INSTRUCTIONS FOR USE

EZ-FPC™ Microorganisms

INTENDED USE

The EZ-FPC™ (Food Process Control) Microorganisms are lyophilized microorganism preparations at a known concentration to be used in industrial laboratories. The applications for these microorganism preparations include a quality control challenge to measure and provide documentation that qualitative and/or quantitative test methods perform within anticipated ranges of tolerance. 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)	Dextrose
Gelatin (Porcine - USA or Canada origin)	Ascorbic acid	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.

EZ-FPC™ 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

Each **EZ-FPC™ Microorganism** is packaged in a kit configuration. Each kit consists of:

- 1 vial containing 10 lyophilized pellets of a single microorganism strain
- Instructions for Use
- Certificate of Assay

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EZ-FPC™

EZ-FPC™ Microorganism preparations are either qualitative or quantitative.

- **Qualitative Process Controls** are intended for Presence/Absence testing and have a guaranteed concentration of 100 CFU to 999 CFU per pellet.
- **Quantitative Process Controls** are intended for test methods where enumeration is required and have a guaranteed concentration of 1,000 CFU to 9,999 CFU per pellet.

The CFU concentration per ml in a challenge test depends on the amount of hydrating fluid used.

Pellet Concentration	**Examples of Concentration (CFU/ml) in Specified Hydrating Fluid Volume**		
	1 ml	**10 ml**	**100 ml**
100 -999	100-999	10-99	<10
1000-9999	1000-9999	100-999	10-99

Quality control documentation includes, but is not limited to, a Certificate of Assay stating:

- The identity of the microorganism
- The traceability of the microorganism to a reference culture
- The microorganism is not more than 4 passages from the reference culture
- The mean assay value for the microorganism preparation

INSTRUCTIONS FOR USE

1. Remove the vial of lyophilized pellets from refrigerated storage. Allow the unopened vial to equilibrate to room temperature (about 30 minutes).
2. Prior to use, warm enrichment broth or dilution fluid to 34°C-38°C as stated in laboratory SOP. Sterile pH 7.2 phosphate buffer is recommended for hydration of the lyophilized pellet when performing quantitative challenges.
3. With a sterile forceps, transfer 1 pellet to the enrichment broth or dilution fluid. Do not remove the desiccant from the vial. Immediately stopper and recap vial and return to 2°C-8°C.

Qualitative Challenge

1. Incubate the inoculated enrichment broth according to the laboratory SOP.
2. At least once during the incubation of the enrichment broth (i.e. following 30 minutes of incubation), mix the flask to ensure an even distribution of the hydrated microorganism population.
3. Proceed with the complete qualitative testing procedure as set forth in the laboratory SOP.

Quantitative Challenge

1. Place the microorganism suspension into a 34°C-38°C incubator for 30 minutes to ensure complete hydration.
2. Immediately following incubation, mix hydrated material until a homogeneous suspension is achieved.
3. Proceed with the challenge according to laboratory protocol.
4. The challenge must be completed within 30 minutes of the hydration process to avoid a change in the challenge suspension concentration.

PRECAUTIONS AND LIMITATIONS

- Not intended for clinical use.
- Not intended for human, animal or pet consumption.
- Refer to the Material Safety Data Sheet for more detailed information. The MSDS can be located on our website at **www.microbiologics.com** or by contacting Technical Support at **1.866.587.5907**.
- **EZ-FPC™ Microorganisms** do not contain any hazardous substances listed in 67/548/EEC or listed in 1272/2008/EC.
- These devices, and growth of these microorganisms, are considered biohazard material. They contain viable microorganisms that may produce disease.
- The microbiology laboratory must be equipped, and have the facilities to receive, process, maintain and store and material. Biohazard materials must be disposed of properly and according to regulations.
- Trained laboratory personnel must employ proper techniques to avoid exposure and contact with any microorganism growth.
- Microbiologics products and packaging are not made with natural rubber latex.

TECHNICAL NOTES

Important Considerations – Please consider the following when using **EZ-FPC™ Microorganisms**.

Mean Assay Value

- The mean assay value obtained at Microbiologics® was calculated using well proven statistical methods. As part of Microbiologics' quality control procedure, pellets from each **EZ-FPC™** 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 assigned mean due to different materials and methods used.
- Variability of hydrating fluid, sampling, different colony counting techniques, incubation conditions, and the use of selective agar media will produce colony counts that vary from the stated mean assay value.

Shelf-Life and Stability

- Exposure to heat, moisture, and oxygen can adversely affect the stability of the microorganism. Both reproducibility and stability are predicated on proper storage of the lyophilized preparations in the original desiccant-containing vial.

Time Restraints

- Hydration activates the respiration and metabolic activity of the lyophilized microorganism. In the absence of critical growth requirements (i.e. nutrients and incubation conditions), the stability of the microorganism population can be affected.
- Quantitative challenges must be completed within 30 minutes of hydration.

