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SGMStrip™ Radiation

Bacillus pumilus

TECHNICAL REPORT

Technical Data and Use of SGMStrip™ Radiation

SGM Part #7707
Rev.
11/2/06

INTRODUCTION

SGMStrip™ is a Biological Indicator used in monitoring the efficacy of radiation sterilization cycles. SGMStrip contains spores of *Bacillus pumilus* 27142.⁽¹⁾

STORAGE

SGMStrip should be stored at room temperature. The strips should not be stored near sterilants or other chemicals and have a 24 month shelf life. Do not desiccate.

MEDIUM

Soybean casein digest broth will provide the spores with a nutrient medium for growth.

USE

1. Identify the spore strips by labeling pertinent process or load location information. Place inside the product or product package and place in the most difficult location to sterilize. Refer to the manufacturer's operating manual for guidelines.
2. Place a sufficient number of spore strips throughout the load to be sterilized.
NOTE: Generally, a minimum of 10 strips are used.
3. Expose the load to the validated sterilization cycle.
4. Following exposure, remove the spore strips and transfer them to the laboratory for culturing.
5. In the laboratory, using strict aseptic technique and working in a Class 100 certified workstation, transfer each spore strip into a tube of soybean casein digest broth.
6. Any microbiological incubator that is adjusted for 30°-35°C will satisfy the incubation conditions for the SGMStrip. **NOTE: It is important that this temperature be maintained to achieve accurate results.** The tubes should be placed in the incubator immediately after the strips are cultured. Their placement in an optimized growth environment is necessary to gain accurate results. The medium should be observed for growth for no less than seven days.

INTERPRETATION

The appearance of a cloudy medium or the formation of sediment indicates bacterial growth. Clear medium indicates no growth and that the spores were killed in the sterilization process.

Act on a positive test as soon as it is noted. Carefully review sterilizer process records to assure that all physical process parameters are within specifications. Always assure that loading configuration and product and package specifications are in agreement with the sterilization validation process. Positive units may be subcultured if identification of positive growth is desired.

A positive control should be prepared periodically or at least weekly. Many users perform a positive and negative control for each cycle tested. The positive control typically turns turbid within 24 to 48 hours of incubation. As soon as the control turns positive, it should be

⁽¹⁾ Culture is traceable to a recognized culture collection identified in USP and ISO 11138.

appropriately recorded, autoclaved, and discarded. The positive control should not be held any longer than necessary because of the possibility of contaminating the work area with the test organisms. The positive control is intended to assure the user that viable spores are present on the spore strip and the culture media will support the growth of the test organism prior to testing the sterilizer.

A positive control that truly has not grown is a serious problem. Fortunately, the causes are few: a grossly malfunctioning incubator; inadvertent sterilization of the positive control strip; or inadvertent “sterilization” of the entire box of indicators due to improper storage.

A negative control (a tube incubated without a spore strip) tests the medium for contamination. It should show no signs of growth.

INCUBATION READOUT TIME

The recommended incubation time for SGMStrip is no less than seven days.

PERFORMANCE CHARACTERISTICS

The SGMStrip biological indicators were irradiated and cultured as described above. Exposure conditions consisted of doses in kilograys. Performance data is presented in Table 1:

Table 1: BI Performance of Irradiated SGMStrip

Lot #	Spore Population	D-value ⁽¹⁾ (kilogray)	Survival Time ⁽¹⁾ (kilogray)	Kill Time ⁽¹⁾ (kilogray)
BPUM 122395/S4	2.1 X 10 ⁶	1.1	4.7	11.4
BPUM 122199A/S2-1	1.3 X 10 ⁶	1.2	4.9	12.2
BPUM 122199A/S3-1	2.5 X 10 ⁷	1.2	6.4	13.7

⁽¹⁾ Calculated by the method described by USP.

POPULATION DETERMINATION

The following procedure has been provided to evaluate the spore population of SGMStrips:

NOTE: To avoid inaccurate plate counts, it is important to perform the serial transfers using a 2 mL pipette or whichever pipette has the largest bore size. This will help avoid clogging the tip of the pipette with cotton fibers.

