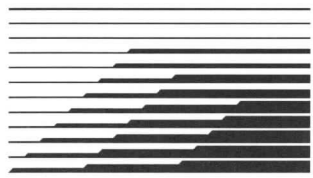


M E S A



L A B S

**CERTIFICATE OF ANALYSIS**

MESA BIOLOGICAL INDICATORS

**ProSpore** self-contained biological indicator - Recommended for use in evaluating Steam sterilization at 121°C.

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

Thomas Halpenny  
Quality Assurance Specialist  
Mesa Labs

Manufacture: **01Mar2013**

Release: **12Mar2013**

Performance Data for Lot # **593**      Batch **1093S**      Expiration Date **9/2014**

Organism: ***Geobacillus stearothermophilus***      ATCC<sup>(R)</sup># 7953

Nominal Population	<b>2.0 x 10<sup>6</sup></b>	CFU* / 4mL ampoule
D <sub>121</sub> Value	<b>1.5</b>	minutes** (Saturated steam at 121.1°C)
D <sub>132</sub> Value	<b>0.07</b>	minutes (Saturated steam, extrapolated from Z Value**)
Z Value	<b>8.0</b>	°C*** (approximate; based on ISO 11138-3)

\* colony forming units

\*\* Determined at time of manufacture, Fraction Negative analysis (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	<b>6.5</b> min.	<b>15.5</b> min.

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

Incubation: 48 hours at 55 - 60°C.

Storage: Refrigerate at 2-8°C.

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

ATCC is a Registered Trademark of the American Type Culture Collection.  
09/10/12

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**Our Quality System is Registered to ISO 13485 Standards**

# Lot# 593: Z-value

◆ D-value G. stearotheophilus (steam)

