

MesaStrip Steam

Geobacillus stearothermophilus

TECHNICAL REPORT

Complies to
USP, ISO 11138,
and all appropriate subsections

Technical Data and Use of the MesaStrip Steam

Rev.4
TR-009

INTRODUCTION

MesaStrip is a Biological Indicator used in monitoring the efficacy of steam sterilization cycles. MesaStrip contains spores of *Geobacillus stearothermophilus* 7953¹, and meets USP and ISO 11138 requirements.

STORAGE

MesaStrip 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

MesaStrip can be cultured into Mesa Labs Purple Releasat Culture Medium consisting of a modified soybean casein digest base, providing spores with a nutrient medium for growth. The culture medium has a pH indicator added to it, which appears as a purple color. If viable spores are added, the medium changes to yellow as the acidic metabolic by-products of the growing bacteria accumulate. If the medium remains purple and clear after the spore strip is added, no microbial growth occurred, indicating that the spores were killed in the sterilization process. Therefore, if the sterilization process was not effective, the spores will grow, and medium will turn yellow and cloudy. If a media tube shows signs of a visual color change or turbidity prior to use, it should be autoclaved and discarded.

Soybean Casein Digest Medium (SCDM)/Tryptic Soy Broth (TSB) will also 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 or product package 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.
3. Expose the load to the validation 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 Mesa Labs Purple Releasat Culture Medium or SCDM/TSB.
6. 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.

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

7. The tubes should be placed in the incubator immediately after the strips are cultured. Their placement in an optimized environment is necessary to gain accurate results. The medium should be observed for growth for no less than seven days.

INTERPRETATION

For Purple Releasat Culture Medium: The appearance of a yellow color read-out indicates bacterial growth. No color change indicates the spores were killed in the sterilization process.

For SCDM/TSB: The appearance of a cloudy medium or 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 (color change to yellow or turbidity) 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 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 is intended to assure 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 media tube incubated without a spore strip) tests the medium for contamination. It should show no signs of growth.

INCUBATION READ-OUT TIME

The recommended incubation time for MesaStrip in Mesa Labs Purple Releasat Culture Medium or SCDM/TSB is no less than seven days.

PERFORMANCE CHARACTERISTICS

The MesaStrip steam biological indicators were exposed in a steam BIER vessel conforming to AAMI standards and cultured as described above. The exposure temperature was $121^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$. This information, the extrapolated 134°C D-value and the z-value are presented in Table 1.

Table 1
BI Performance of MesaStrip Steam Biological Indicators

Lot #	Spore Population	D-value (minutes)		Z-value (°C)
		121°C	134°C	
GST-080612/S4-1	1.8 x 10 ⁵	1.9 ⁽¹⁾	0.07 ⁽²⁾	9.0 ⁽³⁾
GST-100912/S3-1	2.7 x 10 ⁵	1.6 ⁽¹⁾	0.06 ⁽²⁾	9.1 ⁽³⁾
GST-020714/S2-1	2.3 x 10 ⁵	1.8 ⁽¹⁾	0.05 ⁽²⁾	8.3 ⁽³⁾
GST-071012	2.5 x 10 ⁶	2.1 ⁽¹⁾	0.06 ⁽²⁾	8.3 ⁽³⁾
GST-080612/S4-1	2.4 x 10 ⁶	2.2 ⁽¹⁾	0.04 ⁽²⁾	7.7 ⁽³⁾
GST-111115/S2-1	2.0 x 10 ⁶	2.3 ⁽¹⁾	0.08 ⁽²⁾	8.8 ⁽³⁾

⁽¹⁾ Calculated by Fraction Negative method described in ISO 11138-1.

⁽²⁾ Extrapolated data.

⁽³⁾ Calculated by method described in ANSI/AAME ISO1138-3: 2017 and calculated using D values from 121°, 124°, 127° steam data

POPULATION DETERMINATION

Detailed population assay instructions are available in PDF format on the Mesa Labs website.

<http://biologicalindicators.mesalabs.com/documents-manuals/>

CERTIFICATION

Mesa Laboratories tests each lot of MesaStrips prior to release. Each lot of MesaStrips is supplied with a Certificate of Analysis (Figure 1).

Figure 1: Sample Certificate of Analysis

MESASTRIP

BIOLOGICAL INDICATOR
For Industrial Use Only
CERTIFICATE OF ANALYSIS

Reorder No.: SGMS/6

Geobacillus stearothermophilus 7953⁽¹⁾

Biological Indicator for: Steam Sterilization.

Culture: 55 – 60°C. Soybean casein digest broth.

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

Lot No.: **GST-000** Manufacture Date: YYYY-MM-DD

Expiration Date: YYYY-MM-DD

Heat Shocked Population: 0.0 x 10⁶ Spores / Unit

Carrier Size: 1" x ¼" (25 mm x 6 mm)

Assayed Resistance:

	D-Value	Survival	Kill	
121°C	0.0 ⁽²⁾	00.0 ⁽³⁾	00.0 ⁽³⁾	min
134°C	0.0 ⁽⁴⁾	00.0 ⁽⁴⁾	00.0 ⁽⁴⁾	min

Z-value: 00.0°C

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

⁽¹⁾ Culture is traceable to a recognized culture collection identified in USP and ISO 11138.⁽²⁾ Resistance was determined in an AAMI BIER vessel using a paper carrier packaged in glassine and calculated using the Fraction Negative method. The D-value is reproducible only when exposed and cultured under the exact conditions used to obtain results reported here.⁽³⁾ Survival/Kill values are calculated according to USP and ISO 11138. A D-value rounded to four decimal places is used in this calculation⁽⁴⁾ Extrapolated data.

Certified By: _____

Quality Assurance

Date



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