

MesaStrip Radiation

Bacillus pumilus

TECHNICAL REPORT

Complies to
USP, ISO 11138,
and all appropriate subsections

Technical Data and Use of the MesaStrip Radiation

Rev.1
TR-008

INTRODUCTION

MesaStrip is a Biological Indicator used in monitoring the efficacy of radiation sterilization cycles. MesaStrip contains spores of *Bacillus pumilus* 27142¹.

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.

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 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

¹ Culture is traceable to a recognized culture collection.

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 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 is no less than seven days.

PERFORMANCE CHARACTERISTICS

The MesaStrip biological indicators were irradiated and cultured as described above. Exposure conditions consisted of doses in kilograys. Performance data is presented in Table I.

Table I
BI Performance of Irradiated MesaStrip

Lot #	Spore Population	D-value ⁽¹⁾ (kilogray)	Survival Time ⁽¹⁾ (kilogray)	Kill Time ⁽¹⁾ (kilogray)
BPUM 122395/S4	2.1 x 10 ⁶	1.1	4.7	11.4
BPUM 122199A/S2-1	1.3 x 10 ⁶	1.2	4.9	12.2
BPUM 122199A/S3-1	2.5 x 10 ⁷	1.2	6.4	13.7

⁽¹⁾ Calculated by the method described by USP.

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:

MESA STRIP

BIOLOGICAL INDICATOR
For Industrial Use Only

CERTIFICATE OF ANALYSIS

Reorder No.:

Bacillus pumilus 27142⁽¹⁾

Biological Indicator for: Radiation Sterilization

Culture: Soybean casein digest broth.

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

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

Expiration Date: YEAR MONTH DAY

Heat Shocked Population 0.0 x 10⁰ Spores / Unit

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

Assayed Resistance:

D-Value⁽²⁾

Radiation (Co⁶⁰) 0.0 kGy

D-value reproducible only when exposed and cultured under the exact conditions used to obtain results reported here. MPN and Survivor Curve methods used.

Units are manufactured in compliance with Mesa Laboratories' quality standards.

⁽¹⁾ Culture is traceable to a recognized culture collection.

⁽²⁾ D-value calculated using the Limited-Holcomb-Spearman-Karber method.

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