CL627-107

SporAmpule®

BIOLOGICAL MONITORING

SporAmpules are a unitary biological indicator for use with steam and washer/sterilizer processes. Each SporAmpule contains *Bacillus stearothermophilus* ATCC No. 7953 *(Geobacillus stearothermophilus)* spores suspended in a culture medium containing bromcresol purple as a pH indicator. Acid production during growth changes the color from purple to yellow, facilitating detection of growth.

PROCEDURE

Place two or more SporAmpules in sterilizer load in places most difficult to sterilize (i.e. front and back). After processing, open sterilizer door a crack and **allow load to cool before removing SporAmpules.** Write the required information on both "Test" and "Control" labels provided in the record notebook. Affix "Test" labels to the top of the processed SporAmpules and "Control" label to the top of an *unprocessed* SporAmpule and incubate at 56°C. The *unprocessed* SporAmpule should also be incubated as a Control, in order to document the integrity of the Test results.

Examine the incubated SporAmpules (Test and Control) after 48 hours of incubation for the appearance of turbidity (growth) and a yellow color, indicating failure of the sterilization process. The SporAmpule design allows for extended incubation without fear of reversion or medium evaporation. SporAmpules remaining purple indicate that sterilization has been accomplished, provided that the *unprocessed* Control shows growth. Fill in the Recording notebook as indicated and circle test results obtained. **To satisfy your state and local laws, you may retain the used SporAmpules in the original box for physical verification.**

PRECAUTIONS

The contents of sterilizers which are too tightly packed, may not reach the proper temperature for sterilization. Heavily loaded sterilizers require extended come-up times and may cause the SporAmpule to appear a red to brownish color. Such SporAmpules are usually negative and do not develop a yellow color on incubation.

SporAmpules contain live cultures and should be handled with care to prevent breakage. They should be stored in the refrigerator at 2° to 8°C, but should not be stored along with foods or biologicals. Should an ampule be broken, carefully clean up the glass, and wipe the area of the spill with an acceptable disinfectant. Dispose of materials in accordance with institution's procedures for laboratory waste and glassware.

CERTIFICATION

Geobacillus stearothermophilus

Incubate: 55° to 60°C
Storage: 2° to 8°C
Disposal: Autoclave or incinerate

Lot No.	601
Exp. Date:	12/04

Population per SporAmpule: 2.5 X 10^5 CFU * / 1.9 mL ampule
****D-value at 121.1 ± 0.5°C:** 1.9 minutes
*****Z-value:** 9.2°C (approximate, based on 121.1°, 126° & 132°C, exposure temperatures)

Performance Characteristics: (Based on USP Calculations)

PROCESS	TEMPERATURE	SURVIVES (+)	KILLED (-)
Steam (Saturated)	250°F (121.1°C)	6.5 minutes	17.9 minutes

* Colony forming units

** The normal resistance of the SporAmpule; i.e., the time (in minutes) to reduce the spore population by 90%. D-value determined using Fraction Negative analysis (Spearman-Karber method) and is reproducible only when exposed and cultured under the exact conditions used to obtain results reported here. The user should determine the suitability of the SporAmpule for the intended use.

*** The number of degrees (in Celsius) to change the D-value by a factor of 10.

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