

INSTRUCTIONS FOR USE



■ Epower™ Certified Reference Material Microorganisms

INTENDED USE

The Epower™ Certified Reference Material (CRM) microorganisms are lyophilized, quantitative microorganism preparations to be used in industrial laboratories for quality control purposes. A single Epower™ CRM microorganism can be employed as an individual microorganism challenge or several Epower™ CRM microorganisms can be combined and employed as a mixed microorganism population challenge. These microorganism preparations are traceable to the American Type Culture Collection (ATCC®) or other authentic reference culture collection. CRM is recommended for validation of a new method, verification, calibration, and for quality control when a standard with known phenotypic properties is required.

SUMMARY AND HISTORY

Microbiologics is an accredited reference and certified reference material producer under ISO 17034:2016. This standard defines a reference material as “material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.” They also define a certified reference material (CRM) as “material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a reference material certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.” Each lot of Epower™ CRM microorganisms is tested using Microbiologics’ metrologically valid procedures. The results from these procedures including statements of the specified value and associated uncertainty are listed on the Certificate of Analysis and are unique to the stated lot.

FORMULA COMPONENTS

The lyophilized preparation consists of an enumerated microorganism population, skim milk (bovine - USA origin), a carbohydrate, gelatin (porcine - USA or Canada origin), ascorbic acid, and charcoal. 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 charcoal is included to neutralize any toxic substances formed during the lyophilization process.

Epower™ CRM microorganisms conform with Article 5 of EC 1069/2009 as they have reached the endpoint 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

Epower™ CRM microorganisms are packaged in a kit configuration. Each kit consists of:

- 1 vial containing 10 lyophilized pellets of an individual microorganism strain
- Detailed instructions
- Certificate of Analysis

Epower™ CRM microorganisms are available at a variety of challenge concentrations. These concentrations are identified by the code at the end of the catalog number.

For Example:

Catalog number 0392E3-CRM identifies a challenge concentration of 10^3 CFU per pellet. This means each E3 pellet will contain 1,000 – 9,999 CFU.

Catalog number 0392E6-CRM identifies a challenge concentration of 10^6 CFU per pellet. This means each E6 pellet will contain 1,000,000 – 9,999,999 CFU.



Pellet Concentration	Examples of Concentration (CFU/ml) in Specified Hydration Fluid Volume		
	1 ml	10 ml	100 ml
E2	100 – 999	10 – 99	1 – 9
E3	1,000 – 9,999	100 – 999	10 – 99
E4	10,000 – 99,999	1,000 – 9,999	100 – 999
E6	1,000,000 – 9,999,999	100,000 – 999,999	10,000 – 99,999
E7	10,000,000 – 99,999,999	1,000,000 – 9,999,999	100,000 – 999,999
E8	100,000,000 – 999,999,999	10,000,000 – 99,999,999	1,000,000 – 9,999,999

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

- The identity of the microorganism
- The traceability of the microorganism to a reference culture
- That the microorganism is 1 passage from the reference culture
- The certified value for the microorganism preparation
- The expanded uncertainty

MATERIALS REQUIRED BUT NOT PROVIDED

- **Sterile forceps or tweezers**– required for the removal of an individual pellet and placement into the primary dilution fluid.
- **Enrichment broths, dilution fluids, and required testing materials**– for qualitative or quantitative test methods in accordance with each individual laboratory’s SOP.

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 hydration and dilution fluids to 34°C–38°C. Sterile pH 7.2 phosphate buffer is recommended for hydration of the lyophilized preparation.
3. With sterile forceps, transfer the **Epower™ CRM microorganism** pellet(s) to the hydration fluid. Do not remove the desiccant from vial. Immediately stopper and recap the vial and return to 2°C–8°C.
4. Place the microorganism suspension into a 34°C–38°C incubator for 30 minutes to assure complete hydration.
5. Immediately following incubation, vortex hydrated material until a homogeneous suspension is achieved. Charcoal particles, which may be visible in the hydrated suspension, will not compromise the challenge microorganism.
6. Proceed with the challenge according to laboratory protocol. 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.
- **Epower™ CRM 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 products, and growth of these microorganisms, are considered biohazard material.
- These products 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 products.
- 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.
- **Epower™ CRM microorganisms** are not made with natural rubber latex.
- Possible microorganism degradation may occur over time and may affect the certified value.

TECHNICAL NOTES

Certified Value

- The certified value obtained at Microbiologics was calculated using well proven statistical methods. As part of Microbiologics' quality control procedure, pellets from each **Epower™ CRM microorganism** lot are hydrated in Microbiologics Hydrating Fluid. Replicate colony counts are performed on non-selective agar media and enumerated using an automated colony counting device. Results may differ from the certified value due to different materials and methods used.
- Variability of hydration fluid, sampling, different colony counting techniques, incubation and the use of selective agar media will produce colony counts that vary from the stated mean certified 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.
- 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.

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.

Hydration and Hydration Fluid

- Lyophilized microorganisms must be hydrated to achieve viability. The intrinsic properties of hydration fluids can influence recovery and anticipated assay values.
- The structure of the lyophilized pellet is provided by gelatin, which liquefies when warmed. To liquefy the gelatin, and ensure complete hydration and a uniform suspension of the microorganism population, follow the Instructions for Use.

STORAGE AND EXPIRATION

Store **Epower™ CRM microorganisms** at 2°C–8°C in the original, sealed vial. Stored as directed, the lyophilized microorganism preparation is warranted to retain, until the last day of the month of the expiration date stated on the product label, its specifications and performance within the stated limits.

Epower™ CRM microorganisms should not be used if:

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

KEY OF SYMBOLS



Batch Code (Lot)



Manufacturer



Biological Hazards Biological Risk



Temperature Limitation



Catalog Number



Use By



Caution consult accompanying documents
Attention, see instructions for use

* Please refer to product labels for applicable symbols.

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



Microbiologics, Inc.

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ATCC Licensed
Derivative

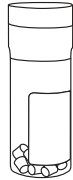
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ILLUSTRATED INSTRUCTIONS

If using the Membrane Filtration Method for water testing, please refer to the Illustrated Instructions (LIT.248) located at www.microbiologics.com.

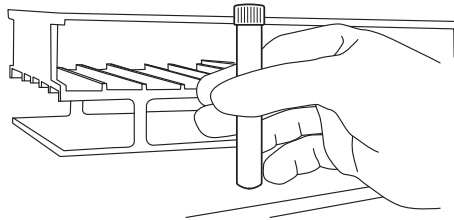
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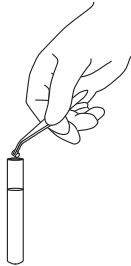
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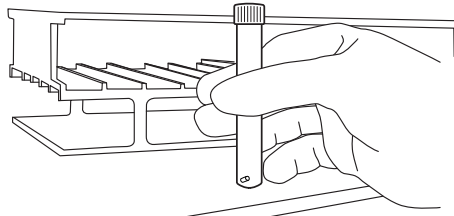
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With sterile forceps, transfer the **Epower™ CRM microorganism** pellet(s) to the hydration fluid. Do not remove the desiccant from vial. Immediately stopper and recap the vial and return to 2°C–8°C.



4

Place the microorganism suspension into a 34°C–38°C incubator for 30 minutes to assure complete hydration.



5

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

Charcoal particles, which may be visible in the hydrated suspension, will not compromise the challenge microorganism.



6

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