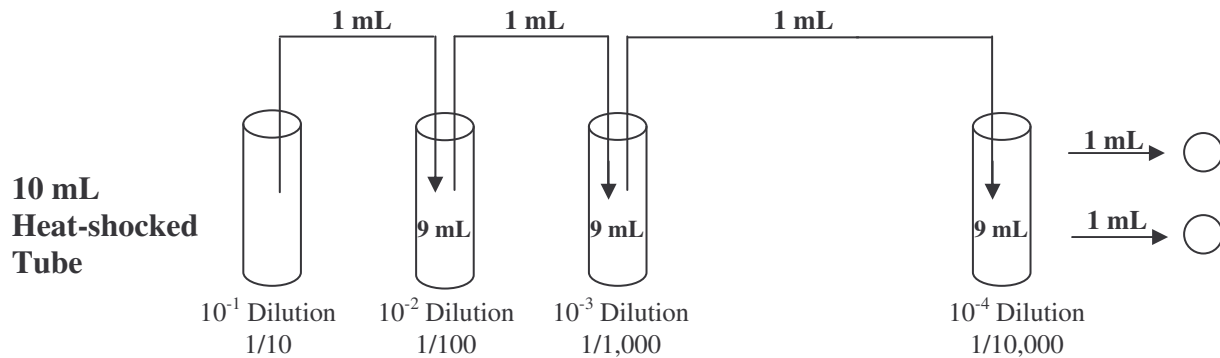
1. Randomly select four inoculated paper carriers from the lot to be assayed.
2. Place each carrier in a sterile, screw cap 19.5 x 145 mm, flat-bottom tube with four 6 mm glass beads, and 5 mL of sterile purified water.
3. Vortex four to seven minutes until the paper carrier is macerated to pulp.
4. Add 5 mL sterile purified water. Vortex again.
5. Heat shock procedure:
 - 5.1. Place the dilution tube in a preheated bath at 65°-70°C for 15 minutes.
 - 5.2. Remove tubes and cool rapidly in ice bath (0°-4°C).

6. Dilution Series:

A dilution series will be made from each tube. Vortex each heat-shocked tube (10^{-1} dilution) for at least 10 seconds. From each tube, transfer a 1 mL aliquot to a dilution tube containing 9 mL of sterile purified water (10^{-2} dilution). Vortex the dilution tube for at least 10 seconds. Transfer 1 mL to a second dilution tube containing 9 mL of sterile purified water (10^{-3} dilution). **Repeat this step one more time** (10^{-4} dilution). Vortex this tube for at least 10 seconds. Pipette 1 mL from this dilution tube into two 15 x 100 mm Petri plates.

NOTE: Alternatively any volume between 0.5 mL and 2 mL may be plated if the 1 mL volume has the potential to fall outside the preferred 30-300 CFUs window.

Pour approximately 20 mL of melted TSA Difco agar cooled to 45° to 50°C into the Petri plates. Swirl to assure adequate mixing and allow the agar to solidify. Do not use agar that has been melted and held longer than eight hours.



NOTE: It is extremely important to make each serial transfer immediately after vortexing.

7. Invert and incubate plates at 30° - 35°C .
8. After 48 hours of incubation, count plates. Preferably plates with counts between 30 and 300 CFUs should be used, but not less than six per USP.
9. Average counts and then multiply by the dilution factor to calculate population per original unit.

CERTIFICATION

SGM Biotech tests each lot of SGMStrips prior to release. Each lot of SGMStrips is supplied with the following certificate:



Reorder No. SGMR/x

Bacillus pumilus 27142⁽¹⁾

For: Radiation Sterilization

Culture: Soybean casein digest broth.

Purity: No evidence of contaminants using standard plate count techniques.

Lot No.: BPUM-

Manufacture Date: YEAR MONTH DAY

Expiration: 24 months from Manufacture Date.

Heat Shocked Population: 0.0 x 10^x Spores/Unit

Assayed Resistance:

D-value⁽²⁾

Radiation (Co⁶⁰) 0.0 kGy

D-value reproducible only when exposed and cultured under the exact conditions used to obtain results reported here. MPN and Survivor Curve methods used.

Units are manufactured in compliance with SGM Biotech's quality standards and all appropriate subsections.

⁽¹⁾ Culture is traceable to a recognized culture collection identified in USP and ISO 11138.

⁽²⁾ D-value calculated using the Limited-Holcomb- Spearman-Karber method.

Certified By: _____