

MesaStrip for EO and Dry Heat

Bacillus atrophaeus

TECHNICAL REPORT

Complies with:
USP
ISO 11138
and all appropriate subsections.

Technical Data and Use of MesaStrip EO and Dry Heat

Rev.2
TR-007

INTRODUCTION

MesaStrip is a biological indicator used in monitoring the efficacy of ethylene oxide or dry heat sterilization processes. MesaStrip contains spores of *Bacillus atrophaeus* 9372¹ 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

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 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 validated sterilization cycle.
4. Following the exposure and appropriate aeration, 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 30-35°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 no less than seven days.

INTERPRETATION

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 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

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

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 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 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 is no less than seven days.

PERFORMANCE & STABILITY CHARACTERISTICS

Ethylene Oxide (EO) resistance assessment testing is performed by exposing MesaStrip biological indicators (BIs) in an EO BIER (biological indicator evaluator resistometer) conforming to ANSI/AAMI/ISO. BIER exposure conditions are 600 mg/L \pm 30 mg/L EO, 54°C and 60% \pm 10% RH (relative humidity). Ethylene oxide exposure performance data is presented in Table 1

Dry Heat (DH) resistance assessment testing is performed by exposing MesaStrip BIs in a DH BIER conforming to ANSI/AAMI/ISO. BIER exposure conditions are 160°C \pm 2.5°C. Additional D-value assessment at 150°C and 170°C are performed for calculation of Z-value. Dry Heat exposure performance data is presented in Table 2.

Table 1
100% Ethylene Oxide Resistance Performance Data

BI Lot Number	Number of Positive Out of Twenty-Five (25)						Population/Unit	D-value ⁽¹⁾ (minutes)
	Exposure Times (in minutes)							
	18	20	22	24	26	28		
BATR-442	25	15	7	0	0	0	2.2 x 10 ⁶	3.1
BATR-445	25	18	7	4	0	0	3.3 x 10 ⁶	3.2
BATR-446	25	18	6	0	0	0	2.4 x 10 ⁶	3.2

(1) Calculated according to USP methods

Table 2
160°C Dry Heat Resistance Performance Data

BI Lot Number	Number Positive Out of Twenty-Five (25)								Population/Unit	D-value ⁽¹⁾ (minutes)
	Exposure Times (in minutes)									
	10	11	12	13	14	15	16	17		
BATR-436	25	25	25	25	16	19	8	0	2.6 x 10 ⁶	2.3
BATR-442	25	24	22	18	0	0	0	0	2.2 x 10 ⁶	2.0
BATR-446	25	25	19	2	3	0	0	0	2.4 x 10 ⁶	1.9

(1) Calculated according to USP methods

POPULATION DETERMINATION

Detailed population assay instructions are available in PDF format on the Mesa Labs website;
<http://biologicalindicators.mesalabs.com/documents-manuals/>

CERTIFICATE

Units are manufactured in compliance with Mesa Laboratories, Bozeman Manufacturing Facility's, quality standards, USP, and ISO 11138 guidelines and all appropriate subsections, with the exception of Dry Heat D-value. A sample Certificate of Analysis can be found in Figure 1.

Figure 1: Sample Certificate of Analysis

MESASTRIP

BIOLOGICAL INDICATOR

For Industrial Use Only

CERTIFICATE OF ANALYSIS

Reorder No.:

Bacillus atrophaeus 9372⁽¹⁾

Biological Indicator for: Ethylene Oxide / Dry Heat Sterilization.

Culture: Soybean casein digest broth

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

Lot No.: **BATR-000** Manufacture Date: **YEAR MONTH DAY**

Expiration: **YEAR MONTH DAY**

Heat Shocked Population: **0.0 x 10⁹** Spores / Unit

Carrier Size: 1" x 1/4" (25 mm x 6 mm)

Assayed Resistance:

	D-Value ⁽²⁾	Survival ⁽³⁾	Kill ⁽³⁾	
Ethylene Oxide (600 ± 30 mg/l, 60 ± 10% RH, 54 ± 1°C) 100% EtO	0.0	00.00	00.00	min
Dry Heat (160°C)	0.0	00.00	00.00	min
Z-value: 0.0°C				

Units are manufactured in compliance with Mesa Laboratories' quality standards, USP, ISO 11138 guidelines, and all appropriate subsections, with the exception of the Dry Heat D-value

⁽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.

Certified By: _____
Quality Representative

Complete Quality Control testing results available upon request.



Bozeman Manufacturing Facility
10 Evergreen Drive
Bozeman, MT 59715
T: 303/987-8000 • F: 406/585-9219
www.mesalabs.com