INSTRUCTIONS FOR USE

Enumerated *Mycoplasma*

INTENDED USE

Enumerated *Mycoplasma* microorganisms are frozen, enumerated microorganism suspensions to be used in industrial laboratories for growth promotion testing of media used in *Mycoplasma* testing. These microorganism preparations are traceable to authentic reference culture collections.

FORMULA COMPONENTS

The frozen suspension consists of:

- An enumerated microorganism population
- SP4 Glucose Broth
- PBS (phosphate buffered saline)
- Glycerol

Enumerated *Mycoplasma* microorganisms conform with Article 5 of EC 1069/2009 as they have reached the end point in the manufacturing chain and are no longer subject to the requirements of EC 1069/2009. The products are considered derived products per Article 36 of EC 1069/2009 and do not pose any significant risk to public or animal health.

SPECIFICATIONS AND PERFORMANCE

Enumerated *Mycoplasma* microorganisms are packaged in a kit configuration. Each kit consists of:

- 5 cryovials each containing 0.5 ml frozen suspension of an individual microorganism strain
- Instructions for Use

When processed in the Microbiologics QC laboratory on SP4 glucose agar (containing thallium acetate and penicillin), **Enumerated *Mycoplasma*** microorganism suspensions are found to contain 10,000-99,000 CFU/ml. The apparent concentration of these organisms varies significantly between brands and types of media. It is imperative that that customer determine the growth equivalency on their specific type of media.

Quality control documentation includes, but is not limited to, an online Certificate of Analysis stating:

- The identity of the microorganism
- The traceability of the microorganism to a reference culture
- That the microorganism preparation is ≤15 passages from the reference culture

INSTRUCTIONS FOR USE

A. IMPORTANT: Before beginning use of the Enumerated Mycoplasma product: Consult TIB.2035. This document contains important information regarding how *Mycoplasma* growth differs on different types and brands of media.

B. Material Preparation

All the materials required for the challenge procedure and the materials to be challenged must be ready for use immediately following the thawing step. Challenge inoculation(s) must be completed within 30 minutes after thawing.

C. Inoculation

1. Determine the dilution required to obtain approximately 100 CFU on the chosen type and brand of media. Consult TIB.2035.
2. Determine how many vials will be needed to inoculate the intended number of plates.
3. Remove the vials from the -80°C freezer. Allow the vials to thaw either on the bench or at 2-8°C.
4. Conduct the dilution series determined by laboratory studies for each specific organism.
5. Vortex the diluted suspension until a homogenous suspension is achieved.
6. Inoculate the solid media with 0.2 ml of the properly diluted suspension.
7. Swirl the plate to ensure even distribution of the suspension.
8. Incubate in microaerophilic conditions at 36±1°C.
9. Discard any remaining hydrated material in accordance with the laboratory protocol for disposal of biohazard materials.

PRECAUTIONS AND LIMITATIONS

- Not intended for clinical use.
- Not intended for human, animal or pet consumption.
- **Enumerated *Mycoplasma*** microorganisms do not contain any hazardous substances listed in 67/548/EEC or listed in 1272/2008/EC.
- Refer to the Safety Data Sheet (SDS) for more detailed information. The SDS can be located at **www.microbiologics.com** or by contacting Technical Support at **1.320.229.7045**
- 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.
- **Enumerated *Mycoplasma*** microorganisms are not made with natural rubber latex.

TECHNICAL NOTES

Shelf Life and Stability

- Product warranty is limited to specifications and performance of the **Enumerated *Mycoplasma*** microorganism stored properly in a -80°C freezer.
- Stability is predicated on proper storage of the capped, frozen suspension. Exposure to heat can adversely affect the stability of the product.

STORAGE AND EXPIRATION

Store the **Enumerated *Mycoplasma*** frozen suspensions in a -80°C freezer. Stored as directed, the frozen suspensions will retain its specifications and perform within the stated limits until the last day of the month of the expiration date stated on the device label.

Microorganisms should not be used if:

- Stored improperly
- There is evidence of excessive exposure to heat or damage to the container
- The expiration date has passed

MATERIALS REQUIRED BUT NOT PROVIDED

Sterile Pipettes: Sterile pipettes are required to inoculate the medium/media to be challenged.

Diluent: Liquid media for *Mycoplasma* growth, such as SP4 Broth, for conducting dilutions to bring the material to the desired, proper concentration

KEY OF SYMBOLS

Batch Code (Lot)


Biological Risks

Catalog Number


Caution, Consult Accompanying Documents


Manufacturer


Temperature Limitation


Use By

PRODUCT WARRANTY

These products are warranted 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
- The products are employed for applications other than the intended use cited in product inserts, instructions, and supportive literature
- If the suspension is thawed and refrozen, Microbiologics cannot guarantee the stated characteristics of the product

WEBSITE

Visit **microbiologics.com** for current technical information, product availability, biohazard cleanup, growth requirements, and Certificate of Analysis.

ACKNOWLEDGEMENTS

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Customer Service
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Email: info@microbiologics.com

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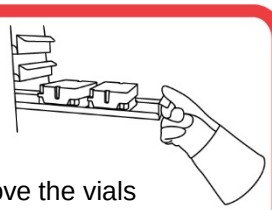
microbiologics.com

ILLUSTRATED INSTRUCTIONS

1. Determine the dilution required to obtain approximately 100 CFU on the chosen type and brand of media. Consult TIB.2035.

2. Determine how many vials will be needed to inoculate the intended number of plates.

3. 
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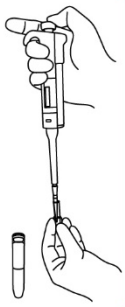

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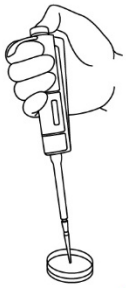

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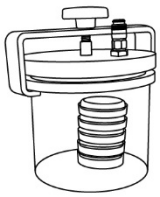
Swirl the plate to ensure even distribution of the suspension.

8. Incubate in microaerophilic conditions at 36±1°C.


9. Discard any remaining hydrated material in accordance with the laboratory protocol for disposal of biohazard materials.

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A safer, healthier world.