PRODUCT CHANGE NOTIFICATION

October 2, 2017
Notification ID: CN-171001
Notification Type: Product Labeling Change

Dear Customer,

We would like to take this opportunity to notify you of a change that will be made to the certificates of analysis for the following Mesa Catalog Numbers:

- 77-01-1-6100 Mesa Spore Strips, Log 6 *Bacillus atrophaeus*
- 77-01-1-4100 Mesa Spore Strips, Log 4 *Bacillus atrophaeus*
- 77-01-1-6500 Mesa Spore Strips, Log 6 *Bacillus atrophaeus*
- 77-01-1-1000 Mesa Spore Strips, Log 6 *Bacillus atrophaeus*
- 77-01-5-1000T Mesa Combined Spore Strips, Log 6/5
- 77-01-5-5100T Mesa Combined Spore Strips, Log 6/5
- 77-01-5-1000C Mesa Combined Spore Strips, Log 6/5
- 77-01-3-4100 Mesa Spore Strips, Log 4 *Geobacillus stearothermophilus*
- 77-01-3-5100 Mesa Spore Strips, Log 5 *Geobacillus stearothermophilus*
- 77-01-3-1000 Mesa Spore Strips, Log 5 *Geobacillus stearothermophilus*
- 77-01-3-6100 Mesa Spore Strips, Log 6 *Geobacillus stearothermophilus*

Effective with the first lots to be released from the Mesa manufacturing facility located at 625 Zoot Way, the certificates of analysis for these products will be changed as follows:

- The address has been changed to reflect the manufacture and distribution of these products from a new facility in Bozeman, MT.
- A part and revision number has been added to the footer.
- The instructions for use have been added to the certificate.
- Mesa will no longer report the Crop Batch number on the certificates of analysis.
- Mesa will no longer provide a Z-value graph for steam products.
- Formatting changes have been made throughout, not considered changes to content, to align with formatting of other site documents.

In addition, data cards will no longer be provided for these catalog numbers, and a certificate of analysis will be included in every box or bag of product. Examples of the revised certificates are attached. As always, if you have any questions, please contact your Mesa Laboratories Representative.

[Signature]
Robert Bradley, Director of Production

[Signature]
Janis E. Smoke, Director of Quality & Regulatory Affairs

Mesa Laboratories Inc.  Bozeman Manufacturing Facility  625 Zoot Way Bozeman, MT 59718 USA
(303) 987-8000  FAX (406) 585-9219  www.mesalabs.com  Symbol “MLAB” on the NASDAQ
Spore Strip
BIOLOGICAL INDICATOR
CERTIFICATE OF ANALYSIS

Reorder No.: 3-4100
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)
Purity: No evidence of contaminants using standard plate count techniques.

Lot No.: 0000000  Manufacture Date:  YYYY-MM-DD

Expiration Date:  YYYY-MM-DD

Heat Shocked Population: 0.0 x 10⁹  CFU / 0.25” x 1.5” paper strip

Assayed Resistance:

<table>
<thead>
<tr>
<th>Temperature</th>
<th>D-Value</th>
<th>Survival</th>
<th>Kill</th>
</tr>
</thead>
<tbody>
<tr>
<td>121°C</td>
<td>0.0(4)</td>
<td>00.0(4)</td>
<td>00.0(4) min</td>
</tr>
<tr>
<td>134°C</td>
<td>0.0(4)</td>
<td>00.0(5)</td>
<td>00.0(5) min</td>
</tr>
</tbody>
</table>

Z-value: 00.0°C

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) 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 BERK 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

Mesa Labs
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625 Zoot Way
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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.

LIMITATION OF LIABILITY AND INDEMNITY: In no event, whether as a result of breach of contract, warranty or tort (including negligence and strict liability) shall Mesa Labs or its suppliers be liable for any consequential or incidental damages including, but not limited to loss of profits or revenues, loss of use of the products or any associated equipment, loss of the Buyer’s Products, damage to associated equipment, cost of capital, cost of substitute products, facilities, service or replacement power, downtime cost, caused by such Products, or claims of the users for such damages. Buyer for itself, its successors and assigns, hereby agrees to indemnify Mesa Labs and to hold Mesa Labs harmless from any and all liability for such consequential or incidental damages. The responsibility of Mesa Labs for damages due to injuries to employees of the Buyer or ultimate user of the Product, caused by the Product, shall be limited to repair or replacement of the item, at the option of Mesa Labs. The Buyer agrees to indemnify Mesa Labs and hold Mesa Labs harmless from any further damages, indemnity or contribution. Mesa Labs liability for any claim of any kind, including performance or breach thereof, or from the Products to Services furnished hereunder, shall in no case exceed the price of the specified Product, system, component or service which gives rise to the claim.
CAUTION: Photocopying or duplicating this certificate is strictly prohibited.

