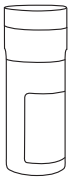
ILLUSTRATED INSTRUCTIONS

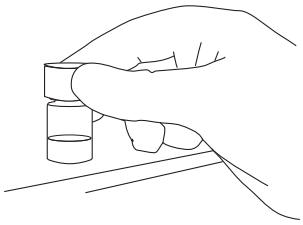
EZ-PEC™ kits include: 2 vials of a single enumerated microorganism (10 lyophilized pellets per vial), 10 vials of hydrating fluid (2 ml in each vial), and a peel off Certificate of Assay

1



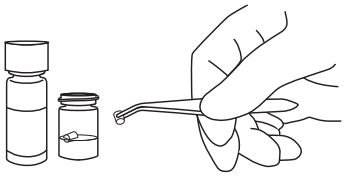
Remove the vial of lyophilized pellets from refrigerated storage (2°C–8°C). Allow the materials to equilibrate to room temperature (about 30 minutes) before opening the vial.

2



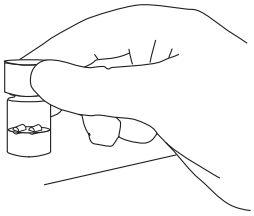
While the pellets are equilibrating, prewarm the hydrating fluid to 34°C–38°C (at least 30 minutes).

3



With a sterile forceps, transfer 2 pellets into the 2 ml vial of hydrating fluid. Do not remove the desiccant from vial. Immediately stopper and recap the pellet vial, and return the remaining lyophilized material to refrigerated storage 2°C–8°C.

4



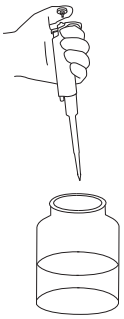
Immediately recap the vial with the hydrated material and place into a 34°C–38°C incubator for 30 minutes to ensure complete hydration.

5

Immediately following incubation, vortex the hydrated material until pellets have completely dissolved and suspension is homogeneous. Charcoal particles, which may be visible in the hydrated suspension, will not compromise the challenge microorganism.

6

With a sterile pipette transfer a volume of hydrated suspension equal to 0.5% to 1.0% of the volume of the product being challenged. A 0.5% to 1.0% addition of microorganisms will automatically result in a concentration of 1.0E+05 to 1.0E+06 CFU per ml of product.



7

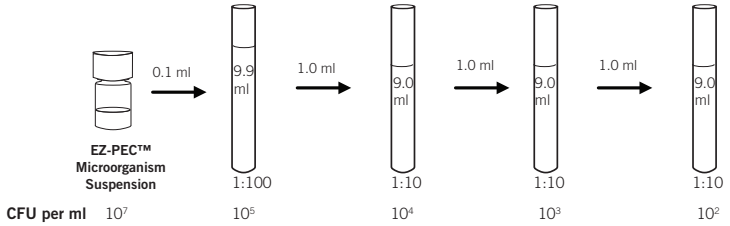
Proceed with the test according to laboratory protocol. The challenge must be completed within 30 minutes of hydration. Discard any remaining hydrated material in accordance with the laboratory protocol for disposal of biohazard materials.

PROCEDURE TO VERIFY CHALLENGE PREPARATION CONCENTRATION

Microbiologics provides a Mean Assay Value for **EZ-PEC™ microorganisms**. If processed as directed, the **EZ-PEC™** product is guaranteed to yield a final concentration of 1.0E+05 to 1.0E+06 CFU per ml of product being tested. To verify the starting CFU concentration of the inoculum, follow the steps below.

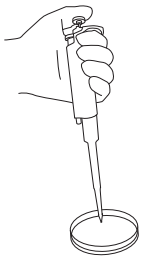
1

Make serial dilutions of the **EZ-PEC™ microorganism** suspension using phosphate buffer pH 7.2.



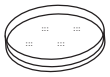
2

Pipette 0.1 ml from the last dilution and plate it in duplicate to Tryptic Soy Agar (TSA) using the spread plate or pour plate method.



3

After incubation, count the colonies and average the number of colonies per TSA plate.



4

Use the following formula to determine the number of CFU added to the product.

$$\text{Number of CFU added to the products} = \text{\# of CFU on TSA} \times 1{,}000{,}000^{*} \times \text{Volume of inoculum}$$

*1,000,000 is the dilution factor

5

Use the following formula to determine the number of CFU per ml of product.

$$\text{Number of CFU per ml of product} = \frac{\text{\# of CFU added to product}}{\text{Volume of product + Volume of inoculum}}$$

Microbiologics®
A safer, healthier world.