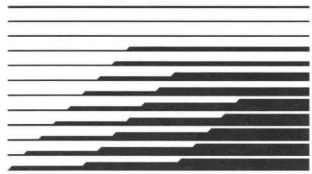


M E S A



L A B S

CERTIFICATE OF ANALYSIS

MESA BIOLOGICAL INDICATORS

ProSpore2 Self-Contained Biological Indicators (with *Geobacillus stearothermophilus*) - Recommended for use in evaluating 121 C **steam** sterilization processes.

This document certifies that the biological indicators for this lot meet 'Mesa Labs' quality control specifications, AAMI/ISO 11138-1, AAMI/ISO 11138-3 and suggested performance parameters published in the current United States Pharmacopeia.

Thomas Halpenny
Quality Assurance Specialist
Mesa Labs

Manufacture: **07Feb2013**

Release: **22Feb2013**

Performance Data for Lot # **1148** Batch **1126S** Expiration Date **8/2014**

Organism: ***Geobacillus stearothermophilus*** ATCC No. 7953

Mean Disc Recovery	2.7 x 10⁵	CFU* / 0.215" x 0.75" paper strip
D ₁₂₁ Value	1.6	minutes** (Saturated steam at 121.1°C)
D ₁₃₂ Value	0.20	minutes (Saturated steam, extrapolated from Z Value**)
Z Value	11.6	C*** approximate; (based on ISO 11138-3)

* colony forming units

** Determined on primary spore crop using Fraction-Negative (Spearman-Karber method). The D-value is reproducible only under the exact conditions under which it was determined. The user would not necessarily obtain the same results. Therefore, the user would need to determine the suitability for its particular use.

*** See reverse side.

Resistance Characteristics: (Based on US Pharmacopeia Calculations)

AGENT	CONDITIONS	SURVIVED	KILLED
Saturated Steam	121.1 ± 0.5°C	5.5 min.	15.1 min.
Saturated Steam	132°C	0.7 min.	1.9 min.

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

Incubation: 24 hours at 55 - 60°C. See instructions for use.

Storage: 60 - 80°F (15-27°C), 30 - 70% RH, away from sterilizing agents, direct sunlight and all other forms of UV light. (Do Not Refrigerate).

Disposal: Do not use after expiration date. Sterilize all cultures before discarding.

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Our Quality System is Registered to ISO 13485 Standards

Lot# 1148: Z-value

◆ D-value G. stearotheophilus (steam)

