MesaStrip Steam

Geobacillus stearothermophilus

TECHNICAL REPORT

Complies to
USP, ISO 11138,
and all appropriate subsections

Technical Data and Use of the MesaStrip Steam

Rev.2
TR-009

INTRODUCTION

MesaStrip is a Biological Indicator used in monitoring the efficacy of steam sterilization cycles. MesaStrip contains spores of *Geobacillus stearothermophilus* 7953[1], 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 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 broth 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.

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

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 soybean casein digest broth.

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.

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. If using TSB, the

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

medium should be observed for growth for no less than seven days. If using Releasat, the medium can be observed for color change at 24 hours.

INTERPRETATION

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

For 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 TSB is no less than seven days.

The recommended incubation time for the Purple Releasat Culture medium is 24 hours. Mesa Labs has performed the FDA protocol for determining the incubation read-out time and the data meets the FDA criteria after 24 hours of incubation.

The incubation time of Mesa Labs' Purple Releasat Culture Medium product was validated according to the Center of Devices and Radiological Health, FDA protocol entitled "Guide for Validation of Biological Indicator Incubation Time". Three lots of Releasat medium were prepared according to Mesa Labs' standard operating procedures for steam exposure. For each lot, 100 biological indicator strips were exposed to a steam BIER cycle for the times indicated in Table 1. Steam exposure conditions were as specified in ISO 18472. The exposed strips were transferred to Releasat medium and incubated at 55-60°C for seven days. The tubes that had microbial growth were counted at 24 hours and seven days. The results of the tests that were valid according to the FDA protocol (between 30% and 80% of the tubes positive for microbial growth) are shown in Table 1.

Table I
Results of the Reduced Incubation Time Study (Steam)

Releasat Lot Number	Exposure Time (Minutes)	Number Positive 24 Hours	Number Positive 7 days	Percent Positive[1]
1	14.0	46	47	98
2	13.5	79	80	99
3	14.5	43	43	100

[1] Acceptable protocol results require greater than 97% of the base number of biological indicators to test positive. This percentage is calculated by using the number of positive biological indicators on day 7 as the base number (denominator data), the number of positive biological indicators at 24 hours as the numerator, and multiplying by 100.

This data shows that the 24 hour incubation time claim was valid (ratio of positives at 24 hours vs. seven days greater than 97%). 24 hour incubation times provide users with a rapid release of sterilized product. It should be emphasized that incubator performance is critical to achieve these incubation times.

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 temperatures were 121°C ± 0.5°C and 134°C ± 0.5°C. This information and the Z-value are presented in Table 1.

Table 1
BI Performance of MesaStrip Steam Biological Indicators at 121°C ± 0.5°C and 134°C ± 0.5°C

Lot #	Spore Population	D-value (minutes)		Survival Time (minutes)		Kill Time (minutes)		Z-value (°C)
		121°C	134°C	121°C	134°C	121°C	134°C	
BST-100300/S5-1	2.1×10^5	2.1[1]	0.05[1]	6.9[1]	0.16[2]	19.6[1]	0.50[2]	7.8[3]
BST-110700/S4-1	3.2×10^5	2.4[1]	0.10[1]	8.4[1]	0.16[2]	22.9[1]	0.50[2]	8.8[3]
BST-093098/S3-1	2.3×10^5	1.9[1]	0.10[1]	6.3[1]	0.17[2]	17.8[1]	0.50[2]	10.0[3]
BST-091900/S3-4	1.1×10^6	1.7[1]	0.02[1]	6.8[1]	0.08[2]	17.0[1]	0.26[2]	8.6[3]
BST-052300/S2-1	1.7×10^6	2.3[1]	0.10[1]	9.7[1]	0.16[2]	23.6[1]	0.50[2]	7.6[3]
BST-093098/S4-1	1.1×10^6	2.0[1]	0.10[1]	8.0[1]	0.17[2]	20.0[1]	0.67[2]	9.8[3]

[1] Calculated by the method described by USP.
[2] Empirically derived data.
[3] Calculated by method described in ANSI/AAME ISO1138-3:2006 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 – Bozeman Manufacturing Facility website. Log onto the mesalabs.com home page. Under documents & Downloads, select Documents; then select Biological Indicators. Under Population Assays/Protocol/Procedures, select Population Assay Procedures (Bozeman Products).

CERTIFICATION

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

MESASTRIP
BIOLOGICAL INDICATOR
For Industrial Use Only

CERTIFICATE OF ANALYSIS

Reorder No.:

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- Manufacture Date:

Expiration Date: 24 months from Manufacture Date.

Heat Shocked Population: x 10^0 Spores / Unit

Carrier Size: 1" x ¼" (25 mm x 6 mm)

Assayed Resistance:

Temperature	D-Value[2]	Survival	Kill	min
121°C		[3]	[3]	
134°C	[4]	0.17 [4]	0.85 [4]	min

Z-value: °C

D-value reproducible only when exposed in an AAMI BIER vessel 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, 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] D-value calculated using the Limited-Holcomb-Spearman-Karber method.
[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 Representative

Complete Quality Control testing results available upon request.

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