or inoculating loops are needed to transfer the hydrated preparation to an agar plate.
CultiControl™ microorganisms require non-selective, nutrient or enriched agar media and specific incubation times and conditions to optimize growth and recovery.
The Technical Sheet CC01 “Recommended Growth Requirements” lists the recommended media and incubation requirements. This Technical Sheet is available from our website at www.liofilchem.net/culticontrol

INSTRUCTIONS FOR USE

Remove the unopened CultiControl™ vial from 2°C to 8°C storage and allow the unopened vial to reach the room temperature.
Aseptically remove one (1) pellet with sterile forceps from the vial. Do not remove desiccant.
Place the pellet in 0.5 mL of sterile fluid (water, saline, TSB, or BHIB).
Immediately stopper and recap vial and return the resealed vial to 2°C to 8°C storage.
Crush the pellet with a sterile swab until the suspension is homogenous.
Immediately heavily saturate the same swab with the hydrated material and transfer to agar medium.
Inoculate the primary culture plate(s) by gently rolling the swab over one-third of the plate.
Using a sterile loop, streak to facilitate colony isolation.
Using proper biohazard disposal, discard the remaining hydrated material.
Immediately incubate the inoculated media at temperature and conditions appropriate to the microorganism.

STORAGE AND EXPIRATION

Store the CultiControl™ microorganisms at 2°C to 8°C in the original, sealed vial or pouch containing the desiccant.
Stored as directed, the lyophilized microorganism preparation will retain, until the expiration date stated on the device label, its specifications and performance within the stated limits.
The CultiControl™ microorganisms should not be used if: • Stored improperly; • There is evidence of excessive exposure to heat or moisture; or, • The expiration date has passed.

QUALITY CONTROL

This product is developed, manufactured, and distributed:
- in conformance with the elements of ISO 9001; and,
- in conformance with CE Mark requirements.

Quality control functions may include, but are not limited to:
- purity and growth characteristics;
- morphological features;
- biochemical activity;
- the identity and traceability of the microorganism preparation to a reference culture; and,
- the number of passages the microorganism preparation has been removed from the reference culture.

The decision to perform additional quality control is the responsibility of each individual laboratory.

PRECAUTIONS AND LIMITATIONS

These products are for in-vitro use only.
Refer to the MSDS for more detailed information. The MSDS can be found on our website at www.liofilchem.net/culticontrol
These devices, and growth of these microorganisms, are considered biohazard material. These devices contain viable microorganisms that may produce disease. Proper techniques must be employed to avoid exposure and contact with any microorganism growth. The microbiology laboratory must be equipped, and have the facilities to receive, process, maintain, store and dispose of biohazard material. Only trained laboratory personnel should use these devices. Agencies and statutes regulate the disposal of all biohazard materials. Each laboratory must be aware of, and comply with, the proper disposal of biohazard materials. The Liofilchem CultiControl™ products and packaging are latex free.

PRODUCT WARRANTY

These products are covered under warranty to meet the specifications and performance printed and illustrated in product inserts, instructions, and supportive literature. The warranty, expressed or implied, is limited when: the procedures employed in the laboratory are contrary to printed and illustrated directions and instructions or the products are employed for applications other than the intended use cited in product inserts, instructions, and supportive literature.

REFERENCES

The following reference cites the basis for the lyophilization method employed on these microorganism preparations.
1. Y. Obara, S. Yamai, T. Nikkawa, Y. Shimoda, and Y. Miyamoto. 1981. J. Clin. Microbiol. 14:61-66.

The selection of reference stock cultures is only one integral part of the overall scheme for QC challenge procedures and techniques. Reference to guidelines for each laboratory's applications is essential. Examples might include:
1. AOAC Compendium of Microbiological Methods.
2. Clinical Microbiology Procedures Handbook. ASM. Washington, D.C.
3. FDA Bacteriological Analytical Manual.
4. Manual of Clinical Microbiology, ASM, Washington, D.C.
5. Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically. CLSI.
6. Official Methods of Analysis of the Association of Official Analytical Chemists.
7. Performance Standards for Antimicrobial Disk Susceptibility Tests. CLSI.
8. Quality Assurance for Commercially Prepared Microbiological Culture Media. CLSI.
9. Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria. CLSI.
10. Standard Methods for the Examination of Dairy Products.
11. Standard Methods for the Examination of Water and Wastewater.
12. US Pharmacopoeia and National Formulary.

TABLE OF SYMBOLS

IVD *In Vitro* Diagnostic Medical Device	Biological risk	Manufacturer	Contains sufficient for <n> tests	Temperature limitation	Do not reuse
REF Catalogue number	Fragile, handle with care	Use by	Caution, consult accompanying documents	LOT Batch code	Consult Instructions for Use

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