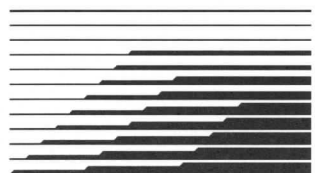


M E S A



L A B S

CERTIFICATE OF ANALYSIS

MESA BIOLOGICAL INDICATORS

Geobacillus stearothermophilus Spore Suspension - Recommended for use in evaluating steam sterilization processes.

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.

Thomas Halpenny
Quality Assurance Specialist
Mesa Labs

Manufacture: **13Feb2013**

Release: **20Feb2013**

Performance Data for Lot # **3061481**

Batch **1148S**

Expiration Date **2/2014**

Organism: ***Geobacillus stearothermophilus***

ATCC^(R)No. 7953

Volume **10**

ml 40% Ethanol in DI water suspension / vial

Label Population Claim **3.1×10^6**

CFU* / 0.1 ml

Mean Suspension Recovery **3.1×10^7**

CFU* / ml

D₁₂₁ Value** **1.6**

minutes (Saturated steam at 121.1°C)

* colony forming units

** Determined on primary spore crop using paper strips in glassine envelopes, using Fraction-Negative analysis (Spearman-Kärber 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.

Resistance Characteristics:

Survival time (in minutes) = not less than (labeled D-value) x (log₁₀ labeled spore count per carrier - 2); and Kill time (in minutes) = not more than (labeled D-value) x (log₁₀ labeled spore count per carrier + 4).

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

Incubation: 7 days in soybean-casein digest broth at a temperature of 55 - 60°C

Storage: Refrigerate at 2 to 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.

01/23/13

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Our Quality System is Registered to ISO 13485 Standards

Lot# 3061481: z-value

◆ D-value *G. stearotherophilus* (steam)