**Spore Strip**

**BIological INDICATOR**

**Dual Species**

**CERTIFICATE OF ANALYSIS**

Reorder No.: 5-1000T

**Geobacillus stearothermophilus** 7953(1)

**Bacillus atrophaeus** 9372(1)

Biological Indicator recommended for use in evaluating steam, dry heat, ethylene oxide gas, and Chemiclave® 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) 7 days at 30-35°C for EO and Dry Heat.

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

Lot No.: 00000000  Manufacture Date: YYYY-MM-DD

Expiration Date: YYYY-MM-DD

Heat Shocked Population:

- **G. stearothermophilus** 0.0 x 10⁶ CFU / 0.25” x 1.5” paper strip
- **B. atrophaeus** 0.0 x 10⁶ CFU / 0.25” x 1.5” paper strip

Assayed Resistance:

**Steam 121°C**

- D-Value
- Survival: 0.00(3)
- Kill: 0.00(3) min

**Steam 134°C**

- D-Value
- Survival: 0.00(3)
- Kill: 0.00(3) min

**Z-value: 00.0°C**

**Ethylene Oxide**

- **(600 ± 30 mg/l, 60 ± 10% RH, 54 ± 1°C)**
  - 100% EO
  - D-Value
  - Survival: 00.00(4)
  - Kill: 00.00(4) min

**Dry Heat (160°C)**

- 00.0°C

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

**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.
   - b. 30-35°C for 7 days for ethylene oxide and dry heat.

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.

**LIMITATION OF LIABILITY AND INDEMNITY:** In no event, whether as a result of breach of contract, warranty or tort (including negligence and strict liability) shall Mesa Labs or its suppliers be liable for any consequential or incidental damages including, but not limited to loss of profits or revenues, loss of use of the Products or any associated equipment, loss of the Buyer’s Products, damage to associated equipment, cost of capital, cost of substitute products, facilities, service or replacement power, downtime cost, caused by such Products, or claims of the users for such damages. Buyer for itself, its successors and assigns, hereby agrees to indemnify Mesa Labs and to hold Mesa Labs harmless from any and all liability for such consequential or incidental damages. The responsibility of Mesa Labs for damages due to injuries to employees of the Buyer or ultimate user of the Product, caused by the Product, shall be limited to repair or replacement of the item, at the option of Mesa Labs. The Buyer agrees to indemnify Mesa Labs and hold Mesa Labs harmless from any further damages, indemnity or contribution. Mesa Labs liability for any claim of any kind, including performance or breach thereof, or from the Products to Services furnished hereunder, shall in no case exceed the price of the specified Product, system, component or service which gives rise to the claim.

**Spore Strip—Dual Species**

**Biological Indicators to demonstrate adequacy of sterilization.**

Certified By: Quality Assurance Date

MesaLabs

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Rev 1
Part No. 7994
Spore Strip
BIOLOGICAL INDICATOR

CERTIFICATE OF ANALYSIS

Reorder No.: 1-6100

Bacillus atrophaeus  9372(1)

Biological Indicator recommended for use in evaluating dry heat, or ethylene oxide gas.

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 before discarding.

Incubation: 7 days in soybean-casein digest broth at a temperature of 30-35C.

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

Lot No.: 00000000 Manufacture Date: YYYY-MM-DD

Expiration Date: YYYY-MM-DD

Heat Shocked Population: 0.0 x 10⁶ CFU / 0.25” x 1.5” paper strip

Assayed Resistance: D-Value (2) Survival Kill

Ethylene Oxide (600 ± 30 mg/l, 60 ± 10% RH, 54 ± 1°C) 100% ETO

0.0 00.00(3) 00.00(3) min

Dry Heat (160°C)

0.0 00.00(3) 00.00(3) min

Z-value: 0.0°C

Units are manufactured in compliance with Mesa Laboratories’ quality standards, 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 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 Assurance Date

INSTRUCTIONS FOR USE

Biological Indicators to demonstrate adequacy of sterilization.

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. 30-35°C for 7 days for ethylene oxide and dry heat.
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.
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