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President

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SGMStrip™ EO Gas and Dry Heat

Bacillus atrophaeus

TECHNICAL REPORT

Complies with:
USP
and
ISO 11138

SGM Part #7706
Rev. 8
17FEB09

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INTRODUCTION

SGMStrip™ is a biological indicator used in monitoring the efficacy of ethylene oxide or dry heat sterilization cycles. SGMStrip contains spores of *Bacillus atrophaeus* 9372[(1)] and meets USP and ISO 11138 requirements.

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 and appropriate aeration 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 containing soybean casein digest broth.

6. Any microbiological incubator that is adjusted for 30-35^{o} 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.

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

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 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.

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 & STABILITY CHARACTERISTICS

Ethylene Oxide (EO) resistance assessment testing is performed by exposing SGM Strip biological indicators (BIs) in an EO gas BIER (biological indicator evaluator resistometer) conforming to ANSI/AAMI/ISO. BIER exposure conditions are 600 mg/L ± 30 mg/L EO, 54°C and 60% ± 10% RH (relative humidity).

Dry Heat (DH) resistance assessment testing is performed by exposing SGMStrip BIs in a DH BIER conforming to ANSI/AAMI/ISO. BIER exposure conditions are 160°C ± 2°C. Additional D-value assessment at 150°C and 170°C are performed for calculation of Z-value.

The 24 month shelf life was determined through real time stability studies in which the spore population is assessed and survival/kill times confirmed at expiration. The data in Table 1 shows BI population and resistance stability for three lots of SGMStrips each manufactured from different *Bacillus atrophaeus* spore crops. In each case, spore population recovery at expiry was within acceptable limits as specified by USP and ISO. All calculated survival and kill time testing at expiry successfully confirmed resistance stability.

Table 1
EO and DH Performance/Stability Data

Lot #	Spore Population		EO Resistance Performance				DH Resistance Performance			
	Initial	24 months	D_{EO}-value (minutes)	Survival Time (minutes)	Kill Time (minutes)	Resistance Confirmation at Expiry (pass / fail)	$D_{160°C}$-value (minutes)	Survival Time (minutes)	Kill Time (minutes)	Resistance Confirmation at Expiry (pass / fail)
031103/S5-1	2.7×10^6	2.2×10^6	4.6	20.38	47.98	Pass	2.1	9.31	21.91	Pass
073002A/S2-3	2.1×10^6	2.2×10^6	4.2	18.1	43.4	Pass	2.2	9.5	22.7	Pass
011105/S3-1	2.0×10^6	2.7×10^6	4.9	21.07	50.47	Pass	1.9	8.17	19.57	Pass

POPULATION DETERMINATION

Detailed population assay instructions are available in pdf format on the SGM Biotech web site. From the www.sgmbiotech.com home page, select 'Population Assay Kit' under the 'Related Products' tab. Then click on 'Product Manuals' on the right.

CERTIFICATION

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

SGM STRIP™

BIOLOGICAL INDICATOR

For Industrial Use Only

CERTIFICATE OF ANALYSIS

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Reorder No.: SGMG/0

Bacillus atrophaeus 9372[1]

Biological Indicator for: Ethylene Oxide / Dry Heat Sterilization.

Culture: Soybean casein digest broth

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

Lot No.: BATR-000 Manufacture Date: YEAR MONTH DAY

Expiration: 24 months from Manufacture Date

Heat Shocked Population: 0.0×10^0 Spores / Unit

Assayed Resistance:	D-Value[2]	Survival[3]	Kill[3]	
Ethylene Oxide: (600 ± 30 mg/L, 60 ± 10% RH, 54 ± 1°C)	0.0	00.00	00.00	min
Dry Heat (160°C):	0.0	00.00	00.00	min

Z-value: 0.0°C

D-value reproducible only when exposed in an AAMI BIER vessel and cultured under the exact conditions used to obtain results reported here. MPN method used.

Units are manufactured in compliance with SGM Biotech's quality standards, USP, ISO 11138 guidelines, 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.
(3) Survival/Kill values are calculated according to USP and ISO 11138.

Certified By: _____

Complete Quality Control testing results available upon request.