

Spore Strip

BIOLOGICAL INDICATOR
CERTIFICATE OF ANALYSIS

Reorder No.: 3-6100

Geobacillus stearothermophilus 7953⁽¹⁾

Biological Indicator recommended for use in evaluating **steam** sterilization processes.

Storage: Cool; 15-27°C (60-80°F), 30-70% RH, away from sterilizing agents, direct sunlight and all other forms of UV light. Do not refrigerate.

Disposal: Do not use after expiration date. Sterilize all cultures by steam 121°C for not less than 30 minutes before discarding.

Incubation: 60°C ± 2°C for 24 hours for steam sterilization or for 72 hours for Chemiclave sterilization when using Mesa Modified Tryptic Soy Broth with Bromocresol Purple.⁽²⁾

Lot No.: **GSS-038** Manufacture Date: 2024-04-19

Expiration Date: 2025-10-19

Heat Shocked Population: 1.9 x 10⁶ CFU / 0.25" x 1.5" paper strip

Assayed Resistance:

Temperature	D-Value	Survival	Kill
121°C	1.8 ⁽⁴⁾	7.52 ⁽⁴⁾	18.06 ⁽⁴⁾ min
134°C	0.03 ⁽⁴⁾	0.11 ⁽⁵⁾	0.28 ⁽⁵⁾ min

Z-value: 7.2°C

Units are manufactured in compliance with Mesa Laboratories' quality standards, USP, and ISO 11138 guidelines and all appropriate subsections, with the exception to Section 4.3.1 where process is not indicated on primary labeling.

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

⁽²⁾ When using media other than Mesa Modified Tryptic Soy Broth with Bromocresol Purple, incubate at 55-60°C for 7 days.

⁽³⁾ 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.

⁽⁴⁾ Survival/Kill values are calculated according to USP and ISO 11138. A D-value rounded to four decimal places is used in this calculation.

⁽⁵⁾ Extrapolated data.

Certified By:

Quality Assurance

Date



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Spore Strip

Biological Indicators to demonstrate adequacy of sterilization

INSTRUCTIONS FOR USE

1. Include several biological indicators with each cycle monitored. Place in the most difficult to sterilize chamber locations.
2. After sterilization, aseptically transfer the processed spore strips and one control strip into prepared sterilized Tryptic Soy Broth.
3. Incubate spore strips at:
 - a. 60°C ± 2°C for 24 hours for steam sterilization (121°C – 135°C) or 72 hours for Chemiclave® sterilization when using Mesa Modified Tryptic Soy Broth with Bromocresol Purple. When using media other than Mesa Modified Tryptic Soy Broth with Bromocresol Purple, incubate at 55-60°C for 7 days.
4. Observe all tubes daily for growth. Gram stain all positives. Gram positive rods are indicative for the indicator organism.
5. Record results. Results are valid only if the strip shows growth.
6. If a positive result is observed for a test strip, repeat the test procedures, placing several indicators throughout the sterilizer.
7. If a positive result is again observed, have the sterilizer examined for malfunction.
8. Store: 15-27°C (60-80°F), 30-70% relative humidity. Protect from sterilants, freezing and light. **DO NOT REFRIGERATE.**
9. Do not use after expiration date. Sterilize all cultures before discarding. This is a single-use product. Use of a unit in multiple cycles will invalidate the results and could potentially result in the release of non-sterile product.

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Part No.7989

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