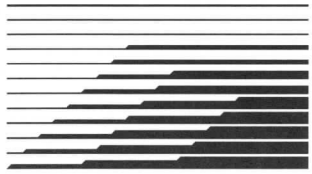


M E S A



L A B S

CERTIFICATE OF ANALYSIS

MESA BIOLOGICAL INDICATORS

Bacillus atrophaeus Spore Strips - Recommended for use in evaluating Dry Heat or Ethylene Oxide gas sterilization processes.

This document certifies that the biological indicators for this lot meet Mesa Labs' quality control specifications, AAMI/ISO 11138:2006 parts 1 & 2 and suggested performance parameters published in the current United States Pharmacopeia.

Thomas Halpenny
Quality Assurance Specialist
Mesa Labs

Manufacture: **18Feb2013**
Release: **04Mar2013**

Performance Data for Lot # **1163151** Batch **315GB** Expiration Date **2/2015**

Organism: ***Bacillus atrophaeus*** ATCC^(R) No. 9372

Nominal Population	4.0 x 10⁶	CFU* /1.5" x 0.25" strip
D _{EtO} Value**	3.9	minutes (600 mg EtO/L, 54°C, 60% RH- This accuracy shall not exceed +/- 0.5)
D ₁₆₀ Value**	1.1	minutes (Dry Heat, 160°C- This accuracy shall not exceed +/- 0.2)
Z-value***	36.7	°C; approximate

* Colony Forming Units

** Determined on primary spore crop using paper strips in glassine envelopes, 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	SURVIVES	KILLED
Ethylene Oxide	54 ± 1°C, 600 ± 30 mg/L, 60 ± 10% RH	17.9 min.	41.3 min.
Dry Heat	160 ± 2°C	5.1 min.	11.7 min.

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

Incubation: 7 days in soybean-casein digest broth at a temperature of 30 - 35°C

Storage: 15 - 27°C (60 - 80°F), 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.

ATCC is a Registered Trademark of the American Type Culture Collection.

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Our Quality System is Registered to ISO 13485 Standards

Lot# 1163151: z-value

◆ D-value *B. atrophaeus* (dry heat)