Analyte Challenge

- If the application requires a food sample, do not add the food sample to the hydrated suspension until IMMEDIATELY before processing and testing.
- The potential exposure of moisture and oxygen in the food sample can have a profound influence on the stability of the microorganisms.
- Food samples can also introduce inhibitory or toxic properties that adversely influence the recovery of microorganism populations.
- A food sample can also introduce an intrinsic population of microorganisms which can produce an inhibitory or toxic influence on the remaining microorganisms in the population.

Pre- Qualification Studies

- Using a single pellet of an **EZ-FPC™ microorganism**, seed the food sample and immediately proceed to the next step in the test method.
- Using a second pellet of the same **EZ-FPC™ microorganism**, directly seed the test method in the ABSENCE of the food sample.
- At appropriate intervals, plate counts can measure what, if any, inhibitory influence the different food samples might have on the recovery, detection and enumeration of the target microorganism.

Re-Qualification Studies

- Based on favorable test results during the pre-qualification studies, at appropriate intervals, a single pellet of an **EZ-FPC™ microorganism** can be used to seed a specified food sample to document consistent and reproducible test results.

Verification and Validation

- ***Qualitative Analysis***
  - Automated presence/absence equipment or detection devices commonly require several logs of growth to 'trigger' a positive test result.
  - A protocol similar to the "Qualiification Studies" can be employed to verify or validate the ability of equipment or devices to detect low-concentrations of target microorganisms.
  - In addition to positive or negative detection test results, the time required for detection of the seeded enrichment broth WITH the food sample versus the seeded enrichment broth WITHOUT the food sample may provide valuable sample matrix validation.
- ***Quantitative Analysis***
  - Automated enumeration equipment commonly requires the detection of metabolic products, conductivity, or impedance in relationship to time to generate enumeration results.
  - A protocol similar to the "Pre-Qualification Studies" can be employed to verify, or validate the ability of automated equipment to enumerate the population of a target microorganism.
  - The enumeration of the seeded dilution fluid WITH the food sample versus a seeded dilution fluid WITHOUT the food sample may provide valuable sample matrix validation.

TECHNICAL NOTES

Store the **EZ-FPC™ Microorganisms** at 2°C-8°C in the original, sealed vial. 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 expiration date is the last day of the month of expiration.

The **EZ-FPC™ 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 forceps or tweezers are required for the removal of an individual pellet and placement into the enrichment broth or primary dilution fluid.
- In accordance with each individual laboratory's SOP, the enrichment broths, dilution fluids, and required testing materials for qualitative and/or quantitative test methods must be provided.

KEY OF SYMBOLS

Batch Code (Lot)


Biological Hazards Biological Risk

Catalog Number


Caution consult accompanying documents Attention, see instructions for use


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

WEBSITE

Visit our website for current Technical Information, Product Availability, Biohazard Cleanup, Certificate of Analysis and Statistical Analysis Certificate.

www.microbiologics.com

ACKNOWLEDGEMENTS

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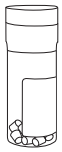
www.microbiologics.com

EZ-FPC™

ILLUSTRATED INSTRUCTIONS

EZ-FPC™ Microorganism kits include: 1 vial containing 10 lyophilized pellets of a single microorangism strain, instructions for use, Peel-Off Certificate of Assay

1

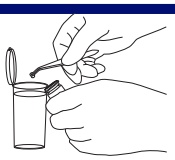


Remove the vial of lyophilized pellets from refrigerated storage. Allow the unopened vial to equilibrate to room temperature (about 30 minutes).

2

Prior to use, warm enrichment broth or dilution fluid to 34˚C-38˚C as stated in laboratory SOP. Sterile pH 7.2 phosphate buffer is recommended for hydration of the lyophilized pellet when performing quantitative challenges.

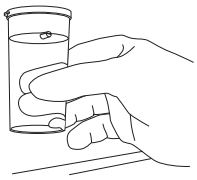
3



With sterile forceps, transfer one 1 pellet to the enrichment broth or dilution fluid. Do not remove the desiccant from the vial. Immediately stopper and recap vial and return to 2˚C-8˚C.

Qualitative Challenge

1



Incubate the inoculated enrichment broth according to the laboratory SOP.

2

At least once during the incubation of the enrichment broth (i.e. following 30 minutes of incubation), mix the flask to ensure an even distribution of hydrated microorganism population.

3

Proceed with the complete qualitative testing procedure as set forth in the laboratory SOP.

Quantitative Challenge

1

Place the microorganism suspension into 34˚C-38˚C incubator for 30 minutes to ensure complete hydration.

2

Immediately following incubation, mix hydrated material until a homogeneous suspension is achieved.

3

Proceed with the challenge according to laboratory protocol.

4

The challenge must be completed within 30 minutes of the hydration process to avoid a change in the challenge suspension concentration.

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