Technical Report

MesaStrip Radiation

I. Introduction

MesaStrip is a biological indicator (BI) used in monitoring the efficacy of radiation sterilization processes. MesaStrip consists of 10^6 or 10^7 *Bacillus pumilus* strain 27142 spores inoculated onto a 6mm x 25 mm paper spore strip, packaged in a 27mm x 73mm glassine envelope. The glassine envelope serves as a microbial barrier which protects the spore strip from post sterilization contamination.

II. Storage

MesaStrip for Radiation should be stored at room temperature. The strips should not be stored near sterilants or other chemicals. Do not desiccate.

III. Shelf Life

MesaStrip for Radiation has a 24-month shelf life from the date of manufacture when stored at recommended conditions.

Do not use after expiration date printed on package. Dispose of expired indicators by autoclaving at 121°C for not less than 30 minutes or per site procedures.

IV. 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.

   NOTE: Inspect each strip prior to use for the following:

   - Damage that has left an opening in the glassine envelope
   - Separation along the edge of the glassine envelope
   - The presence of a strip in the glassine envelope
   - Two strips in one glassine envelope

   Dispose of any damaged or questionable units per site procedure.

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

3. Expose the load to the validated sterilization cycle.

4. Following the 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 clean, dust free room and within confines of a laminar flow hood, transfer each spore strip into a tube containing soybean casein digest broth.

6. 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.

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V. Incubation and Readout Time

The recommended incubation for MesaStrip Radiation is not less than seven days at 30 - 35°C. Placement in an optimized growth environment which maintains the correct incubation temperature is necessary to gain accurate results.

VI. Interpretation

The appearance of turbid medium or the formation of sediment indicates bacterial growth and a positive result. 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 incubation. As soon as the control turns positive, it should be appropriately recorded, autoclaved and discarded. The positive control is intended to confirm viable spores are present on the spore strip and the culture media will support growth of the test organism.

A positive control that 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.

VII. Performance Characteristics

MesaStrip BIs were irradiated and cultured as described above. Exposure conditions consisted of gradient gamma radiation exposures measured in kilogray (kGy). D-value is determined using the paper carrier packaged in glassine, cultured in Difco™ Soybean Casein Digest Broth, and calculated using the Fraction Negative method.

VIII. Population Determination

Detailed population assay instructions, TS-403 Paper, Quartz, & Cotton Thread Carrier Products, are available on Mesa's website.

IX. Compliance

MesaStrip for Radiation is manufactured in compliance with Mesa Laboratories' quality standards.

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