

PRODUCT CHANGE NOTIFICATION

25 May 2018

Notification ID: CN-180502

Notification Type: Product Testing and Labeling Changes

Dear Customer,

We would like to take this opportunity to notify you of changes that will be made to **1-6100TT *Bacillus atrophaeus* Spore Cotton Thread** biological indicators. As detailed in previous notifications, Mesa Labs relocated manufacturing operations from its facility at 8607 Park Drive, Omaha, NE 68127 to a newly constructed facility at 625 Zoot Way, Bozeman, MT 59718.

Effective with the first lots to be released from the Mesa manufacturing facility located at 625 Zoot Way, the following changes are being implemented:

Product Testing

Resistance testing will be determined in an AAMI BIER vessel using a paper carrier packaged in glassine and calculated using the Fraction Negative method.

This change is being made to support the multiple intended uses of the product. Since use of the product by the customer can result in inconsistencies within primary and secondary packaging, the reported D-value will instead be based on results of testing of the same spore culture lot inoculated on paper spore strips, packaged in glassine envelopes and tested in ethylene oxide.

As was also true before the change, the resistance data should serve as a reference point for lot-to-lot variation only.

Product Labeling – Certificate of Analysis and Bag Label

A number of changes have been made to the certificate of analysis provided with each lot.

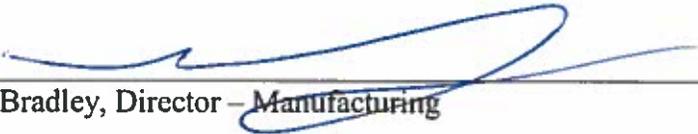
- The instructions for use have been added to the certificate.
- A part number and revision number have been added to the certificate.
- A new lot number format will be used. A prefix BAT will be assigned followed by a 3-digit sequential number. Example: BAT-001
- The format of the expiration date format has been aligned with regulatory requirements (YYYY-MM-DD.)
- The release date is the date of the Quality Assurance signature on the certificate.
- The crop number is no longer reported.
- The survive and kill time calculations are no longer provided. Instead, reference is made to the USP and ISO 11138 standard upon which the calculations are based.



MesaLabs

- As described above, the reported resistance on the certificate of analysis is based on previously assessed paper spore strip D-value data instead of on testing of the threads in glassine. The note regarding resistance testing included on the Certificate of Analysis has been revised.
 - Previous statement: *Determined on primary spore crop, using cotton threads in glassine envelopes, Spearman-Karber method. The D-value is reproducible only under the exact conditions under which it was determined. The user would not necessarily obtain the same results. Therefore, the user would need to determine the suitability for its particular use.*
 - New statement: *Resistance was determined in an AAMI BIER vessel using a paper carrier package 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.*
- The address has been changed to reflect the manufacture and distribution of this product from the new facility in Bozeman, MT.

An example of the revised certificate is attached. As always, if you have any questions, please contact your Mesa Laboratories Representative.


Robert Bradley, Director – Manufacturing 25 May 2018
Date


Janis E. Smoke, Director – Quality & Regulatory Affairs 25 May 2018
Date

Spore Cotton Thread

For Industrial Use Only

CERTIFICATE OF ANALYSIS

Reorder No.: 1-6100TT

Bacillus atrophaeus 9372⁽¹⁾

For: Ethylene Oxide sterilization

Culture: Soybean casein digest broth.

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

Lot No.: **BAT-000** Manufacture Date: YYYY-MM-DD

Expiration: YYYY-MM-DD

Heat Shocked Population: 0.0 x 10⁶ Spores/Unit

Carrier Size: 3/4"

Assayed Resistance:

	D-value ⁽²⁾	
Ethylene Oxide (600 ± 30 mg/l, 60 ± 10% RH, 54 ± 1°C) 100% EtO	0.0	min

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 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.

Certified By: _____

Quality Assurance

_____ Date



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Spore Cotton Thread Biological Indicators to demonstrate adequacy of sterilization

INSTRUCTIONS FOR USE

Sterilization:

1. Place spore threads inside materials to be processed. Package or wrap as usual.
2. Locate test packages in areas of sterilizer most difficult to sterilize (usually four corners front, four corners rear, center-center and center-top). Identify test packages as to location in sterilizer.
3. After sterilizing, forward sufficient spore threads to test laboratory along with at least one non-sterilized spore thread marked **POSITIVE CONTROL**.

Test Laboratory:

1. All testing should be performed in a clean, dust-free room - and within confines of a laminar flow hood. All transfers and manipulations must be conducted with rigid aseptic techniques to avoid "false positive" samples.
2. Procedure:
 - a. Aseptically transfer spore threads with sterile forceps to individual tubes containing sterile soybean casein digest broth. Identify tubes.
 - b. Incubate spore threads seven days at appropriate temperature:

Bacillus atrophaeus ...30-35°C

- c. Observe tubes daily for growth:

Turbid = growth = **non-sterile**

Clear = no growth = **sterile**

Test Thread cultures should show no growth if sterilization has been achieved. If turbidity and bacterial growth occur in test thread cultures, it suggests that the spores have survived the sterilization process and are non-sterile.

3. Controls:

- a. **Positive:** One or more positive controls should be included in each test series. Transfer a non-sterilized spore thread to culture medium and incubate with test series. Turbidity and growth indicates that the medium possesses suitable growth promoting qualities and that the spore threads contain viable spores. If positive control does not grow, do not use units from that package. Contact Mesa Labs.
- b. **Negative:** One or two tubes of culture medium incubated with test series. Absence of growth indicates that the medium was sterile prior to sterility testing.

Storage and Disposal:

1. Store biological indicators at 15-27°C, 30-70% RH.
2. Do not store these indicators near sterilants or other chemicals. Avoid sunlight and all other forms of UV light.
3. The biological indicator has 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.

Rev.2
Part No. 77036

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.