



MesaLabs

PRODUCT CHANGE NOTIFICATION

August 10, 2017

Notification ID: CN-170801

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 instructions for use on all Certificates of Analysis for SterilAmp and MagnaAmp. This change notification impacts all SterilAmp and MagnaAmp catalog numbers.

Effective immediately, the instructions for use will contain the following statement:

The 48-hour incubation time was validated according to the CDRH Guidance for Industry and FDA Staff: Biological Indicator (BI) Premarket Notification [510(k)] Submissions, issued October 4, 2007. The CDRH RIT protocol for validation of RIT may or may not meet each user's requirements for regulatory compliance. Users should therefore confirm regulatory requirements for reduced incubation time, or incubate for 7 days.

We are making this change to ensure our customers are aware of the basis for our RIT claim.

An example of a certificate including the revised instructions for use is attached.

As always, if you have any questions, please contact your Mesa Laboratories Representative.

Garrett Krushchewski, Senior VP of Operations, BI Division

14 AUG 2017

Date

Janis E. Smoke, Director of Quality & Regulatory Affairs

14 Aug 2017

Date



BIOLOGICAL INDICATOR

FOR INDUSTRIAL USE ONLY

CERTIFICATE OF ANALYSIS

Reorder No: SA/

Geobacillus stearothermophilus 7953 (1)

Biological Indicator for: Steam Sterilization of solutions at 121°C.

Culture: 55 – 60°C. The supplied bacteriological medium will meet requirements for growth promoting ability.

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

Lot No: SA-000 Manufacture Date: YEAR MONTH DAY

Expiration: YEAR MONTH DAY

Heat Shocked Population: 0.0 x 10⁰ Spores / Unit

Assayed Resistance:

	D-Value	Survival	Kill	
Steam 121°C	0.0 (2)	00.00 (3)	00.00 (3)	min
F ₀		00.0 (4)	00.0 (4)	min

Z-value: 00.0°C

Units are manufactured in compliance with Mesa Laboratories, Bozeman Manufacturing Facility's 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) Resistance was determined in an AAMI BIER vessel 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.

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

(4) Empirically derived data.

Certified by:

Quality Representative

Date



Bozeman Manufacturing Facility

10 Evergreen Drive

Bozeman, MT 59715

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www.mesalabs.com

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Biological Indicators for Monitoring Steam Sterilization of Liquids

INSTRUCTIONS FOR USE

Sterilization:

- Place **SterilAmp® II** inside representative liquid containers to be sterilized. Package or seal as usual.
- Locate test samples in areas of the load considered most difficult to sterilize or in convenient areas that have been validated. Identify test samples as to location in sterilizer.
- After sterilizing, send **SterilAmp II** and products to test laboratory along with at least one non-sterilized **SterilAmp II** marked POSITIVE CONTROL.

Test Laboratory:

- All **SterilAmp II** are fully self-contained BIs which do not require subculture.
- Procedure:
 - SterilAmp II** may be left in the sterilized container or transferred to a rack or container which allows visual observation during incubation.
 - Incubate **SterilAmp II** for 48 hours at 55-60°C.
 - The 48-hour incubation time was validated according to the CDRH Guidance for Industry and FDA Staff: Biological Indicator (BI) Premarket Notification [510(k)] Submissions, issued October 4, 2007. The CDRH RIT protocol for validation of RIT may or may not meet each user's requirements for regulatory compliance. Users should therefore confirm regulatory requirements for reduced incubation time, or incubate for 7 days.
 - Observe daily for growth.
Yellow and/or turbid = growth = non-sterile
Purple = no growth = sterile
SterilAmp II should show "no growth" if sterilization has been achieved. If color change to yellow or presence of turbidity occurs in **SterilAmp II** cultures, it indicates that the spores have survived the sterilization process and are non-sterile.
- Controls:
 - Positive:** At least one positive control should be included in each test series. Incubate a non-sterilized **SterilAmp II** with test series. Color change from purple to yellow or presence of turbidity indicates that the medium possesses suitable growth promoting qualities and that the **SterilAmp II** contains viable spores. If positive control does not grow, do not use the units from that package. Contact Mesa Labs.
 - Negative:** The distinguishing characteristic of the negative control is a 2 mm stainless steel bead that is placed in the glass tube before it is sealed. The negative control is placed in the sterilizer load along with units that contain spores. Color changes due to thermal degradation can be observed and compared. This documents the normal shift in color from the process.

