MesaLabs

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.

Robert Bradley, Director of Production — Date: 02Oct2017

Janis E. Smoke, Director of Quality & Regulatory Affairs — Date: 02 Oct 2017

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 121C 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: 0.0×10^0 CFU / 0.25" x 1.5" paper strip

Assayed Resistance:

Temperature	D-Value	Survival	Kill	
121°C	0.0[4]	00.0[4]	00.0[4]	min
134°C	0.0[4]	0.00[5]	0.00[5]	min

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 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

MesaLabs

Bozeman Manufacturing Facility
625 Zoot Way
Bozeman, MT 59718
T: 303/987-8000 ♦ F: 406/585-9219
www.mesalabs.com

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.

Rev.1
Part No.7985

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 121C 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	0.0×10^0	CFU / 0.25" x 1.5" paper strip
B. atrophaeus	0.0×10^6	CFU / 0.25" x 1.5" paper strip

Assayed Resistance:	D-Value	Survival	Kill	
Steam 121°C	0.0[3]	00.00[3]	00.00[3]	min
Steam 134°C	0.0[5]	00.0[5]	00.0[5]	min

Z-value: 00.0°C

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[4]	00.00[4]	min
Dry Heat (160°C)	0.0	00.00[4]	00.00[4]	min

Z-value: 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.

[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 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

MesaLabs

Bozeman Manufacturing Facility
625 Zoot Way
Bozeman, MT 59718
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Spore Strip—Dual Species

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.
   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.

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: 0.0×10^6 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: 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.

[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

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www.mesalabs.com

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. 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.

Rev.1
Part No.7981