MesaStrip™ LTS/Formaldehyde

Geobacillus stearothermophilus

TECHNICAL REPORT

Complies with:
USP
ISO 11138
and all appropriate subsections.

Rev.1
TR-010

INTRODUCTION

MesaStrip LTS/Formaldehyde is a biological indicator used in monitoring the efficacy of low-temperature steam and formaldehyde sterilization cycles. MesaStrip LTS/Formaldehyde contains spores of *Geobacillus stearothermophilus*, 7953[1] and meets ISO 11138 and ISO 18472 requirements.

STORAGE

MesaStrip LTS/Formaldehyde should be stored at room temperature. The strips should not be stored near sterilants or other chemicals, and have a 24 month shelf life. Do not desiccate.

MEDIUM

Soybean casein digest broth will provide the spores with a nutrient medium for growth.

USE

1. Identify the spore strips by labeling pertinent process or load location information. Place inside the product, product package or challenge device and place in the most difficult location to sterilize. Refer to the manufacturer's operating manual for guidelines.

2. Place a sufficient number of spore strips throughout the load to be sterilized.

   NOTE: Generally, a minimum of 10 strips are used.

3. Expose the load to the validated sterilization cycle.

4. Following exposure, remove the spore strips and transfer them to the laboratory for culturing.

5. In the laboratory, using strict aseptic technique and working in a Class 100 certified workstation, transfer each spore strip into a tube containing soybean casein digest broth.

6. Heat shock the tubes at 90°C for 60 minutes, cool in an ice bath, then incubate. NOTE: This step is not required but is recommended in ISO 11138-5.

7. Any microbiological incubator that is adjusted for 55 – 60°C will satisfy the incubation conditions for the MesaStrip. NOTE: It is important that this temperature be maintained to achieve accurate results. The tubes should be placed in the incubator immediately after the strips are cultured. Their placement in an optimized growth environment is necessary to gain accurate results. The medium should be observed for growth for seven days.

INTERPRETATION

The appearance of a cloudy medium for the formation of sediment indicates bacterial growth. Clear medium indicates no growth and that the spores were killed in the sterilization process.

Act on a positive test as soon as it is noted. Carefully review sterilizer process records to ensure that all physical process parameters are within specifications. Always ensure that loading configuration and

[1] Culture is traceable to a recognized culture collection identified in USP and ISO 11138.

product and package specifications are in agreement with the sterilization validation process. Positive units may be subcultured if identification of positive growth is desired.

A positive control should be prepared periodically or at least weekly. Many users perform a positive and negative control for each cycle tested. The positive control typically turns turbid within 24 to 48 hours of incubation. As soon as the control turns positive, it should be appropriately recorded, autoclaved and discarded. The positive control should not be held any longer than necessary because of the possibility of contaminating the work area with the test organisms. The positive control is intended to ensure the user that viable spores are present on the spore strip and the culture media will support the growth of the test organism.

A positive control that truly has not grown is a serious problem. Fortunately, the causes are few: a grossly malfunctioning incubator, inadvertent sterilization of the positive control strip; or inadvertent 'sterilization' of the entire box of indicators due to improper storage.

A negative control (a tube incubated without a spore strip) tests the medium for contamination. It should show no signs of growth.

INCUBATION READOUT TIME

The recommended incubation time for MesaStrip LTS/Formaldehyde is seven days.

PERFORMANCE CHARACTERISTICS

The MesaStrip LTS/Formaldehyde biological indicators were exposed per ISO/AAMI/EN 11138-5, Annex A, to 1M formaldehyde liquid. A D_{60}-value (in minutes) is assessed and results are listed in Table 1.

Table 1
BI Performance of MesaStrip Steam Biological Indicators at 60°C in 1M Liquid Formaldehyde

Lot #	Spore Population	D-value (7 days)	Survival Time[1] (in minutes)	Kill Time[1] (in minutes)
BST-090398	3.2×10^6	18.8	84.7	197.5
BST-295	2.3×10^6	11.7	51.0	121.2
BST-298	2.0×10^6	15.3	65.8	157.6

[1] Calculated by the method described in ISO.

POPULATION DETERMINATION

Detailed population assay instructions are available in PDF format on the website. Log onto the www.mesalabs.com home page and select: Documents & Downloads → Documents → Biological Indicators → Population Assays/Protocol/Procedures → Population Assay Procedures (Bozeman products).

CERTIFICATION

Mesa Laboratories, Bozeman Manufacturing Facility, tests each lot of MesaStrip prior to release. Each lot of MesaStrip is supplied with the following certificate.

MESASTRIP

BIOLOGICAL INDICATOR

For Industrial Use Only

CERTIFICATE OF ANALYSIS

Reorder No.:

Geobacillus stearothermophilus 7953[1]

For: Low-Temperature Steam and Formaldehyde Sterilization

Culture: Soybean casein digest broth

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

Lot No.: GSLF-000 Manufacture Date: YEAR MONTH DAY

Expiration: YEAR MONTH DAY

Heat Shocked Population: 0.0×10^0 Spores/Unit

Carrier Size: 1" x ¼" (25 mm x 6 mm)

Assayed Resistance:

Temperature	D-value[2]	Survival	Kill	
60ºC	0.0	00.00[3]	00.00[3]	minutes

D-value reproducible only when tested in accordance with ISO 11138-5, Annex A, and cultured under the exact conditions used to obtain results reported here. MPN method used.

Units are manufactured in compliance with Mesa Laboratories' quality standards, ISO 11138 and all appropriate subsections.

[1]Culture is traceable to a recognized culture collection identified in USP and ISO 11138.
[2] D-value calculated using the Limited-Holcomb-Spearman-Karber method.
[3] Empirically derived data. A D-value rounded to four decimal places is used in this calculation.

Certified By: _____
Quality Representative

Complete Quality Control testing available upon request.