INSTRUCTIONS FOR USE

EZ-Accu Shot™ Microorganisms

EZ-Accu Shot™ Select Microorganisms

INTENDED USE

EZ-Accu Shot™ and EZ-Accu Shot™ Select microorganisms are lyophilized, enumerated microorganism preparations to be used in industrial laboratories for quality control purposes. Processed as directed, these preparations provide a challenge of 10–100 CFU per 0.1 ml on non-selective media. This is the required concentration for growth promotion testing of culture media to be employed in most microbial enumeration tests, tests for specified microorganisms, and sterility tests. These microorganism preparations are traceable to the American Type Culture Collection (ATCC®) or other authentic reference culture collections.

FORMULA COMPONENTS

The lyophilized preparation consists of:

An enumerated microorganism population	Skim milk (Bovine – USA origin)	Carbohydrate
Gelatin (Porcine – USA or Canada origin)	Ascorbic acid	

The gelatin serves as a carrier for the microorganism. Skim milk, ascorbic acid, and a carbohydrate protect the microorganism by preserving the integrity of the cell wall during freeze-drying and storage.

The hydrating fluid is a working solution of pH 7.2 phosphate buffer. The fluid contains:

Monobasic potassium phosphate	Deionized water
Sodium hydroxide	Magnesium chloride as required

EZ-Accu Shot and EZ-Accu Shot Select 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.

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SPECIFICATIONS AND PERFORMANCE

EZ-Accu Shot microorganisms are packaged in a kit configuration. Each kit consists of:

- 5 vials each containing 1 lyophilized pellet of an individual microorganism strain
- 5 hydrating fluid vials each containing 1.2 ml of hydrating fluid
- Instructions for Use

EZ-Accu Shot Select microorganisms are packaged in a kit configuration including the five USP compendial strains for Growth Promotion Testing. Each kit consists of:

- 5 vials each containing 1 lyophilized pellet of an individual microorganism strain
- 5 hydrating fluid vials each containing 1.2 ml of hydrating fluid
- Illustrated Instructions

Processed as directed, **EZ-Accu Shot and EZ-Accu Shot Select** microorganisms will provide a challenge concentration of 10–100 CFU per 0.1 ml on non-selective 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 3 passages from the reference culture
- The mean assay value for the microorganism preparation

INSTRUCTIONS FOR USE

A. Material Preparation

All the materials required for the challenge procedure and the materials to be challenged must be ready for use immediately following the hydration step. Following hydration of the lyophilized strain, challenge inoculation(s) must be completed within 8 hours. The remaining suspension must be refrigerated at 2°C–8°C between uses to avoid a change in the challenge suspension concentration. The exception to the 8 hour stability is catalog number 0484 which must be used within 30 minutes.

B. Hydration

The instructions and hydrating fluid provided in the kit must be used in the hydration procedure. The hydrating fluid is formulated to optimize the hydration, pellet matrix dissolution, and the uniform suspension of the lyophilized microorganism. Other fluids that might be used for hydration may not provide these critical properties. Only use the hydration fluid that came in the kit for that organism.

1. Remove 1 vial of hydrating fluid and 1 foil pouch containing the lyophilized pellet from refrigerated storage. Allow the unopened pouch and hydrating fluid to equilibrate to room temperature (about 30 minutes).
2. Tear open the foil pouch and remove the vial containing 1 lyophilized pellet.
3. Remove the cap from the pellet vial and the hydrating fluid vial. Tip 1 pellet into the vial of hydrating fluid. Only 1 pellet must be used to obtain the challenge concentration of 10–100 CFU per 0.1 ml on non-selective media. Immediately recap the hydrating fluid vial.
4. Vortex the hydrated material until the pellet has completely dissolved and the suspension is homogeneous.
5. With a sterile pipette, transfer 0.1 ml of the hydrated suspension to the material being challenged (0.1 ml contains 10–100 CFU). Note: Remaining suspension can be refrigerated and used for up to 8 hours, with the exception of catalog number 0484, which must be used within 30 minutes. Test the suspension immediately after removing it from refrigerator.

6. Proceed with the challenge procedure according to laboratory protocol. Refrigerate the suspension at 2°C–8°C if it will be used again. 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.
- **EZ-Accu Shot and EZ-Accu Shot Select** microorganisms do not contain any hazardous substances listed in 67/548/EEC or listed in 1272/2008/EC.
- Refer to the SDS for more detailed information. The SDS can be located on our website 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.
- **EZ-Accu Shot and EZ-Accu Shot Select** microorganisms are not made with natural rubber latex.