Storage and Disposal:

- Refrigerate at 2 – 8°C. Protect from light.
- Incinerate or autoclave at 121°C for not less than 30 minutes.
- SterilAmp II** biological indicators have a shelf life which is clearly designated on each package. Rotate your stock accordingly.

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



BIOLOGICAL INDICATOR

For Industrial Use Only

CERTIFICATE OF ANALYSIS

Reorder No.: MA/

Geobacillus stearothermophilus 7953(1)

Biological Indicator for: Steam Sterilization of solutions

Culture: 55 – 60°C. The supplied bacteriological medium will meet requirements for growth promoting ability.

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

Lot No: MA-000 Manufacture Date: YEAR MONTH DAY

Expiration: YEAR MONTH DAY

Heat Shocked Population: 0.0 x 10⁰ Spores / Unit

Assayed Resistance:

	D-Value	Survival	Kill	
Steam 121°C	0.0 ⁽²⁾	00.00 ⁽³⁾	00.00 ⁽³⁾	min
F ₀		00.0 ⁽⁴⁾	00.0 ⁽⁴⁾	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) Resistance was determined in an AAMI BIER vessel 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.

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

(4) Empirically derived data.

Certified by:

Quality Representative

Date



Bozeman Manufacturing Facility

10 Evergreen Drive

Bozeman, MT 59715

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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.



Biological Indicators for Monitoring Steam Sterilization of Liquids

INSTRUCTIONS

Sterilization:

1. Place **MagnaAmp**™ either inside a large container or next to a container containing a liquid for sterilization. Package or seal as usual.
2. Locate test samples in areas of the load considered most difficult to sterilize or in convenient areas that have been validated. Identify test samples as to location in sterilizer.
3. After sterilizing, send **MagnaAmp** and products to test laboratory along with at least one non-sterilized **MagnaAmp** marked POSITIVE CONTROL.

Test Laboratory:

1. All **MagnaAmp** are fully self-contained BIs which do not require subculture.
2. Procedure:
 - a. **MagnaAmp** may be left in the sterilized container or transferred to a rack or container which allows visual observation during incubation.
 - b. Incubate **MagnaAmp** for 48 hours at 55-60°C.
 - c. The 48-hour incubation time was validated according to the CDRH Guidance for Industry and FDA Staff: Biological Indicator (BI) Premarket Notification [510(k) Submissions, issued October 4, 2007. The CDRH RIT protocol for validation of RIT may or may not meet each user's requirements for regulatory compliance. Users should therefore confirm regulatory requirements for reduced incubation time, or incubate for 7 days. Incubate for 72 hours when monitoring SSM-150 medical waste treatment cycles.
 - d. Observe daily for growth.
 Yellow or turbidity = growth = **non-sterile**
 Purple = no growth = **sterile**
MagnaAmp should show "no growth" if sterilization has been achieved.
 If color change, or turbidity, occurs in **MagnaAmp** cultures, it indicates that the spores have survived the sterilization process and are non-sterile.
3. Positive Controls: At least one positive control should be included in each test series. Incubate a non-sterilized **MagnaAmp** with test series. Color change from purple to yellow, or turbidity, indicates that the medium possesses suitable growth promoting qualities and that the **MagnaAmp** contains viable spores. If positive control does not grow, do not use the units from that package. Contact Mesa Labs.

Storage and Disposal:

1. Refrigerate at 2 – 8°C. Protect from light.
2. Incinerate or autoclave at 121°C for not less than 30 minutes.
3. **MagnaAmp** biological indicators have a shelf life which is clearly designated on each package. Rotate your stock accordingly.

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