TECHNICAL NOTES

Mean Assay Value

- The mean assay value obtained at Microbiologics is based on well proven statistical methods. As part of Microbiologics' quality control procedure, pellets from each **EZ-Accu Shot and EZ-Accu Shot Select** microorganism lot are hydrated in pH 7.2 phosphate buffer. Replicate colony counts are performed on non-selective agar media and enumerated using an automated colony counting device. Results may differ from the mean assay value that Microbiologics obtained due to different materials and methods used.
- Variability of hydrating fluid, sampling, different inoculation and colony counting techniques, incubation and the use of selective agar media will produce colony counts that vary from the stated mean assay value.

Shelf Life and Stability

- Product warranty is limited to specifications and performance of the **EZ-Accu Shot and EZ-Accu Shot Select** microorganism stored properly in the sealed pouch.
- Exposure to heat, moisture, and oxygen can adversely affect the stability of the mean assay value. Expiration dating, reproducibility and stability are predicated on proper storage of the lyophilized pellets in the original desiccant-containing pouch.

STORAGE AND EXPIRATION

Store the **EZ-Accu Shot and EZ-Accu Shot Select** microorganism pouches and hydrating fluid at 2°C–8°C in their original, sealed packages. Stored as directed, the lyophilized microorganism preparation will retain, until the last day of the month of the expiration date stated on the device label, its specifications and performance within the stated limits.

EZ-Accu Shot and EZ-Accu Shot Select microorganisms should not be used if:

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

MATERIALS REQUIRED BUT NOT PROVIDED

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

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 resuscitated culture is frozen, Microbiologics cannot guarantee the stated characteristics of the product.

WEBSITE

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

ACKNOWLEDGEMENTS

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St. Cloud, MN 56303 USA

Customer Service
Tel. 320-253-1640
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Technical Support
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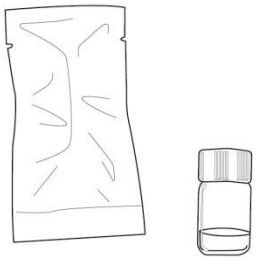
U.S. Toll Free 866-286-6691
Email: techsupport@microbiologics.com
www.microbiologics.com

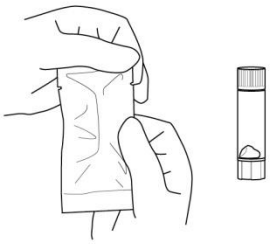
ILLUSTRATED INSTRUCTIONS

1

Remove 1 vial of hydrating fluid and 1 foil pouch containing lyophilized pellet from refrigerated storage. Allow unopened pouch and hydrating fluid to equilibrate to room temperature (about 30 minutes).



2



Tear open the foil pouch and remove the vial containing 1 lyophilized pellet.

3

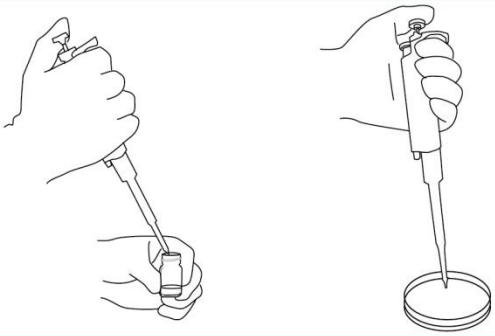
Remove the cap from the pellet vial and the hydrating fluid vial. Tip 1 pellet into the vial of hydrating fluid. Only 1 pellet must be used to obtain the challenge concentration of 10–100 CFU per 0.1 ml on non-selective media. Immediately recap hydrating fluid vial.

4

Vortex hydrated material until pellet has completely dissolved and suspension is homogeneous.

5

With a sterile pipette, transfer 0.1 ml of the hydrated suspension to the material being challenged (0.1 ml contains 10–100 CFU). Note: Remaining suspension can be refrigerated and used for up to 8 hours, with the exception of catalog number 0484A, which must be used within 30 minutes. Test suspension immediately after removing it from refrigerator.



6

Proceed with the challenge procedure according to laboratory protocol. Refrigerate suspension at 2°C–8°C if it will be used again. Discard any remaining hydrated material in accordance with the laboratory protocol for disposal of biohazard materials.

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